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JAMES J. VILT JR., CLERK
U.S. DISTRICT COURT
W/D OF KENTUCKY

Date: _____

IN THE UNITED STATES DISTRICT COURT
WESTERN ISTRICT OF KENTUCKY
Louisville Division

SANDRA K. DOWNEY, *Plaintiff* vs. CARTIVA, INC. and WRIGHT MEDICAL TECHNOLOGY, INC. and STRYKER, B.V. *Defendants*	No. 3:26CV-765-GNS

OMPLAINT IN CIVIL ACTION

OMPLAINT

Plaintiff, Sandra K. Downey ("Plaintiff" or "Downey"), by counsel, and for her Complaint against Defendants Cartiva, Inc. ("Defendant" or "Cartiva") and Wright Medical Technology, Inc., ("Defendant" or "Wright") and Stryker, B.V. ("Defendant" or "Stryker"), alleges and states as follows.

This is a products liability lawsuit involving a defective toe implant device that fails in approximately two-thirds of patients, but which continued to be sold in the U.S. market for years

until it was recalled globally on Oct. 31, 2024.[1] The allegations in this Complaint are similar, but not identical, to those of plaintiffs with claims pending in MDL 3172, In Re: Cartiva Synthetic Cartilage Implant Product Liability Litigation in the Eastern District of Arkansas, U.S. District Court. For this reason, Plaintiff has reason to believe this case may be properly transferred to MDL 3172 pursuant to 28 U.S.C. § 1407.

PARTIES

1. Plaintiff Sandra K. Downey is, and at all times relevant to this action was, a citizen and resident of the State of Kentucky, residing in Louisville in Jefferson County.

2. Defendant Cartiva, Inc. is a corporation with its principal place of business at 1209 Orange Street, Wilmington, Delaware 19801. It was previously based in Alpharetta, Georgia. As a manufacturer of medical devices, Cartiva is, and at all times relevant was, subject to regulations and consensus industry standards governing the medical device industry, including those promulgated by the United States Food and Drug Administration ("FDA").

3. Defendant Wright Medical Technology, Inc. ("Wright Medical" or "WMT") is a corporation with its principal place of business at 1023 Cherry Road, Memphis, Tennessee 38117. Wright Medical was the operating subsidiary of Wright Medical Group, N.V., which acquired Cartiva in 2018. Two years later, in November 2020, the Wright Medical entities merged with and were acquired by Stryker, B.V., a wholly owned subsidiary of Stryker Corp. ("Stryker").

4. Defendant Stryker, B.V. is a corporation with its principal place of business at 2825 Airview Boulevard, Kalamazoo, Michigan 49002. Stryker assumed all of the assets and liabilities of both Cartiva and Wright Medical in the above mentioned transaction.

[1] See Urgent Medical Device Recall for Cartiva Synthetic Cartilage Implant, available at https://www.stryker.com/content/dam/stryker/foot-and-ankle/resources/CartivaFSN30Oct2024_US.pdf (last visited September 10, 2026.

5. At all times material hereto, Defendants Cartiva and Wright Medical and Stryker developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name "Cartiva SCI" (Synthetic Cartilage Implant hereinafter referred to as "Cartiva" or "SCI" or "Defective Device"), either directly or indirectly, to members of the general public within the State of Kentucky, including Plaintiff.

6. As a direct and proximate result of Defendants placing the defective Cartiva SCI into the stream of commerce, Plaintiff has suffered and continues to suffer both injuries and damages within the State of Kentucky, including but not limited to: past, present and future physical and mental pain and suffering, loss of the ability to enjoy the pleasures of life, disfigurement; and, past, present and future medical, hospital, monitoring, rehabilitative and pharmaceutical expenses and lost wages.

7. Upon information and belief, at all relevant times, Defendant was present and transacted, solicited, and conducted business in the State of Kentucky through its employees, agents and/or sales representatives, and derived substantial revenue from such business.

8. Defendant is conclusively presumed to have been doing business in the State of Kentucky and is subject to Kentucky's long arm jurisdiction.

9. At all relevant times, Defendant expected or should have expected that its acts and omissions would have consequences within the United States and the State of Kentucky.

JURISDICTION AND VENUE

10. This Court has original jurisdiction pursuant to diversity jurisdiction prescribed by 28 U.S.C. § 1332 in that the amount of controversy exceeds $75,000.00, exclusive of costs and interest, and involves citizens of different states.

11. Defendants have submitted to the jurisdiction of this Honorable Court by doing, personally or through agents, at all times material to this lawsuit, the following acts:

a. Committing tortious acts within this state by selling and delivering defective products, including the defective Cartiva SCI, to persons, firms, corporations, physicians, or hospitals in this state via its distributors, dealers, wholesalers, retailers and/or brokers. Such products were used by healthcare providers on consumers/patients in the State of Kentucky in the ordinary course of trade, commerce or healthcare;

b. Conducting and engaging in substantial business and other activities in the State of Kentucky by selling its products to persons, firms, corporations, physicians, or hospitals in this state via its distributors, dealers, wholesalers, retailers and/or brokers;

c. Causing injuries to persons in the State of Kentucky, including Plaintiff, and likely others. Before, at or about the time of said injuries, the Defendant engaged in solicitation activities in the State of Kentucky to promote the sale of its products;

d. Selling defective products, including the defective Cartiva SCI, with knowledge or reason to foresee that its product would be shipped in interstate commerce and would reach the market of users or consumers in the State of Kentucky.

12. Venue is proper in the U.S. District Court for the Western District of Kentucky because the unlawful actions giving rise to this Complaint, and the injuries suffered, occurred within the district. Furthermore, Plaintiff is a resident of the State of Kentucky in the County of Jefferson.

GENERAL ALLEGATIONS

13. This lawsuit arises from the Defendants' negligence, choice to manufacture, market, and sell a defective product, and violations of various sections of the Federal Code of Regulations all of which caused harm to Plaintiff.

14. Big toe arthritis affects about 2.2 million people in the United States. As arthritis deteriorates the joint's cartilage a person develops an extremely painful bone-on-bone rubbing of the bones. This condition can be surgically treated with 1) Arthrodesis a/k/a "fusion" or 2)

Arthroplasty a/k/a "joint replacement, including, according to the Defendant's representations, a Cartiva® SCI, which is supposed to act like a cushion to prevent the bone-on-bone pain.

A. **artiva Implant Treatment Option**

15. The Cartiva implant is a molded cylindrical implant that is placed into the metatarsal head in the first metatarsophalangeal joint via press-fit implantation using instruments specifically designed for placement of the device.

16. Defendants touted Cartiva as a simple procedure, which enables surgeons to replace the damaged cartilage with a bullet-sized implant they can place into an intraoperatively created pilot hole in the first metatarsal head.

17. Defendants specifically marketed the Cartiva to surgeons as being 40 percent faster than toe fusion surgery, with a 97 percent reduction in pain for patients. They also told surgeons that the Cartiva would last patients a "lifetime."

18. The Cartiva implant was promoted for use in the treatment of patients with painful degenerative or post-traumatic arthritis (hallux limitus or hallux rigidus) in the first metatarsophalangeal joint with or without the presence of mild hallux valgus.

19. The Cartiva instrumentation is used to drill a cavity in the metatarsal head and deploy the Cartiva implant into the prepared cavity.

20. Defendants claimed that joint resurfacing with a Cartiva implant is simple, does not require removal of healthy tissue, and typically results in nominal surgical trauma and rapid recovery.

21. Cartilage is a specialized tissue responsible for mediating contact between bones on surfaces with relative movement. Since cartilage is not vascularized, chondrocytes depend

mainly on anaerobic metabolism and get their nutrients through diffusion from the synovial fluid into the matrix.

22. Cartilage does not restore itself or recover quickly from injury. The complete turnover of the human femoral head cartilage would take approximately 400 years[2] Joint replacement with polyvinyl alcohol-based hydrogels (PVA), such as the one used in Cartiva is a joint replacement alternative to traditional fusion treatment.

23. The biomechanical design of these implants relies on "hard-on-hard" and "hard-on-soft" interactions. This type of design does not mimic the soft-on-soft interactions that occur in natural cartilage.

24. PVA is biocompatible and has good swelling properties.[3] But the characteristics of the resulting hydrogel also could have been tailored by adjusting the production method or by combining PVA with other materials to produce a more suitable and stable material than the design used by Cartiva.[4]

B. **usion Treatment Option**

25. In contrast to the implantation of a Cartiva SCI, an arthrodesis (hereinafter "fusion") is a procedure where the phalangeal and metatarsal bones are cut and shaped to fit (fuse) together to relieve toe joint pain.

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[2] Maroudas a. Physicochemical properties of cartilage in the light of ion exchange theory. Biophys J. 1968;8(5):575-595. doi:10.1016/S0006-3495(68)86509-9

[3] *Id*

[4] Id. Ma R, Xiong D, Miao F, Zhang J, Peng Y. Novel PVP/PVA hydrogels for articular cartilage replacement. *Mater Sci Eng C*. 2009;29(6):1979-1983. doi:10.1016/j.msec.2009.03.010; Fathi E, Atyabi N, Imani M, Alinejad Z. Physically crosslinked polyvinyl alcohol-dextran blend xerogels: Morphology and thermal behavior. *arbohydr Polym* 2011;84(1):145-152. doi:10.1016/j.carbpol.2010.11.018

26. The two bones are then aligned, set at a predetermined angle and permanently fixed with either screws and/or a plate so the two bones "fuse" together permanently. A typical fusion procedure eliminates the ability to move the big toe but eliminates the patient's pain.

27. Although range of motion is limited after fusion, patients with a fusion surgery may still be able to participate in a wide range of activities, including sports, high speed walking and even long-distance running.

C. **Medical Facts - Injury**

28. Plaintiff files the instant suit against Defendants seeking compensation for injuries and damages Plaintiff sustained due to the implantation of the Defective Device into Plaintiff.

29. On or about September 24, 2024, at Baptist Health Louisville, in Louisville, Kentucky, Dr. Michael McQuillen, MD, performed surgery on Plaintiff whereby the Cartiva SCI was implanted in her right great toe.

30. Plaintiff was induced to purchase the Defective Device based on the Defendant's representations that the recovery time would be faster and less painful than a traditional toe fusion, and that it would be permanent and last a lifetime. Plaintiff and her surgeon were unaware that just weeks after her initial surgery, Defendants issued a global recall of the Cartiva device due to higher than expected failure rates.

31. On information and belief, Defendants had already made the decision to issue the recall prior to Plaintiff's implant surgery, and already had conducted a Health Hazard Evaluation and/or Health Risk Assessment which showed the Cartiva's high failure rate. Defendants had the ability to disclose this information to Plaintiff and her medical providers, but they did not do so.

32. Plaintiff subsequently developed chronic pain and stiffness in the right foot with limited range of motion as a result of the Defective Device.

33. As Plaintiff's chronic foot pain continued to persist, she again presented to Dr. McQuillen on or about October 21, 2025, for removal of the Defective Device and a fusion of Plaintiff's big toe at the same facility, Baptist Health Louisville.

34. At all times material hereto, the Cartiva SCI implanted in Plaintiff's great toe was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

35. As a result of the implantation of the Defective Device, Plaintiff has suffered additional medical expenses for removal of the implant and fusion surgeries, all of which were needed to correct the toe deformity and bone loss caused by the Defective Device and causing additional loss of income, loss of enjoyment of life, and pain and suffering.

D. **A Questionable Study Raises Questions by Insurance Carriers and Surgeons**

36. Defendants had a duty to be truthful about the risks of their products in marketing and promotion of the product. Yet, Defendants suppressed medical industry knowledge from the FDA and public that the Cartiva SCI has a high failure rate due to migration of the implant caused by implant subsidence and shrinkage.

37. Defendant obtained Premarket Approval Application ("PMA") approval for Cartiva as a Class III device, yet failed to follow the requirements of the PMA and made voluntary statements to patients and the medical community that misrepresented the safety and performance of the Cartiva device.

38. The pivotal clinical study ("Motion Study")[5] for the PMA compared the Cartiva implant to the traditional gold standard fusion treatment. The study was a non-inferiority clinical

[5] Baumhauer JF, Singh D, Glazebrook M, Blundell C, De Vries G, Le IL, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Younger AS, Daniels T; for and on behalf of the CARTIVA Motion Study Group. Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. 2016 May;37(5):457-69. doi: 10.1177/1071100716635560. Epub 2016 Feb 7. PMID: 26922669.

study of 202 subjects treated at 12 sites in the United Kingdom and Canada. The "Motion Study," put simply, is a comparison to a fusion procedure. However, the results of the Motion Study have not been replicated in clinical practice and the Cartiva's actual failure rate is much higher.[6]

39. Not only have the Motion Study results not been replicated in clinical practice, but a later examination of the Study showed that any of three reasonable alternative means of defining surgical success would have altered the final outcome of Motion, and a more rigorous non-inferiority margin would have resulted in failure of the trial overall. Gregory P Guyton, *Philosophies of Surgical Care Are mbedded in Outcome Studies: An Illustrative Reanalysis of the Cartiva MOTION Trial*, 43 Foot & Ankle Int'l 1347, 1347–52 (2022); *see also* Solangel Rodriguez-Materon and Gregory P. Guyton, *The Philosophy of Surgical Success and Outcomes of Cartiva Versus Fusion* 29 Foot & Ankle Clinics 521, 521–27 (2024).

40. The Motion Study also has been widely criticized by insurance experts because of its insufficient sample size, prompting Cigna to deem the use of the Cartiva implant to treat big toe arthritis "experimental" based upon the lack of sufficient scientific evidence to support the successful treatment claims made by Defendant.[7]

41. In support of its position, Cigna cited a report by Hayes, Inc. which found that individual outcome measures were inconsistent and some suggested better outcomes with arthrodesis. Patients treated with Cartiva SCI reported statistically significantly worse pain scores

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[6] https://www.medtechdive.com/news/wright-medical-shares-tumble-amid-report-of-cartiva-slowdown/558132/

[7] Partial or total replacement of the first MTP joint or any other foot joint using ANY of the following is considered experimental, investigational or unproven: Page 2 of 12 Medical Coverage Policy: 0446

• _ceramic implant (e.g., Moje prosthesis [Orthosonics, Ltd., Devon UK])

• _synthetic cartilage implant (e.g., Cartiva Synthetic Cartilage Implant)

Hayes, Inc. Hayes Health Technology Brief. Cartiva Synthetic Cartilage Implant (Wright Medical Group) for Treatment of First Metatarsophalangeal Joint Arthritis. Hayes, Inc.; March 2019; updated May 2020.

(i.e., more pain) when compared with the arthrodesis group from six weeks to two years post-procedure. The Hayes report concluded that the very-low-quality body of evidence relied upon by the Defendant was insufficient to draw conclusions regarding the effectiveness and safety of the Cartiva implant for treatment of first MTP joint arthritis. Hayes Inc., noted that substantial uncertainty exists regarding the efficacy and benefit of the Cartiva implant due to a single identified trial, inconsistencies within the individual study results, and lack of long-term comparative effectiveness data. Hayes, Inc., and, in turn, Cigna, concluded that large studies assessing the comparative effectiveness and safety of the Cartiva implant are needed.

42. The Defendant's Motion Study reported on a prospective, randomized non-inferiority study to compare the efficacy and safety of the Cartiva implant to great toe fusion surgery for advanced-stage hallux rigidus. The study included 152 implants and 50 arthrodesis patients. The three primary study outcomes assessed were pain, function, and safety. There were no cases of implant fragmentation, wear, or bone loss. This study is the basis of the PMA approval for the Cartiva implant.

43. Cigna also recognized that clinical practice guidelines suggest a different implant design is recommended which renders the Cartiva implant unreasonably dangerous by design. Clinical practice guidelines published by the First Metatarsophalangeal Joint Disorders Panel of the American College of Foot and Ankle Surgeons in 2003 states that interposition arthroplasty with double-stem silicone hinged implants is still a useful procedure for the end-state arthrosis of hallux, and that titanium grommets are recommended to minimize ectopic bone formation and protect the implant from the adjacent bone. In addressing total joint systems, the guideline states that numerous implant systems have been developed during the years and several are still used

clinically, although long-term clinical usefulness has yet to be established. Judicious use and strict criteria are recommended to avoid complications and problematic revisions (Vanore, et al., 2003).

44. Outside the U.S., the National Institute for Health and Care xcellence (NICE) in England published Interventional Procedure Guidance in 2005 based on an analysis of seven case series: Hanyu et al. (2001); Sharnkar, et al., (1991); Cracchiolo et al., (1992); Granberry et al., (1991); Bommireddy et al., (2003); Ibrihim et al., (2004); and Malviya et al., (2004). The guidance states there is little evidence supporting the durability of newer implants, and that complications may necessitate removal of the device. These complications include persistent pain, infection, implant loosening, implant fracture, osteolysis, bone over-production, cyst formation, silastic granulomas and transfer metatarsalgia.

. Defendant Suppressed Adverse Data from FDA/Medical Providers

45. On information and belief, Defendant had knowledge at all relevant times of the clinical guidelines and outside studies mentioned herein but have suppressed the medical data and information and failed to update the label, failed to update physicians, and failed to voluntarily recall the defective device.

46. An analysis of publicly available data from adverse events shows an average delay of 692 days — almost two years — compared to the 30-day required deadline for a manufacturer to inform the FDA about a product failure.[9]

47. Out of 396 unique adverse events reported to the FDA, by far the largest number were reported after the acquisition of Wright Medical by Stryker in 2020.[10] For example, at least

[9] Adverse event data is published by FDA on its Manufacturer and User Facility Device Experience, or MAUDE, database. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

[10] The search of MAUDE was based on reports sent to FDA between 2016 and 2026.

75 adverse events were provided to FDA in 2022 through retrospective reporting, which typically occurs when a manufacturer discovers that its reporting guidelines — or the guidelines of a predecessor company — did not meet industry standards. However, in the annual report sent to FDA for that same year, Defendants reported that "… no changes have occurred as a result of an MDR or recall."[11]

48. Defendants failed to provide summaries of new adverse events and complaints to FDA, in violation of both 21 CFR 814.84 as well as the Pre Market Approval (PMA) order for the device issued by FDA on July 1, 2016, which specifically stated that Cartiva had to report adverse events within 30 days pursuant to 21 CFR 803.50 and 21 CFR 803.52.

49. Many of the PMA annual reports sent to FDA for the Cartiva device failed to identify any adverse events at all, despite the fact that the PMA order asked for safety data on the device so it could provide FDA with the context necessary to "… ascertain the frequency and prevalence of adverse events."

50. Even a cursory glance at the PMA annual reports for the Cartiva device shows the lack of compliance with FDA regulations. While it is common for such annual reports to span hundreds of pages, the annual report for the Cartiva rarely exceeded ten pages and did not include any discussion of adverse event statistics, trends or failure mechanisms. For example, the report was only seven (7) pages long in 2017, only eight (8) pages in 2018 and seven (7) pages long in 2019.

51. Even in more recent years, as medical literature revealed deep concerns about the safety and performance of the Cartiva device, Defendants failed to provide that information to FDA as required in the initial approval order. For example, in the last annual report in 2024,

[11] MDR stands for Medical Device Reporting.

Defendants told FDA that there were "no known reports in the scientific literature concerning the device," even though 72 days later Defendants issued a global recall for the device due to higher than expected failure rates.

52. In other instances, Defendants did share summaries of medical literature in the PMA annual reports but they downplayed or ignored serious health concerns. For example, in the 2022 annual report, Defendants disclosed two new articles about adverse events for greater toe implants, but told the FDA that "the literature and data presented do not impact the known safety and effectiveness profile of the device." But the reality was quite different. In the first study, the authors found that Cartiva made up the largest share of adverse events and product failures compared to other competing toe implant devices.[12] The second article found that implant subsidence was the most common failure mechanism for the Cartiva, contrary to what Defendants told patients in their brochures and advertising.[13]

53. Cartiva also failed to share information with FDA and with medical practitioners that surgeons were unable to replicate the results in the initial clinical study.

54. For example, in a follow up to the "Motion Study", Baumhauer et al. (2017) ("Motion II Study"), a study funded by Cartiva, retrospectively evaluated the Motion Study finding identical success rates between fusion surgery and the Cartiva implant.

55. However, numerous surgeons and podiatrists informed Cartiva soon after device approval that the Cartiva device was failing at a high rate and not performing as intended. When

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[12] Craig C. Akoh et al., *Adverse Events Involving Hallux Metatarsophalangeal Joint Implants: Analysis of the United States Food and Drug Administration Data from 2010 to 2018*, 27 Foot & Ankle Surgery 381, 381–88 (2021), https://doi.org/10.1016/j.fas.2020.05.002

[13] Sreenivasulu Metikala et al., *Adverse Events Related to Cartiva Hemiarthroplasty of First Metatarsal: An Analysis of Reports to the United States Food and Drug Administration*, 15 Foot & Ankle Specialist 113–18 (2022), doi:10.1177/1938640020943715

these surgeons contacted Cartiva, they were told the device was safe and they simply needed to adjust their expectations for patient recovery and pain.

56. For example, Dr. Mark Hardy of Ohio told Cartiva in early 2018 about numerous surgeries where patients experienced device failure and subsidence. On information and belief, Defendants never shared this information with the FDA and did not take the steps necessary to fully investigate these early failures. For example, Dr. Hardy asked employees at Cartiva if they planned to make any "design modifications" to the Cartiva as a result of these early failures, and the Cartiva sales representative asked a fellow employee if the company should "begin the paperwork" for a product complaint, but instead of reporting these complaints to FDA Cartiva intentionally did not disclose the product failures due to "lack of detail." Cartiva's senior director of regulatory and quality affairs also decided not to report the 2018 complaints because they did not involve "fracture and dislodgement" even though Cartiva was aware of other devices failing due to subsidence.

57. Another surgeon, Dr. Andrea Gazdag of Maryland, started implanting the Cartiva in 2016 in reliance on marketing materials but quickly found that patients experienced pain and swelling in their joints among other complications. Cartiva told Dr. Gazdag that he needed to let patients remain in pain for up to two years before they would start seeing benefits from Cartiva. On information and belief, Defendants never shared this information with the FDA and did not take the steps necessary to fully investigate these early failures.

58. Another surgeon, Dr. Gregory Guyton of Maryland, stopped using Cartiva after a year because he found it to be a high-risk device that was only suitable for a niche demographic of patients engaging in activities such as ballet who needed more range of motion than a fusion

surgery would provide. Dr. Guyton's patients experienced a 40% percent failure rate with the Cartiva.

59. Another surgeon, Dr. David Thordarsen, wrote an article in 2019 based on a retrospective chart review of 64 patients and found that 38 percent of the patients were either unsatisfied or very unsatisfied with the Cartiva, and there was a 20 reoperation rate.[14]

60. Another retrospective study performed by a surgeon found a high failure rate in patients, including implant subsidence in 60 percent of patients 4 weeks after surgery and 90 percent of patients at the final follow-up. A full 40 percent of patients had erosion of the proximal phalanx of the great toe, and more than one third of cases were considered as failures.[15]

61. Yet instead of investigating the above complaints and studies, Cartiva argued to the FDA in its annual reports that the "…literature and data do not impact the known safety and effectiveness profile of the device." Cartiva also claimed that it could not further analyze complaints from surgeons because it did not have their contact information, even though it would have been easy to reach the well-respected surgeons who complained to sales representatives and other company officials.

62. Even sales representatives for Cartiva complained about how poorly the device was performing in patients, and reported being forced to continue selling the Cartiva to hospitals and practitioners until the October 2024 recall. The extent of Defendants' communications with Plaintiff's specific sales representative can only be known after discovery is complete, including document production and testimony from the specific sales representative involving in Plaintiff's initial surgery.

[14] Cassinelli, et. al., Early Outcomes and Complications of Synthetic Cartilage Implant for Treatment of Hallux Rigidus in the United States, Foot Ankle Int. 2019 Oct; 40(10): 40 -1148.
[15] Shimozono, et. al., Early Failures of Polyvinyl Alcohol Hydrogel Implant for the Treatment of Hallux Rigidus, Foot Ankle Int. 2021 March; 42(3): 340-46.

63. Clearly, the claimed success rate of the Cartiva did not exist in clinical practice. Actual patients have reported failure rates as high as 64% as opposed to the 13.5% failure rate Defendant reported to the FDA. A 2020 study by Rosas revealed high failure rates of the Cartiva implant in patients with Hallux Rigidus and significant radiologic subsidence with lysis around the implant, erosion of the proximal phalanx countersurface as well as recorded implant wear are harbingers for concern in the long term.[16]

64. One of the conditions of approval required a post-approval study ("PAS") that demonstrates no greater than 13.5% complication rate and tracking the number of patients that were converted to arthrodesis (a/k/a fusion) surgery.

65. If the Defendants had reported these studies and failure rates to FDA, or if Defendants had performed a thorough analysis of this information as required by the PMA, these risks would have been shared with Plaintiff and the medical community, who never would have agreed to use the Cartiva in the first place.

66. On July 12, 2019, the FDA approved Defendant's updated label based upon the findings of the Post-Approval Motion Study to include implant subsidence. However, Defendants incorrectly claimed a majority (76%; 13/17) of the Cartiva serious adverse events were for pain. Additionally, Defendant incorrectly stated in the updated label that 9.2% of Cartiva subjects and 12% of fusion subjects had the implant and/or hardware removed during the course of the study. On information and belief, Defendant has misrepresented the failure rates to the FDA by labeling the adverse event as pain rather than implant subsidence.

[16] Rosas K, Hurley ET, Kennedy JG. Early Failures of Polyvinyl Alcohol Hydrogel Implant for the Treatment of Hallux Rigidus. Foot & Ankle Orthopaedics. October 2020. doi:10.1177/2473011420S00414

67. Prior to the implantation of Plaintiff's Cartiva implant, Defendant was aware of higher than reported loss of toe mobility, pain, and high failure rates of the Cartiva implant due to shrinkage and subsidence and loosening and other factors.

68. The Patient Brochure for the Cartiva does not list loss of range of motion of the toe, bone lysis, shrinkage of implant, bone erosion or the inability to walk as a known risk. The only risks cited in the brochure were taken directly from the results of the initial clinical study, which found that just 1 out of 152 patients experienced loosening and no patients experienced sensitivity or allergies, bone loss, poor positioning or other problems.[17]

69. Plaintiff relied upon the representations made in the Patient Brochure, which formed the basis of Plaintiff's decision to use the Cartiva implant.

70. Device migration was underreported as a risk that occurred in 1 out of 152 patients in a two-year clinical study. However, upon information and belief, Defendant's label and patient brochures failed to provide Plaintiff with information relating to the true failure rate due to migration and prevalence of those failures sufficient to make an informed decision prior to surgery.

71. Defendants' label reflects a Cartiva implant failure rate of 13.5%. However, in view of continual and ongoing reports and studies, the actual rate of failure of the defective Cartiva device is likely 6-7 times higher than Defendants' reported failure rate, which it is believed the Defendant knew about.

72. Unfortunately, for patients with Cartiva implant failure, many in the medical community believe that loss of toe range of motion is a symptom of shrinkage (aka implant subsidence), which is a precursor to failure. By any account, the number of Cartiva implant failures

[17] The patient brochure changed over time. These claims are based on a version of the brochure available on Cartiva's website in 2020.

is not only exponentially greater than Defendants will admit but the failure rate has reached alarming proportions.

73. However, during the time Defendants marketed, labeled, and sold the Cartiva implant to Plaintiff, they knew or should have known that the likelihood of patients experiencing implant shrinkage and loosening was significantly higher than they reported, and in fact is higher than any comparable product on the market and that pain and discomfort would be a likely consequence of implant shrinkage and migration.

74. The Cartiva implant was touted as a revolution in great toe arthritis therapy. It came out with a splash and the original studies to get the implant through FDA approval showed striking results.

75. Bob Baravarian, DPM, FACFAS, was involved in helping launch Cartiva and educating other surgeons on the proper use of the Cartiva SCI. However, Dr. Baravarian's clinic, University Foot and Ankle Institute, began to see failures due to the implant slipping into the bone, a process referred to as subsidence. After using the device in about 50 patients, Dr. Baravarian and his clinic turned away from Cartiva, because the failures of Cartiva implants in clinical practice occur more frequently than the results noted in Cartiva's "Motion Study".[18] In an article published in Podiatry Today, Bavarian issued the following warning in July 2019:

> "We have stopped using the implant as a primary treatment option unless the patient is fully informed as to the risk of failure. Some patients want this procedure and understand that if it fails, they can have a revision with little anticipated difficulty. Even so, should we perform this procedure if we have experienced a 50 percent failure rate?"

[18] https://www.hmpgloballearningnetwork.com/site/podiatry/examining-obligations-when-implant-procedure-fails-reflections-surgeon (last visited Sept. 15, 2026)

76. Dr. Baravarian is not alone in his findings, despite airing his concerns five years before the Cartiva was finally recalled. For example, a retrospective review of 64 Cartiva SCI procedures by Cedars Sinai Medical Center showed a higher level of patient dissatisfaction with implant outcomes than was seen in Cartiva's Motion Study clinical trial. In the Cedars Sinai trial 37.5% of the patients underwent revision surgery at average 20.9 months of follow-up. More importantly, the radiographic loss of MTP (great toe) joint space and progression of arthritis were present for all cases studied. MRI revealed bony channel widening and a smaller implant-evidence of subsidence (a/k/a shrinkage) with peri-implant fluid suggesting instability at the implant bone interface. Persistent edema was observed in soft tissues and bone.

77. Defendants did not share the negative experiences of surgeons, or the results in follow-up studies such as those from Cedars Sinai, with the FDA or with other surgeons. If Defendants had shared this information about soaring failure rates, they would have recalled the device sooner, or surgeons would have stopped using it entirely

. Defendants Finally Issue a Global Recall of the Cartiva SCI evice

78. After years of surgeon complaints and product failures, Defendants finally issued a global recall of the Cartiva SCI device on October 31, 2024 based on higher rates of revision, removal, displacement, pain, or nerve damage than previously disclosed in premarket and post approval studies. Plaintiff's failed Cartiva device is within the scope of the global recall, and Plaintiff's device failed for reasons consistent with the recall.

79. The recall notice instructed healthcare providers to remove and quarantine any remaining Cartiva SCI devices in their inventory and return them to Stryker. It also asked physicians to continue monitoring their patients, and look for new or worsening symptoms including pain, and difficulties walking.

80. A recall is an alternative to a Food and Drug Administration-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall. See 21 CFR § 7.40(a).

81. Defendants knew or should have known the Cartiva SCI should have been recalled long before October 31, 2024, in violation of federal regulations including making an adulterated device that proximately and directly caused Plaintiff's injuries and damages.

G. Degradation of Cartiva (PVA Gel Implant)

82. The Cartiva implant is a Polyvinyl membrane gel implant. Cartiva implants have had degradation of the PVA membrane, as noted in Rosas and other studies, with findings of loosening, marring and deformity of the implant.

83. Upon information and belief, Plaintiff's Cartiva implant had loosening of the implant due to shrinkage, marring and deformity of the implant caused by PVA degradation which directly and proximately caused implant failure, subsequent multiple surgeries, pain, loss of mobility and bone.

84. The PVA degradation is not an anticipated or intended outcome of the manufacture of the Cartiva implant.

85. The PVA degradation is a mechanical defect that rendered the Cartiva implant inserted in the Plaintiff defective and unreasonably dangerous.

86. The importance of *swelling behavior* is connected to the mechanical and tribological properties of the Cartiva SCI hydrogel, as well as how swelling behavior impacts the risk of implant failure. In 2007, PVA hydrogels were used for treatment of knee cartilage defects

in adult rabbits. Results revealed growth over the implant and implant shrinkage.[19] Gels can react to osmotic gradients and swell and de-swell accordingly, even in hydrated conditions. This volume change may induce detachment from the tissue or implant and interfacial debonding.[20]

87. Since Cartiva implants are composed of PVA which is soluble in water, crosslinking is a crucial step for PVA gel formation. Without a stable structure, the gel is not able to withstand the swelling pressure upon fluid intake and may dissolve.[21]

88. Cartiva is a proprietary PVA-based hydrogel, and its production consists of successive freeze-thawing cycles.

89. The Cartiva implant is a PVA based hydrogel. PVA hydrogels are problematic because the method of manufacturing may result in 1) air bubbles, 2) PVA clumping, 3) fragility of the PVA hydrogel, 4) improper binding of crystallites, 5) disintegration and 6) striation.



Partially disintegrated Freeze Thawed PVA gel

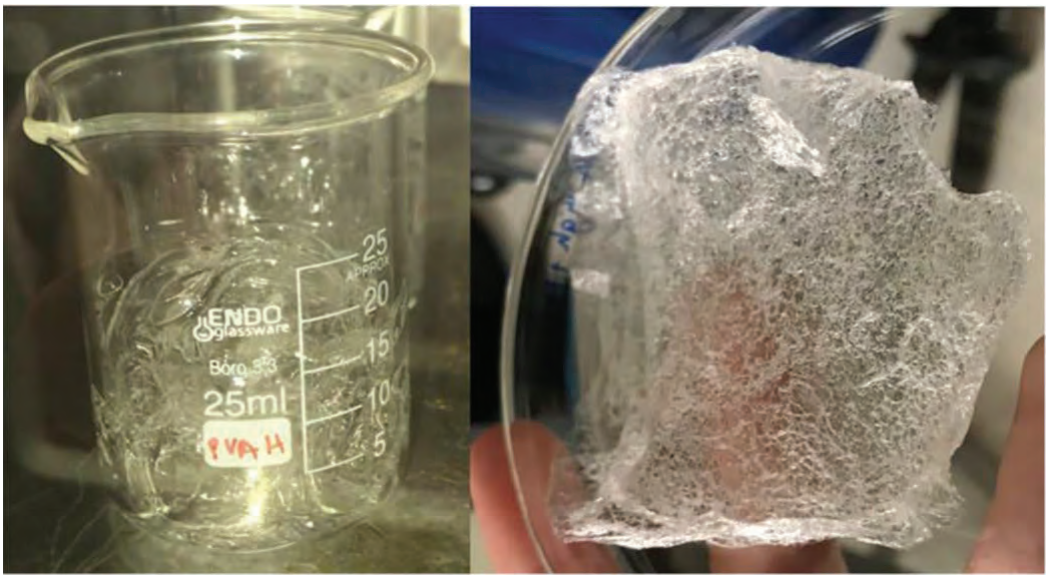
[19] Maher SA, Doty SB, Torzilli PA, et al. Nondegradable hydrogels for the treatment of focal cartilage defects. J Biomed Mater Res - Part A. 2007;83(1):145-155. doi:10.1002/jbm.a 31255

[20] Carolina Borges, Rogério Colaço & Ana Paula Serro (2019) Poly(vinyl alcohol)-based hydrogels for joint prosthesis, Annals of Medicine, 51:sup1, 105, DOI: 10.1080/07853890.2018.156271

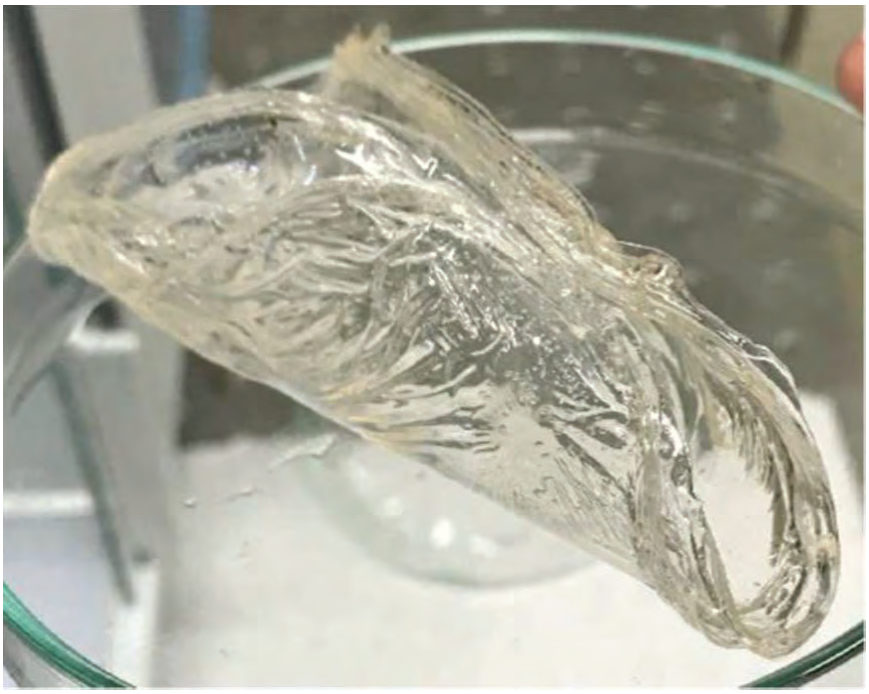
[21] Peppas NA. Hydrogels in Medicine and Pharmacy. Boca Raton: CRC Press; 1989



Striations on gel caused by rapid cooling and oxygenation of pre gel solution.



Effects of vacuum on gelation of PVA cause air bubbles to be trapped inside hydrogel.



Semi-irreversible contracture of thick PVA hydrogel

90. Manufacturing methods are more problematic for thicker gels like the Cartiva implant. Thicker gels are prone to a lot more variation, and small tweaks in temperature and aeration can contribute to these variations. Consistent temperature and aerations are much harder to produce on a larger scale in a manufacturing environment.

91. The violations of federal regulations, including but not limited to making an adulterated device because the manufacture of the defective device failed to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements proximately and directly caused Plaintiff's injuries and damages. See 21. U.S.C. §351.

H. Product Representations

92. Defendant's label and patient brochures and other marketing materials failed to provide accurate substantive or quantitative prevalence rates of failure or other adverse effects to Plaintiff prior to her surgery.

93. Defendant represented in patient marketing literature that Cartiva is a quick 35 minute procedure where your physician replaces the damaged cartilage in your big toe with a new synthetic cartilage that behaves like the natural cartilage of your big toe joint.

94. Defendant additionally told patients, including Plaintiff, that "movement matters" and further stated in marketing materials that "Your big toe joint is uniquely designed for movement and provides most of the force needed for walking and running. Unlike fusion surgery, which locks the joint in place, CARTIVA Synthetic Cartilage Implant (SCI) reduces pain while also allowing your joint to move how it's supposed to."

95. In addition to promises about increased toe mobility and function, Defendants alleged in marketing that the Cartiva implant is proven to provide *long-term pain reduction* and *increased foot mobility*, with *97% reduction in pain* demonstrated at almost six years post-procedure. These statements exceed the scope of the FDA approved label, and they contradicted information known to Defendants based on higher-than-expected failure rates in subsequent years.

96. Plaintiff was induced to purchase/use a Cartiva implant based on the Defendants' representations about the safety and efficacy of the product. Furthermore, Plaintiff has endured medical expenses, loss of income, and pain and suffering based upon Plaintiff's reliance on Defendants' product representations and will continue to have future expenses to repair the bodily harm caused by the defective Cartiva implant.

97. Defendants' labeling was false and/or misleading. Defendants violated the federal regulations in the labeling of Plaintiff's Cartiva implant thereby causing a misbranded medical device to be ultimately implanted into Plaintiff's body.

98. The conditional approval letter relating to the Cartiva implant stated: "CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws."

99. Failure to comply with the conditions of approval invalidates this approval order.

100. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Food, Drug and Cosmetic Act. 21 U.S.C. §§ 301 et seq.

101. Defendants violated the conditional approval requirements and consequently the federal regulations in, among other things, making untrue, inaccurate and/or misleading statements regarding Plaintiff's Cartiva implant. For example, the marketing brochures for Cartiva stated that patients would experience "significantly less pain as soon as two weeks post-surgery" even though their own paid consultants performed research that revealed pain relief did not begin until 31 months after surgery due to bone section and other factors.[22] See, e.g., Judith F. Baumhauer et al., *New Technology n the Treatment of Hallux Rigidus with a Synthetic Cartilage Implant Hemiarthroplasty* 50 Orthop. Clin. N. Am. 109, 109–18 (2019).[23]

[22] Other marketing brochures for Cartiva told patients that relief from pain and stiffness would begin "immediately after surgery" and that the device would last a lifetime.

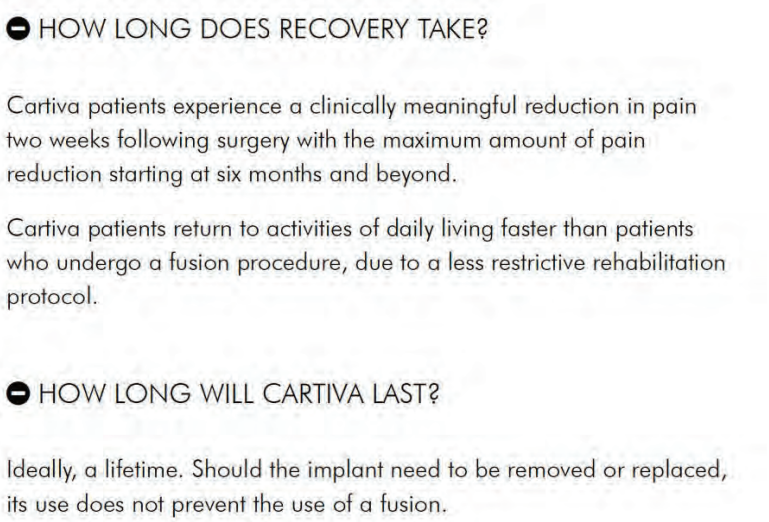
[23] Dr. Baumhauer was one of the key opinion leaders for Cartiva in 2017 and later years. She was paid by Cartiva to perform studies and present to other physicians at events hosted by groups such as the American Orthopaedic Foot & Ankle Society. Cartiva paid her $47,886 in 2016, $33,168 in 2 7 and $57,797 in 2018 according to publicly available figures from Pro Publica's Doctors for Dollar database, available at https://projects.propublica.org/docdollars/ (last visited Sept. 17, 2026).

102. Defendants furthermore violated the conditional approval requirements and consequently the federal regulations by distributing marketing brochures in print and online to U S. patients before the Cartiva was approved for distribution in the United States, and before FDA approved the Cartiva for sale. These materials promoted Cartiva as offering "immediate pain relief" and being a favorable alternative to fusion. These foreign marketing materials were viewed by U.S. surgeons and patients, who relied on them in choosing to use the Cartiva device even though these claims were not substantiated in the clinical trials used to gain PMA approval.

103. Dr. Baumhauer served as the medical monitor for the clinical study for the Cartiva, and as such was involved in the study design and safety oversight of patients. When criticism started to grow over the performance of the device, Defendants paid Dr. Baumhauer to appear on conference calls with investors and stock analysts to defend the device's failure rate.[24]

104. Defendants also published statements in their marketing materials, including at www.Cartiva.net, stating that the device would last a "lifetime" and that "maximum pain reduction" would begin at six months instead of the 31 months revealed in Dr. Baumhauer's research.

[24] Baumhauer told investors that it takes up to a year to realize the full benefits of Cartiva, even though her own research showed that pain relief did not begin for 31 months. Wright Medical Group Q2 2019 Earning Call Transcript, available at https://www.fool.com/earnings/call-transcripts/2019/08/08/wright-medical-group-wmgi-q2-9-earnings-call-tr.aspx (last visited Sept. 16, 2026).



HOW LONG DOES RECOVERY TAKE?

Cartiva patients experience a clinically meaningful reduction in pain two weeks following surgery with the maximum amount of pain reduction starting at six months and beyond.

Cartiva patients return to activities of daily living faster than patients who undergo a fusion procedure, due to a less restrictive rehabilitation protocol.

HOW LONG WILL CARTIVA LAST?

Ideally, a lifetime. Should the implant need to be removed or replaced, its use does not prevent the use of a fusion.

105. If Defendants had not made these voluntary statements and violated the requirements and regulations, Plaintiff would have chosen an alternative treatment option such as fusion or a different device for implantation.

I. efendants Failed to Comply with the Terms of the PMA-Post-Approval Surveillance Study

106. The PMA approval order for the Cartiva implant required Defendants to collect data to assess the following primary and secondary study endpoints:

a. **Primary Study Endpoints** The primary endpoint will evaluate the long-term safety of the Cartiva implant by demonstrating the following:

i. Durability of the implant over the longer term.

ii. Assessment of no unanticipated safety concerns that arise after Month 24 up to 5 years.

Addressed by:

1. determining the incidence of serious device-related adverse events per year and overall from Month 24 to Year 5; and

2. summarizing device-related radiographic major complications over time from Month 24 to Year 5.

b. Provide the following secondary endpoints:

i. Evaluation of maintenance of range of motion;

ii. Wear characteristics or device degradation for any Cartiva implant removed;

iii. Pain and function over time (Visual Analog Scale [VAS] pain scores, Foot and Ankle Ability Measure [FAAM] Activities of Daily Living [ADL] function scores and FAAM Sports function scores); and

1. Evaluation of radiographic findings (radiolucency, bony reactions, and heterotopic ossification) looking at presence or progression from 24 months to 5+ years as well as correlation with the 5+ years clinical outcomes (effectiveness and safety).

107. In addition to *not* following the PMA post-approval orders, Defendants largely ignored the endpoints the FDA placed in the PMA to protect public safety. For example, the safety data the FDA established did not narrow the Defendants' focus to the Motion study participants. Yet, Defendants violated the FDA's PMA order by not assessing the safety of each endpoint for each device with reported adverse events. Defendants specifically violated this provision by failing to report hundreds of adverse events not involving the Motion study participants, and by failing to share complaints from orthopedic surgeons and podiatrists who experienced high failure rates among patients and who were not able to replicate the Motion study results.

108. The lack of safety surveillance served to suppress information from the FDA in violation of the PMA order and the lack of safety surveillance makes the product unreasonably dangerous to end consumers, including Plaintiff.

109. Defendants failed to develop practices and procedures to assure compliance with 21 C.F.R. §814 concerning device modifications, instructions for use, pre-market approval conditions; and to comply with 21 C.F.R. §§803, 806 and 820, concerning maintaining MDRs, implementing device Removals and Corrections and establishing Quality Systems.

110. Defendants failed to develop practices and procedures to assure compliance with the federal requirements for reporting adverse events, or MDRs, in accordance with 21 U.S.C. §360. Instead of reporting adverse events in compliance with FDA regulations and the terms of the PMA, Defendants looked for reasons to avoid reporting product failures and patient injuries. For example, Defendants intentionally searched for missing pieces of information in patient records and complaints and then claimed they could not or did not need to report those injuries to FDA due to insufficient information.

111. In just one example of Defendants' efforts to conceal product failures, the FDA wrote a letter to Cartiva on August 13, 2018, pointing out that the Post Approval Study Protocol required any implant removals to be retained and stored in sterile saline so that the explanted devices could be evaluated for wear characteristics and degradation. The FDA's letter then stated that 9 patients enrolled in the study had undergone removal surgery, but there was no data provided on wear or degradation.

112. Despite the obligations described above, and the obligations of every medical device manufacturer to comply with federal law, Defendants failed to meet numerous federal requirements in their manufacture and sale of the Cartiva implant prior to Plaintiff's surgery and

implantation of the Cartiva device which caused Plaintiff to have implanted a defective and adulterated device causing injuries and damages.

113. Defendants' failure to meet the specific federal requirements outlined above which are applicable to the Cartiva implant, directly and proximately caused Plaintiff's Cartiva implant to be defective and proximately caused harm and injury to Plaintiff.

114. The causes of action set forth in this complaint are not preempted by § 360k(a), because the violations alleged are all based on an exclusively federal statutory and regulatory standard of care which includes no "requirement, which is different from, or in addition to, any requirement applicable under" the Food, Drug and Cosmetic Act and regulations promulgated thereunder. As such, the claims set forth in this cause of action contain requirements that are parallel to the Food, Drug and Cosmetic Act and regulations promulgated thereunder.

J. Defendant's Corporate Facts

115. Prior to obtaining FDA approval, Cartiva Inc, raised revenue on July 24, 2013, with an equity funding by offering a round of Regulation D security offerings totaling $4,312,712.00.

116. Three years later on July 1, 2016, Cartiva, Inc. obtained premarket approval of the Cartiva SCI.

117. On or about October 10, 2018, Wright Medical Group purchased Cartiva, Inc. for $435,000,000.00. Stock analysts considered it a hefty price tag but also were impressed with strong early adoption of Cartiva SCI, which offers an alternative to fusion surgery which is the gold standard for treating severe arthritis in the big toe.

118. Despite the initial excitement at product launch, stock analysts quickly caught wind of the reports of Cartiva implant failure. By July 2019, RBC stock analysts found some surgeons were implanting fewer of the devices or they had even stopped offering the treatment altogether.

Problems with post-operative pain, degree of motion, or the device slipping into the bone in a process known as subsidence ("shrinkage") were reported. Doctors have been unable to replicate the positive results of the company's Motion clinical trial in the broader patient population and have stopped implanting the device or are more cautious about using it. Despite analyst concerns that physicians were dropping offering Cartiva SCI to patients due to failed implants, Wright Medical Group CEO Bob Palmisano remained upbeat on prospects for Cartiva.

119. On the company's earnings call in May 2019, Palmisano said sales growth for the device was exceeding expectations, and he identified the market for treatment of big toe arthritis as a $400 million opportunity.

120. However, failure rates for the Cartiva SCI were much higher in clinical practice than reported in the Motion Study. Wright's CEO Bob Palmisano confirmed Cartiva sales in the second quarter of 2019 fell short of Wright's expectations while touting Wright still maintained gross profit margins of 79%. Palmisano further commented,

> "The unexpected weakness in our U.S. lower extremities business was due to a combination of factors, including the significant reduction in sales by the Cartiva distributors and disappointing performance in our core foot products driven by a higher-than-normal level of sales rep turnover that occurred in a concentrated period of time mid-quarter. To address this, we acted quickly and terminated the Cartiva distributors, and as of August 1, the U.S. Cartiva business has been transitioned to our direct U.S. lower extremities sales force. **We also adjusted the sales compensation program for our entire U.S. lower extremities sales team and are increasing the size of the sales force and aggressively adding experienced reps. We are confident that the actions we have taken will improve the growth rates of artiva** and the whole U.S. lower extremities business; however it will take some time for the benefits of these actions to be evident in the sales results, and we believe our updated guidance takes that timing appropriately into account."

121. Stryker, B.V., a wholly owned subsidiary of Stryker Corp., purchased Wright Medical Group on or about November 11, 2020 for $4.7 billion.[25]

122. The basis of the "Motion Study" that helped Cartiva gain FDA approval was premised upon a claim that there was a less than 10% failure of the Cartiva implant group that would require subsequent conversion to fusion surgery within the first two years of the implant.[26]

123. Defendants alleged the Cartiva implant was determined to be statistically equivalent to arthrodesis (fusion surgery) but with the added benefit of greater mobility and less surgical downtime.

124. Initial results for the Cartiva implant were encouraging, however, unbiased reviewers adopted the position that more independent, non-industry funded research is necessary with larger cohorts to identify implant survivorship and long-term efficacy[27] - something the FDA had already required the Defendant to do in the PMA approval order.

125. Since 2016, Defendants have manufactured, introduced and/or delivered the Cartiva SCI into the stream of interstate commerce in clear violation of the PMA order issued by the FDA.

126. Before commercially distributing the Cartiva in the United States, federal law required Defendants to submit an application for premarket approval ("PMA") of the device to the Secretary of Health and Human Services. On July 1, 2016, the Food and Drug Administration

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[25] https://investors.stryker.com/press-releases/news-details/2020 Stryker-completes-acquisition-of-Wright-Medical/default.aspx

[26] Baumhauer JF, Singh D, Glazebrook M, Blundell C, De Vries G, Le IL, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Younger AS, Daniels T; for and on behalf of the CARTIVA Motion Study Group. Prospective, Randomized, Multi-centered Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. 2016 May;37(5):457-69. doi: 10.1177/1071100716635560. Epub 2016 Feb 7. PMID: 26922669.

[27] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7067982/pdf/main.pdf

("FDA") completed its review of Defendant, Cartiva, Inc.'s PMA application for the Cartiva implant.

127. Based on the materials submitted, the FDA conditionally approved the Cartiva implant for commercial distribution.[28] The conditional approval letter from the FDA stated that "[c]ommercial distribution of a device that is not in compliance with these conditions is a violation of the [Food, Drug and Cosmetic] act, [21 U.S.C.§§301, et seq.] "

K. Plaintiff's Cartiva Implant

128. The surgical procedure to implant the Cartiva in Plaintiff's great toe has not been effective at alleviating pain or restoring range of motion.

129. As a result of the implantation of the Defective Device, Plaintiff suffered additional surgeries and medical expenses, and causing loss of income, loss of enjoyment of life, and pain and suffering.

130. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiff had been injured, the cause of the injury and the tortuous nature of the wrongdoing that caused the injury. Plaintiff did not become aware of the defective nature of the Cartiva device until the date of her fusion surgery, and Defendants failed to notify her surgeon Dr. McQuillen even though Defendants and their sales representatives had access to records showing his use of the Cartiva SCI device

[28] PMA # P150017

131. Plaintiff's discovery of Cartiva defects is premised on Defendants' communications with physicians, sales representatives and/or distributors and the FDA that failures of a successful Cartiva implant were due to surgical technique and not the implant.

132. Despite diligent investigation by Plaintiff, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relation to the Plaintiff's Cartiva and Defendants' wrongful conduct was delayed and could not have been discovered, until a date within the applicable statute of limitations for filing each of Plaintiff's claims.

133. The full extent of Defendants' communications with Plaintiff's healthcare providers can only be known following discovery, and Plaintiff remains at a disadvantage without the benefit of such discovery.

134. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendants when they had a duty to disclose those facts. The Defendants' purposeful and fraudulent acts of concealment have kept Plaintiff ignorant of vital information essential to the pursuit of Plaintiff's claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's causes of action. The Defendants' fraudulent concealment did result in such delay

135. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of its Cartiva implants.

OUNT I
STRICT PRODUCTS LIABILITY
SIGN, MANUFACTURE AND FAILURE TO WARN

136. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

137. The Cartiva SCI device implanted in Plaintiff's big toe was designed and/or manufactured in violation of the Federal Food, Drug and Cosmetic Act ("Act") and regulations promulgated pursuant to it, including but not limited to improper workmanship and errors at the point of manufacture which caused defects in the Cartiva implants that occurred in the manufacturing process.

138. These defects caused Plaintiff's Cartiva implants to shrink and migrate from the initial implant site causing pain, loss of mobility and bone loss due to the defective product.

139. At the time the Cartiva implant was placed inside Plaintiff's body, the Defective Device was unreasonably dangerous due to non-compliance by the Defendant with the regulations promulgated pursuant to it in one or more of the following ways:

a. Failed to accurately establish the *in vivo* life expectancy of the Cartiva SCI, in violation of 21 C.F.R. 820.30(f). There have been reports of synthetic cartilage implant failure with ballooning osteolytic cyst formation throughout the first metatarsal head.[20] There was a large degree of reactive tissue around the hydrogel implant. The implant was grossly loose. The implant demonstrated pitting and wear. Rather than establishing this life expectancy, Defendants instead marketed the Cartiva device as lasting a "lifetime" in most patients;

b. Failed to validate the anticipated wear of the Cartiva SCI prior to its release into commercial distribution, in violation of 21 C.F.R. 820.30(g). Despite peer-reviewed literature backed by radiological evidence that Cartiva does not perform as expected long-term as seen in the Rosas and Fogelman and Shimozono and other studies, and Defendants did not reported these findings to the FDA or undertake any similar study, or Defendants downplayed the importance of these studies and their findings;

c. Failed to establish and maintain appropriate reliability assurance testing to validate the Cartiva design both before and after its entry into the marketplace, in violation of 21 C.F.R. 820.30 (g);

d. Failed to conduct adequate bio-compatibility studies to determine the Cartiva implant's propensity to migrate from the joint space. Radiologic evidence of implant shrinkage is evident in peer-reviewed literature, but Defendants have not undertaken studies to analyze the implant shrinkage when exposed to deep matrix bone;

e. Failed to identify the component discrepancy, in violation of 21 C.F.R. 820.80(c);

f. Failed to capture the component discrepancy or defect during their Final Acceptance Activities, in violation of 21 C.F.R. 820.80(d);

g. Failed to establish and maintain procedures for implementing corrective and preventative action in response to, *inter alia*, complaints regarding the Cartiva and other quality problems associated with the Cartiva, in violation of 21 C.F.R. 820.100;

h. Failed to appropriately respond to adverse incident reports that strongly indicated the Cartiva implant was malfunctioning [as defined in 21 C.F.R. 803.3], or otherwise not responding to its Design Objection Intent, in violation of 21 C.F.R. 820.198. Physician complaints report failure rates of 50-64% with Cartiva implants and Defendants largely ignored the clinical evidence by not adequately responding to adverse incident reports or initiating a voluntary recall until October 2024, years after they knew about higher than expected failure rates;

i. Failed to conduct complete device investigations on returned Cartiva implants and components in violation of 21 C.F.R. 820.198. Defendants failed to investigate and analyze Cartiva implant failures; and/or

a. Continued to inject Cartiva implants into the stream of interstate commerce when Defendants knew, or should have known, that the Cartiva implants were malfunctioning [as defined in 21 C.F.R. 803.3] or otherwise not responding to its Design Objective Intent. Multiple press releases by Wright Medical Group demonstrate an awareness of high Cartiva failure rates coupled with physicians ceasing to use Cartiva, but Defendant responded to these failures by increasing sales commissions and aggressive sales strategies, describing the sales as a "knife fight."

140. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, the Cartiva device implanted in Plaintiff failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff as defined in 21 C.F.R. 803.3.

141. As a direct result, Plaintiff endured pain and suffering, including, but not limited to failure of the Cartiva implant, osteoarthritic spurring, chronic pain, bone loss, loss of mobility, and multiple fusion surgeries. Plaintiff has incurred significant medical expenses in the past and will

incur additional medical expenses in the future; physical pain and suffering, both past and future; mental anguish and emotional distress, both past and future, including, but not limited to, annoyance and aggravation.

142. This cause of action is based entirely on the contention that Defendants violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied statutory cause of action, but rather Plaintiff is pursuing parallel state common law claims based upon Defendants' violations of the applicable federal regulations.

143. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. §306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement, which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder.[21] As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder and not preempted.

144. Plaintiff cannot presently identify the confidential batch/manufacturing records and PMA specifications because those records are exclusively within Defendants' possession, but will identify the particular deviation through discovery.

145. As a direct and proximate result of Defendants' aforementioned actions, Plaintiff prays for judgment against Defendants in an amount in excess of Seventy- Five Thousand Dollars ($75,000.00).

146. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, the Defective Device implanted in Plaintiff failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff as defined in 21 C.F.R. 803.3.

147. As a direct result, Plaintiff endured pain and suffering, including, but not limited to implant failure, scarring and disfigurement and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; physical pain and suffering, both past and future; mental anguish and emotional distress, both past and future, including, but not limited to, annoyance and aggravation.

148. This cause of action is based entirely on the contention that Defendants violated federal safety statutes and regulations. Plaintiff did not bring the underlying action as an implied statutory cause of action, but rather they are pursuing parallel state common law claims based upon Defendants' violations of the applicable federal regulations.

149. Under Kentucky law, Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of negligence.

150. Plaintiff alleges that at the time the subject components were in Defendants' control, (i) one or more were defective because they deviated in a material way from the manufacturer's or designer's specifications, (ii) such defective condition rendered them unreasonably dangerous to the user, and (iii) such condition proximately caused the damages for which recovery is sought herein.

OUNT II

MISBRANDING AND ADULTERATION

151. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

152. Plaintiff has endured multiple, painful surgeries, scarring, and nerve damage caused by the defective Cartiva implant. The original Cartiva implant was a Class III device, and all instruments used to insert the Cartiva implant are Class II devices designed and/or manufactured by Defendants and placed into the interstate stream of commerce

153. Defendants marketed, distributed and/or permitted use of its Cartiva implant and insertion instruments in violation of the Act and regulations promulgated to it.

154. It was the duty of Defendants to comply with the Act, and the regulations promulgated pursuant to it, yet, notwithstanding this duty, Defendant violated the Act in one or more of the following ways:

a. Failed to warn patients and the medical community of the risk of implant shrinkage, subsidence, migration and bone loss after receiving numerous complaints and adverse event reports and medical literature about these risks Despite Defendants' knowledge of higher failure rates than previously reported, Defendants chose to do nothing and in fact concealed adverse event reports from FDA and told the agency in annual reports that no new safety information was available. Defendants had a duty to report the failure rates and manufacturing problems to the FDA, and to request permission to strengthen the warning language in the device's labeling. These steps include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device:

i. New indications for use of the device.
ii. Labeling changes.
iii. The use of a different facility or establishment to manufacture process, or package the device.
iv. Changes in sterilization procedures.
v. Changes in packaging.
vi. Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

vii. Changes in the marketing materials and Instructions for Use to make surgeons and patients aware of these risks.

b. Defendants sold, distributed and permitted use of the Cartiva in violation of the regulations prescribed under 21 U.S.C. §360j(e) and 21 U.S.C. § 352(q) which required design validation and manufacturing controls to assure the Defendants would not produce a medical device with impurities or inconsistencies. Defendants also had a duty to provide a label that was truthful about the risks associated with the Cartiva implant and Defendants failed to do so;

c. Failed to comply with the requirements of 21 U.S.C.§ 360i which provides a device manufacturer shall report to the FDA when the manufacturer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, or has malfunctioned and that such device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. As mentioned herein, Defendants had knowledge that failure rates were far higher than the rates reported to the FDA, yet they took no action to protect the public, including Plaintiff, from harm caused by the defective Cartiva implant; and,

d. Defendants failed to comply with 21 U.S.C.§ 360l which required Defendant to submit a surveillance plan for its device once commercial distribution began to detect adverse health events to the public. Instead Defendants has relied solely on the Motion Study and the follow-up Motion Extend study to continue with commercial distribution ignoring the adverse event reports and

other studies correlating findings the failure rate is 6-7 times higher than reported by Defendants. By the time Defendants finally issued a global recall on October 31, 2024, it was too late for those already implanted with the device.

155. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, Plaintiff had a Cartiva implanted using Cartiva instruments and it failed, and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Plaintiff as defined in 21 C.F.R. 803.3. Plaintiff has suffered additional, painful surgeries and accumulated additional medical expenses caused by the Defective Device, and causing additional loss of income, loss of enjoyment of life, and pain and suffering both past and future; mental anguish and emotional distress, both past and future, including, but not limited to, annoyance and aggravation.

156. This cause of action is based entirely on the contention that Defendants violated federal safety statutes and regulations. Plaintiff does not bring the underlying action as an implied statutory cause of action, but rather they are pursuing parallel state common law claims based upon Defendants' violations of the applicable federal regulations.

157. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. §306(k) because the violations alleged are all based on an exclusively federal statutory and regulatory set of requirements which include no "requirement, which is different from, or in addition to, any requirement applicable under" the Act and regulations promulgated thereunder. See; *Bausch v. Stryker*, 630 F.3d 546, 556 (7th Cir. 2010) (claims for negligence and strict products liability relating to a Class III medical device were not expressly preempted by federal law to the

extent they were based on the defendants' violations of federal law). As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder.

158. As a direct and proximate result of Defendants' aforementioned actions, Plaintiff prays for judgment against Defendants in an amount in excess of $75,000.00.

COUNT III

NEGLIGENT TRAINING

159. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

160. One of the requirements of the Cartiva PMA approval order restricted use of the device under section 515(d)(1)(B)(ii) of the Act and mandated that the device labeling must "… specify the specific training or experience practitioners need in order to use the device."

161. Defendants failed to restrict the use of the Cartiva implant and instruments in violation of 21 U.S.C. §352(r) and the PMA approval order for Cartiva. In direct violation of the PMA order, Defendants' Instructions For Use merely stated that "The Cartiva SCI device should only be used by experienced surgeons who have undergone training in the use of this device".

162. Defendants gave no limitation on the physician's experience or specialty type or certification, nor do the instructions provide any details about the type of training required.

163. The PMA approval order further states the FDA has determined that these restrictions on sale and distribution were necessary to provide reasonable assurance of the safety and effectiveness of the device. "Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices."

164. As mentioned herein, Defendants had a duty to print on the label and marketing materials of the Cartiva implant all relevant warnings, precautions, side effects, Instructions For Use and contraindications.

165. Defendants voluntarily offered a training program to physicians but it contained misleading and inaccurate information, and intentionally omitted post-approval risks.

166. When Defendants voluntarily offered statements as part of the surgeon training materials, they assumed a traditional state-law duty to perform that training with reasonable care.

167. For example, in the training materials, Defendants did not disclose known information about the risks of subsidence, shrinkage, bone erosion, migration or persistent pain in patients. They also did not disclose that, at the time of Plaintiff's implant surgery, physicians were unable to reproduce the outcomes in the Motion Study, and Defendants did not disclose the limitations of the five-year patient follow-up population.

168. The written training materials furthermore stated that there were "no unanticipated safety concerns" with the Cartiva device, even after serious safety concerns including excessive failure rates became known to Defendants.

169. This misleading guidance, in violation of the terms of the PMA, is critical to Plaintiff's claims because there were no similar hydrogel devices on the U.S. market being used in hemiarthroplasty.

170. Defendants knew that implanting surgeons would reasonably rely upon Defendants' training program as an authoritative source of information concerning the safe selection of patients, implantation of the device, expected clinical performance, and known risks of Cartiva SCI.

171. Having voluntarily undertaken to train implanting physicians concerning matters necessary for the protection of Cartiva patients, Defendants assumed a duty under the law of Kentucky, independent of the federal regulations, to perform that undertaking with reasonable care and to avoid providing materially inaccurate, incomplete, or misleading information within the subjects Defendants chose to address.

172. Defendants breached that independent duty by providing training materials that made affirmative representations concerning Cartiva's safety, effectiveness, durability, radiographic performance, revision rates, and long-term clinical outcomes while omitting material information necessary to prevent those representations from being misleading.

173. The misleading information in the training materials, including for Plaintiff's specific surgeon, contributed to the Cartiva device failing prematurely in Plaintiff.

174. If Defendants had provided adequate training to surgeons, Plaintiff's medical providers would have been more aware of and familiar with the risks of the Cartiva device, and Plaintiff would have been better informed about those same risks. The lack of training contributed to the failure of Plaintiff's device.

175. At the time Defendants provided the training materials relevant to Plaintiff's implant surgery, Defendants knew or, through the exercise of reasonable care, should have known of information materially qualifying or contradicting those representations, including reports of implant subsidence, shrinkage, migration, bone erosion or osteolysis, persistent pain, revision surgery, and clinical outcomes that were not consistent with the results reported in the Motion Study.

176. The full extent of the lack of training provided to Plaintiff's surgeon can only be known following discovery on this topic, including the exact materials — if any — provided to

Plaintiff's implanting surgeon, and Defendants' awareness of the number of Cartiva surgeries performed by Plaintiff's providers and their respective medical backgrounds.

177. As a direct and proximate result of Defendants' aforementioned actions, Plaintiff prays for judgment against Defendants in an amount in excess of $75,000.00.

OUNT IV

STATE LAW AND COMMON LAW CLAIMS OF PRODUCT LIABILITY AND NEGLIGENCE FOR CLASS II DEVICES/CLASS III DEVICES

178. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

179. The Cartiva implant and corresponding Cartiva instruments used on Plaintiff were designed, manufactured and distributed by Defendants and placed into the stream of interstate commerce by Defendants.

180. The components were defective in design and/or manufacture, as illustrated by hundreds of adverse event reports for failed Cartiva devices, medical literature showing an excessively high failure rate, and the eventual global recall of the device in October 2024

181. The defects in the Cartiva SCI existed when the components left the hands of Defendants, making the components unreasonably dangerous beyond the contemplation of the ordinary user.

182. Defendants further breached applicable implied and express warranties, including warranties of merchantability and fitness for a particular purpose.

183. Further, Defendants failed to provide appropriate warnings regarding the potential dangers associated with the use of said components, including warnings regarding the risk of

migration of Cartiva implant and shrinkage and subsidence of the Cartiva SCI, such as was experienced by Plaintiff.

184. As a direct and proximate result of the design and/or manufacturing defects, failure to warn and breach of express and implied warranties related to Defendants' Cartiva implant and corresponding instruments designed, manufactured, distributed, sold and/or placed into the stream of commerce by the Defendants, Plaintiff suffered severe and permanent injuries, including, but not limited to, scarring and disfigurement, pain, and suffering, and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional medical expenses in the future; physical pain and suffering, both past and future; mental anguish and emotional distress, both past and future, including but not limited to, annoyance and aggravation; and has been damaged in an amount in excess of $75 000.00.

185. As a direct and proximate result of the willful, wanton, intentional acts, reckless and/or the willful, wanton, intentional acts, reckless and/or the willful, wanton, intentional and reckless failures to act by Defendants, Plaintiff suffered the aforesaid damages and, as such, Plaintiff demands that punitive damages be awarded against Defendants.

OUNT V

REACH OF EXPRESS WARRANTY

186. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

187. Defendants knew that its Cartiva implant had problems, including but not limited to shrinkage and migration out of joint space into the bone. Defendants advertised Cartiva implants as a non-invasive procedure, designed to quickly restore toe mobility with a simple procedure. None of Defendants' advertising, marketing, or informational materials to the Plaintiff mentioned that Cartiva had the ability to cause a condition that results in a permanent disfigurement to the

body that can only be resolved through invasive surgeries resulting in the opposite effect of the device's advertised purpose.

188. Defendants' marketing materials specifically promoted the Cartiva as lasting a "lifetime" when the actual device survivorship was closer to 10 years.[29]

189. Cartiva's promises about longevity were made to both the general public and also to surgeons, who were left with the impression that the device would last a lifetime. For example, a surgeon in Colorado shared that same information on his clinic's website in an article dated July 28, 2017, not long after the initial FDA approval order. [30]

DOES CARTIVA LAST FOR A LONG TIME?

Yes, the Cartiva implant should last for your entire life. In some cases there may be a need to replace the implant. You can find out more at the Cartiva website: www.cartiva.net

WHAT IF I'M INTERESTED IN HAVING THE CARTIVA IMPLANT?

It's important to remember that any medical procedure is highly dependent upon individual circumstances. If you think Cartiva is right for you, contact Dr. Elton today.

190. By comparison, Defendants' own records show the expected product lifetime of the Cartiva was just 5 years, the same time frame after which Defendants stopped studying patient outcomes. But Defendants did not tell patients and surgeons and the public that the

[29] See also supra ¶ 99-100, also describing how Cartiva materials promised "maximum pain reduction" would begin at six months instead of the 31 months revealed in the company's own research.

[30] Dr. John Paul Elton, *What is the Cartiva Implant*, available at https://www.drelton.com/blog/what-is-the-cartiva-implant? (last visited Sept. 18, 2026).

Cartiva's intended lifetime was only 5 years, and they instead promoted the product as being a "long term" solution or a lifetime solution.

191. Plaintiff relied on the skill and judgment of the Defendants that the device was adequately tested and rendered safe to use for its intended purpose. However, the true extent of the promises made to Plaintiff and the medical community can only be known after discovery is completed, and after Defendants have provided full details about the documents and other marketing materials provided to Plaintiff and the relevant Cartiva sales representative.

192. Plaintiff became interested in and underwent the Cartiva implant procedure based on the Defendants' representation about the procedure, including that it would last a lifetime and that pain relief would begin immediately.

193. Because of the innate defective nature of the Cartiva implant, Plaintiff and the individuals performing the Cartiva implant procedure on Plaintiff, through the use of reasonable care could not have discovered the defective nature of the Cartiva device or its perceived dangers.

194. As the direct and proximate result of Defendants' conduct, Plaintiff sustained serious injuries that were directly caused by the defective, unsafe, and unreasonably dangerous Cartiva implant that could not safely be used for the purpose for which it was marketed, advertised, promoted and intended.

195. As the direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered and continue to suffer economic losses, emotional distress, permanent disfigurement, continuous physical pain, mental anguish, diminished enjoyment of life and future medical expenses.

OUNT VI

REACH OF IMPLIED WARRANTY

196. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

197. At all times mentioned herein, Defendants manufactured, portrayed, distributed, recommended, merchandized, advertised, promoted and sold its Cartiva implant and instruments.

198. At the time Defendants marketed, sold, and distributed the Cartiva implant and instruments to be used on Plaintiff, Defendants knew of the use for which the Cartiva device was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

199. Defendants impliedly represented and warranted to the users of the Cartiva devices and/or their physicians, and/or healthcare providers, and/or the FDA that the devices were safe and of merchantable quality and fit for the ordinary purpose for which said products were to be used.

200. These representations and warranties were false, misleading, and inaccurate in that the Cartiva devices were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

201. Plaintiff and/or members of the medical community and/or healthcare professionals relied on these implied warranties of merchantability and fitness for a particular use and purpose.

202. Plaintiff and/or physicians and/or healthcare professionals reasonably relied upon the skill and judgment of the Defendants as to whether the Cartiva devices were of merchantable quality and safe and fit for its intended use.

203. Defendants' Cartiva devices were injected into the stream of commerce by Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

204. Defendants herein breached the aforesaid implied warranties, as the Cartiva devices were neither merchantable nor fit for their intended purposes and uses, because they did not provide the pain relief sought by patients, they did not last a lifetime as advertised, and they carried an excessive risk of premature failure due to subsidence and shrinkage and other failure mechanisms that were concealed from Plaintiff and the medical community.

205. By reason of the foregoing, Plaintiff has experienced and continues to experience, serious and dangerous side effects including but not limited to, mobility problems and disability, as well as other severe and personal injuries which are permanent and lasting in nature, ongoing physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

206. As a result of the foregoing acts and omissions, Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

OUNT VII

AILURE TO WARN

207. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

208. Defendants are, and at all times mentioned in this Complaint were, engaged in the business of designing, manufacturing, assembling, and selling a medical device product known as Cartiva SCI with the purpose of gaining profits from the distribution thereof.

209. Defendants directly or through their agents, apparent agents, servants, or employees designed, manufactured, tested, marketed, and commercially distributed the Cartiva SCI system that was used on Plaintiff.

210. Defendants knew that the Cartiva devices were unreasonably dangerous, unsafe, and/or defective and could cause harm to those who used it, including Plaintiff.

211. Defendants knew that implant migration into the bone was an unavoidable risk of undergoing the Cartiva SCI procedure, and that the Cartiva had an excessive failure rate due to shrinkage and subsidence among other failure mechanisms.

212. Defendants had superior knowledge about implant migration and shrinkage because data and research was in their possession and they had access to facts and information about the condition that was not available to anyone else. As the manufacturer of the device, Defendants were a centralized hub of information about the device's adverse effects, including migration and shrinkage. They had received numerous of reports of users developing the condition, had access to those patients' medical records and information regarding diagnosis, treatment, and occurrence rate, which they did not disclose to the medical community.

213. Defendants had a duty to provide adequate warnings about implant shrinkage and migration, a dangerous adverse effect of its Cartiva SCI system, to Plaintiff's healthcare providers, who acted as learned intermediaries between the manufacturer and patients

214. Defendants specifically failed to warn patients and the medical community that the actual failure rate of the Cartiva was 50% or higher based on independent third party studies, that their sales representatives were told to continue selling the device even after expressing safety concerns, and that numerous surgeons had complained that they were unable to replicate the results in Cartiva's initial clinical trials.[31]

[31] See, e.g., supra ¶53-64.

215. Defendants were well aware of complaints from surgeons through both direct communications and reports from patients and sales representatives. Some doctors even commented publicly about the device's poor outcomes on social media:





216. The above examples are not exhaustive, and the full extent of Defendants' knowledge about the defective nature of Cartiva can only be ascertained through discovery, including depositions and document production.

217. On information and belief, Defendants also delayed or avoided issuing a global recall for the Cartiva until October 2024 even though they could have issued a recall years earlier based on reports about high failure rates.

218. Defendants were in possession of numerous reports and studies showing the Cartiva device had an excessive failure rate and that a common failure mechanism was subsidence or shrinkage, which was not included in the marketing materials and labeling for the device. Defendants therefore could have and should have performed a Health Hazard Evaluation (HHE) or a Health Risk Assessment (HRA) for the Cartiva device, but they instead chose to continue selling the device and promoting its profit potential investors

219. Although the true extent of Defendants' knowledge can only be known with the benefit of discovery, concerns about the device's performance were so widespread that even some of the initial clinical study physicians later published research questioning the safety of the Cartiva device. For example, Dr. Timothy Daniels co-authored an article in acknowledging "poorer patient outcomes" and "high rates of concerning radiographic findings, including implant subsidence, osteolysis, and MT [metatarsal] erosion." The article also discussed Guyton's reanalysis of the original Baumhauer/MOTION RCT, noting that when certain assumptions were changed, Cartiva fell below the study's noninferiority margin.[32]

220. Another article co-authored by Dr. Mark Glazebrook, also part of the initial clinical study team, found that Cartiva patients implanted between 2009 and 2021 had higher non-union rates and worse function outcomes compared to primary arthrodesis.[33]

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[32] Timothy Daniels, Caroline Cristofaro & Mansur Halai, *artiva: A Review of the Best Evidence* , 29 Foot & Ankle Clinics 485, 485–493 (2024), https://doi.org/10.1016/j.fcl.2023.11.004 (last visited Sept. 18, 2026).

[33] Mark Glazebrook, et al, *Failures of Polyvinyl Alcohol Hydrogel Implant for Hallux Rigidus and Outcomes of Revision to Arthrodesis: Mid-Term to Long-Term Results*, Foot & Ankle Specialist (Nov. 26, 5), https://doi.org/10.1177/19386400251385718 (last visited Sept. 18, 2026)

221. Defendants failed to provide adequate warnings to Plaintiff's provider because the language used by Defendants to describe risks in its training materials was:

a. Inaccurate in content and ambiguous in manner of expression;

b. Did not adequately inform the providers about a condition which is: 1) unfamiliar to the medical community, 2) is only associated with the Cartiva device, and 3) about which Defendants had superior knowledge;

c. Creatively used insufficient and vague language that did not provide enough specificity about the condition, which was necessary for the Cartiva providers to know about the risks of using the device;

d. Misrepresented facts about the adverse effects of Cartiva SCI;

e. Did not use concrete terms like "shrinkage" and "implant migration" and "subsidence" to describe the risks;

f. Did not warn that it is likely that multiple surgeries may be necessary to remove and/or correct a failed Cartiva SCI;

g. Did not disclose that Cartiva implant failure can cause permanent nerve damage and deformity, infection and/or amputation of the great toes.

222. Defendants are liable for Plaintiff's damages because their product was defective due to its failure to adequately warn Cartiva SCI providers about the danger of the Cartiva Implant system.

223. As the direct and proximate result of Defendants' wrongful conduct, Plaintiff suffered and continue to suffer economic losses, emotional distress, permanent disfigurement, physical pain, mental anguish, diminished enjoyment of life and future medical expenses.

OUNT VIII

PUNITIVE/EXEMPLARY DAMAGES

224. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein.

225. Defendants' conduct in deceiving Cartiva providers and/or convincing providers to participate in the scheme, in not informing Plaintiff of the seriousness, permanency, and frequency of implant shrinkage and migration, in concealing material information regarding the serious adverse effect of the Cartiva implant, and in creating a system by which consumers did not have fair access to important information about Cartiva, was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct.

226. Defendants, as corporations, actively and knowingly participated in the dissemination of misrepresentations and concealment of material information related to implant shrinkage and migration and its Cartiva SCI implant system.

227. Defendants and their agents' malicious and fraudulent conduct must be punished to deter future harm to others. Therefore, exemplary damages are appropriate under the circumstances.

PRAYER FOR RELIEF

228. Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein. and further prays:

229. So far as the law of Kentucky and this Court allows, Plaintiff demands judgment against Defendants on each count as follows:

a. All available compensatory damages for the described losses with respect to each cause of action;

b. Past and future medical expenses, as well as the cost associated with past and future life care;

c. Past and future lost wages and loss of earning capacity;

d. Past and future emotional distress.

e. All available noneconomic damages, including without limitation pain, suffering, and loss of enjoyment of life;

f. Punitive damages with respect to each cause of action;

g. Costs of this action;

h. Pre-judgment and all other interest recoverable; and

i. Such other additional, further, and general relief as Plaintiff may be entitled to in law or in equity as justice so requires.

MAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all issues raised in this Complaint.

Respectfully submitted,

ALEX DAVIS LAW OFFICE PSC

s/ Alex C. Davis
Alex C. Davis
Mason H. Forrest
445 Baxter Avenue, Suite 275
Louisville, Kentucky 40204
Phone: (502) 882-6000
Fax: (502) 587-2007
alex@acdavislaw.com
mason@acdavislaw.com
Attorneys for the Plaintiff

JS 44 (Rev. 03/24)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS

Sandra K. Downey

(b) County of Residence of First Listed Plaintiff Jefferson (Ky)
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*

Alex C. Davis, Alex Davis Law Office, 445 Baxter Ave., Suite 275, Louisville KY 40204 P: 502 882-6000

DEFENDANTS

Cartiva, Inc.

County of Residence of First Listed Defendant New Castle (DE)
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*

(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☐ 365 Personal Injury - Product Liability
- ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

INTELLECTUAL PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent - Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit (15 USC 1681 or 1692)
- ☐ 485 Telephone Consumer Protection Act
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation - Transfer ☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)***:
28 US 1332

Brief description of cause:
Products Liability Toe Implant

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND $ 75,000

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE Hon. Kristine Baker, E.D. Ark. DOCKET NUMBER MDL 3172

DATE Sep 23, 2026

SIGNATURE OF ATTORNEY OF RECORD /s/ Alex C Davis

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I.(a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below**; NOTE: federal question actions take precedence over diversity cases.**)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: Nature of Suit Code Descriptions.

V. Origin. Place an "X" in one of the seven boxes.
Original Proceedings. (1) Cases which originate in the United States district courts.
Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related cases, if any. If there are related cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.