IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ANDREA KELLER, Case No.

Plaintiff,

vs.

CARTIVA, INC.

Defendant.

COMPLAINT IN CIVIL ACTION

COMES NOW Plaintiff, Andrea Keller ("Plaintiff" or "Mrs. Keller"), by counsel, and for her Complaint against Defendant Cartiva, Inc. ("Defendant" or "Cartiva") 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 on Oct. 31, 2024.[1]

PARTIES

1. Plaintiff Andrea Keller is, and at all times relevant to this action was, a citizen and resident of the State of Pennsylvania, with a residence at 473 Lancer Drive in Columbia, Pennsylvania (Lancaster 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

[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 May 7, 2026.

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. At all times material hereto, Defendant 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 Pennsylvania, including Plaintiff.

4. Defendant's Defective Device was placed into the stream of interstate commerce and was implanted in Plaintiff's left big toe on or about Jan. 8, 2019, at Hershey Outpatient Surgery Center in Hershey, Pennsylvania by Umur Aydogan, MD.

5. On or about December 6, 2024, Plaintiff underwent revision and fusion surgery at the Wellspan Surgery and Rehabilitation Hospital in York, Pennsylvania by Christian Hall, MD. In his operative findings, Dr. Hall noted that, upon removal, Plaintiff "developed erosion and persistent pain and the Cartiva implant has subsided into the first metatarsal head." Dr. Hall removed the defective Cartiva SCI during the procedure and fused the joints of Plaintiff's left big toe together.

6. Dr. Hall later performed another surgery on Plaintiff's left foot on or about May 21, 2025, due to a complication from the failed Cartiva. This surgery was due to a Morton's neuroma between the third and fourth metatarsal heads and a left second plantar plate tear.

7. As a direct and proximate result of Defendant 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 Pennsylvania, 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.

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

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

10. 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 Pennsylvania.

JURISDICTION AND VENUE

11. 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.

12. Defendant has 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 Pennsylvania in the ordinary course of trade, commerce or healthcare;

B. Conducting and engaging in substantial business and other activities in the State of Pennsylvania 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 Pennsylvania, including Plaintiff, and likely others. Before, at or about the time of said injuries, the Defendant

engaged in solicitation activities in the State of Pennsylvania 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 Pennsylvania.

13. Venue is proper in the U.S. District Court for the Eastern District of Pennsylvania 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 Pennsylvania in the County of Lancaster.

GENERAL ALLEGATIONS

14. This lawsuit arises from the Defendant's 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.

15. Big toe arthritis affects about 2.2 million in the United States. As arthritis deteriorates the joint's cartilage a person develops an extremely painful bone-on-bone painful 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. Cartiva Implant Treatment Option

16. 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.[2]

[2] Home > For Physicians > Implant Procedure(https://www.cartiva.net) (https://www.cartiva.net/for-physicians/)

17. Defendant 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.

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 an appropriately sized cavity in the metatarsal head and deploy the Cartiva implant into the prepared cavity.

20. Defendant claims that joint resurfacing with a Cartiva implant is simple, does not require significant removal of healthy tissue, and typically results in nominal surgical trauma and rapid recovery.[3]

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- e.g. the complete turnover of the human femoral head cartilage would take approximately 400 years.[4] Joint replacement with polyvinyl alcohol-based hydrogels (PVA), such as the one used in Cartiva is a joint replacement alternative to traditional fusion treatment.

---

[3] *Id*.

[4] 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

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.[5] But the characteristics of the resulting hydrogel could also be tailored by adjusting the production method or by combining PVA with other materials to produce a more suitable and stable material than the current design.[6]

B. **Fusion 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.

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.

C. **Medical Facts - Injury**

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

28. On or about Jan. 8, 2019, Umur Aydogan, MD performed surgery on Plaintiff whereby the Cartiva SCI was implanted in her left great toe at Hershey Outpatient Surgery Center in Hershey, Pennsylvania.

---

[5] *Id*.

[6] 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. *Carbohydr Polym*. 2011;84(1):145-152. doi:10.1016/j.carbpol.2010.11.018

29. Plaintiff was induced to purchase the Defective Device based on the Defendant's representations that her recovery time would be faster and less painful than if she underwent a traditional fusion.

30. At all times material hereto, the Cartiva SCI implanted in Plaintiff's left big toe was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendant.

31. As a result of the implantation of the Defective Device, Plaintiff has suffered numerous complications and was required to have corrective surgery as described above, along with 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**

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

33. Defendant obtained Premarket Approval Application ("PMA") approval for Cartiva as a Class III device, yet the approval was largely based on the "substantial equivalence" of the Cartiva implant performing similarly to the gold standard treatment of fusion. Substantial equivalence is generally used for Class II medical devices and evades a full FDA safety review.

34. The pivotal clinical study ("Motion Study")[7] compared the Cartiva implant to the traditional gold standard fusion treatment. The study was a non-inferiority clinical study of 202

[7] 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

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 failure rate is much higher.[8]

35. The Motion Study has been widely criticized by industry 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.[9]

36. In support of its position, Cigna cited a report by Hayes, Inc.[10] 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 (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 Defendants 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

---

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 27. PMID: 26922669.

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

[9] 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)

[10] 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.

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.

37. 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.

38. 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).

39. Outside the U.S., NICE published Interventional Procedure Guidance in 2005 based on 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 also states there is little evidence on the durability of newer implants, and that complications may necessitate removal of the joint. These complications include

persistent pain, infection, implant loosening, implant fracture, osteolysis, bone over-production, cyst formation, silastic granulomas and transfer metatarsalgia.

E. **Defendant Suppressed Adverse Data from FDA/Medical Providers**

40. 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.

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

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

43. For example, Dr. Mark Hardy of Ohio told Cartiva in early 2018 about numerous surgeries where patients experienced device failure and subsidence.

44. 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.

45. 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.

46. 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.[11]

47. 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 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.[12]

48. 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.

49. 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.

50. Cartiva's claimed success rates do not exist in clinical practice. Actual patient results have reported failure rates of 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

[11] 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):1140-1148.
[12] 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.

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.[13]

51. 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.

52. 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, Defendant 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.

53. 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 including but not limited to over 144 adverse event reports filed with the FDA.

54. To date there are at least 144 adverse event reports in the Maude database with the majority of events attributed to implant loosening or failure. The loosening is likely due to shrinkage of the implant that is well supported by peer-reviewed literature mentioned herein.

55. The Patient Brochure for the Defective Device 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

[13] 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

of the Cartiva implant. Plaintiff relied upon the representations made to her in the Patient Brochure, provided to her directly and/or communicated by her healthcare provider, which formed the basis of her decision to use the Cartiva implant.

56. 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 for her to make an informed decision prior to her surgery.

57. Defendant's label reflects a Cartiva implant failure 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 Defendant's reported failure rate, which it is believed the Defendants knew of before December 2019.

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

59. However, during the time Defendant has marketed, labeled, and sold the Cartiva implant to Plaintiff, they knew or should have known that the likelihood of patients experiencing implant shrinkage 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.

60. 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.

61. 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. Dr. Baravarian and his clinic will no longer use Cartiva, because the failures of Cartiva implants in clinical practice occur more frequently than the results noted in Cartiva's "Motion Study".[14] "Currently, we no longer use the Cartiva implant as a treatment option for first MPJ arthritis as we have found an over 50 percent failure rate in our cases."

62. Dr. Baravarian is not alone in his findings, 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.

[14] https://www.hmpgloballearningnetwork.com/site/podiatry/examining-obligations-when-implant-procedure-fails-reflections-surgeon

F. **Defendant Issued a Recall of the Cartiva SCI Device**

63. As failure rates continued to rise, Defendant issued a recall of the Cartiva SCI device on October 31, 2024 based on reports, including the Rosa study, indicating patients, including Plaintiff, who received a Cartiva SCI implant experienced alarmingly high rates of revision, removal, displacement, pain, or nerve damage than previously disclosed in premarket and post-approval studies.

64. 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.

65. 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).

66. The Defendant 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)

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

68. 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.

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

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

71. 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.[15] 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.[16]

72. 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.[17]

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

---

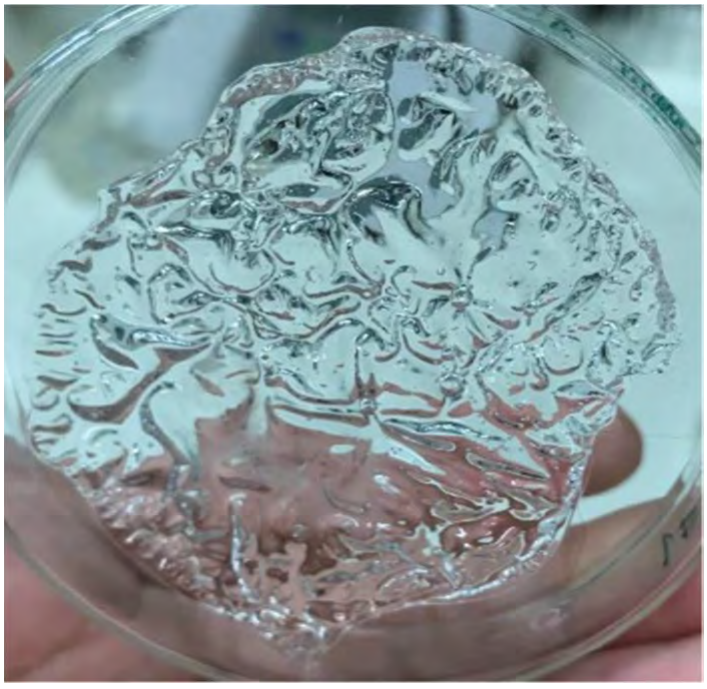
[15] Maher SA, Doty SB, Torzilli PA, et al. Nondegradable hydrogels for the treatment of focal cartilage defects. J Biomed Mater Res - Part A. 2007;83(1):145-155. doi:10.1002/jbm.a.31255

[16] 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

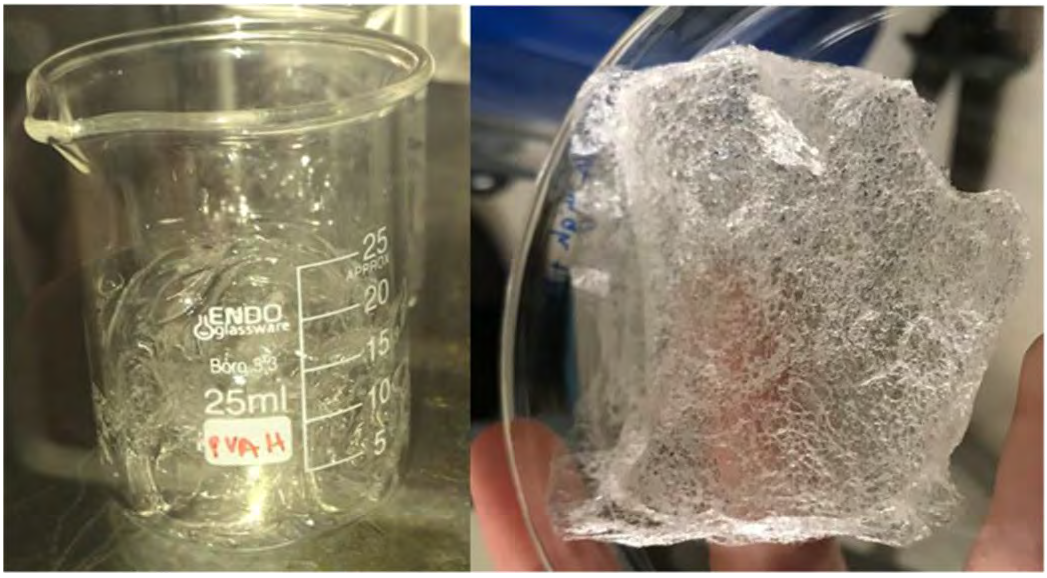
[17] Peppas NA. Hydrogels in Medicine and Pharmacy. Boca Raton: CRC Press; 1989

74. 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



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

75. 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.

76. 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

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

78. Defendant has 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.

79. Defendant additionally told patients, including Plaintiff that "movement matters" further stating in marketing materials - "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."

80. In addition to promises about the increased toe mobility and function, Defendant alleges 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.

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

82. Defendant's labeling was false and/or misleading. Defendant 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.

83. 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".

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

85. 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.

86. Defendant 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. If Defendant had not made these statements and violated the requirements and regulations, Plaintiff would have chosen an alternative treatment option or a different device for implantation into her body.

I. **Defendant Failed to Comply with PMA-Post-Approval Surveillance Study**

87. The PMA approval order of the Cartiva implant required Defendant 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).

88. In addition to *not* following the PMA post-approval orders, Defendant has largely ignored the endpoints the FDA placed in the PMA to protect public safety. The safety data the

FDA established did not narrow the Defendant's focus to the Motion study participants. Yet, Defendant has violated the FDA's PMA order by not assessing the safety of each endpoint for each device with reported adverse events, including the Plaintiff's defective device.

89. 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.

90. Defendant 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.

91. Defendant 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.

92. Despite the obligations described above, and the obligations of every medical device manufacturer to comply with federal law, Defendant failed to meet numerous federal requirements in their manufacture and sale of the Cartiva implant prior to Plaintiff's surgery and implantation of her Cartiva device which caused him to have implanted a defective and adulterated device causing her injuries and damages.

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

94. The causes of action set forth in this complaint are not preempted by § 360k, 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

95. 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 Four Million Three Hundred Twelve Thousand and Seven Hundred Twelve Dollars ($4,312,712.00).

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

97. On or about October 10, 2018, Wright Medical Group purchased Cartiva, Inc. for Four Hundred Thirty-Five Million Dollars ($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.

98. 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.

99. 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.

100. The failure rates of Cartiva SCI were much higher in clinical practice than reported in the Motion Study. Wright Medical Group 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 Cartiva** 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."

101. Stryker, B.V., a wholly owned subsidiary of Stryker, purchased Wright Medical Group on or about November 11, 2020 for Four Billion Seven Hundred Thousand Dollars ($4,700,000,000.00).[18]

102. 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.[19]

---

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

[19] 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

103. Defendant 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.

104. 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[20] - something the FDA had already required the Defendant to do in the PMA approval order.

105. Since 2016, Defendant, Stryker f/k/a Cartiva has 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.

106. Before commercially distributing the Cartiva SCI in the United States, federal law required Defendant, Stryker f/k/a Cartiva, Inc 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 ("FDA") completed its review of Defendant, Cartiva, Inc.'s PMA application for the Cartiva implant.

107. Based on the materials submitted by Defendant, Stryker f/k/a Cartiva, the FDA conditionally approved the Cartiva implant for commercial distribution.[21] 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.]."

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 27. PMID: 26922669.

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

[21] PMA # P150017

K. Plaintiff's Cartiva Implant

108. On or about January 8, 2019, Umur Aydogan, MD, performed surgery on Plaintiff whereby the Defective Device was implanted in her left big toe.

109. This surgical procedure has not been effective at alleviating pain or restoring range of motion.

110. As a result of the implantation of the Defective Device, Plaintiff has suffered additional surgeries and medical expenses, including an additional surgery in December of 2024, and, the removal of the implant and subsequent surgery to "fuse" her big toe bones together, all of which was 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.

111. 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,

112. Plaintiff's discovery of Cartiva defects is premised on Defendant's 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.

113. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relation to the Plaintiff's Cartiva and Defendant's 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.

114. Any applicable statutes of limitations have been tolled by the knowing and active concealment and denial of material facts known by the Defendant when it had a duty to disclose those facts. The Defendant's 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 filing of her causes of action. The Defendant's fraudulent concealment did result in such delay.

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

COUNT I

STRICT PRODUCTS LIABILITY
DESIGN, MANUFACTURE AND FAILURE TO WARN

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

117. The Cartiva SCI device implanted in Plaintiff's right 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.

118. 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.

119. 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 of 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;

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 studies, Defendants have not reported these findings to the FDA or undertaken any similar study;

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 Defendant has 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 Defendant has largely ignored the clinical evidence by not adequately responding to adverse incident reports or initiating a voluntary recall;

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

a. Continued to inject Cartiva implants into the stream of interstate commerce when Defendant 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".

120. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, the Cartiva implant 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.

121. 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.

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

123. 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.

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

125. As a direct and proximate result of Defendant's 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.

126. 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.

127. This cause of action is based entirely on the contention that Defendant 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 Defendant's violations of the applicable federal regulations.

128. Under Pennsylvania law, Defendant's violations of the aforementioned federal statutes and regulations establish a prima facie case of negligence.

129. Plaintiff alleges that at the time the subject components were in Defendant's control, (i) one or more were defective because they deviated in a material way from the manufacturers 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.

130. Alternatively, Plaintiff alleges that at the time the subject components were in Defendant's control, (i) one or more were designed in a defective manner, (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. Further, (i) Defendant knew, or given reasonably available knowledge or in the exercise of reasonable care should have known, about the danger for which recovery is sought herein, and (ii) the Cartiva SCI collectively failed to function as expected and there existed a feasible design alternative that would have to a reasonable probability have prevented the harm and injury which occurred to Plaintiff.

COUNT II

NEGLIGENCE -DESIGN, MANUFACTURE, MISBRANDED AND IMPROPER TRANSFER OF 510K/PMA WITHOUT FDA APPROVAL

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

132. Plaintiff is in the class of persons that Defendant should reasonably foresee as being subject to the harm caused by defectively designed Cartiva implants insofar as Plaintiff was the type of person for whom Cartiva implant was intended to be used.

133. At all times herein mentioned, Defendant created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed its Cartiva implant as hereinabove described that was used by the Plaintiff.

134. Defendant could reasonably have foreseen that its Cartiva was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without

substantial change in the condition in which they were produced, manufactured, sold, distributed and marketed by Defendant.

135. The Defective Device implanted in Plaintiff on or about May 11, 2018 was a class III device while the instruments used to insert Cartiva implants are all Class II devices designed and/or manufactured by Defendant and placed into the interstate stream of commerce.

136. Defendant marketed, distributed and/or permitted use of its Cartiva implants in violation of the Act and regulations promulgated to it.

137. It was the duty of the Defendant 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 accurately establish the in vivo life expectancy of the Cartiva, in violation of 21 C.F.R. 820.30(f);

B. Failed to accurately 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)and the PMA approval order for Cartiva;

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

D. Failed to conduct adequate bio-compatibility studies to determine the Cartiva SCI's latent propensity to loosen, migrate into bone and failure to integrate into the joint space as required by the PMA approval order for Cartiva;

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) and as required by the PMA approval for Cartiva;

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

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 and the PMA approval order for Cartiva; Failed to conduct complete device investigations on returned Cartiva implants and components, in violation of 21 C.F.R. 820.198 and the PMA approval order for Cartiva; and/or

I. Failed to comply with the FDA policies and procedures to transfer ownership of the 510k and/or PMA. Without proper transfer of ownership pursuant to FDA requirements it is not certain the Cartiva device is within the PMA issued for Cartiva, Inc. which means preemption is a non-issue for an unregulated manufacturer.

138. The Cartiva implant and accompanying instruments have been owned by three corporations: Cartiva, Inc. (2015-2017), Wright Medical Group (2018-2020) and Stryker (2020-present), yet the 510k for instruments and the Cartiva implant is still listed with the FDA as Cartiva, Inc with no PMA Supplement approving new manufacturing sites with ownership changes which implies the FDA has not reviewed or approved ownership of the 510k transfer.

139. **FDA TIMELINE:**

Date	**FDA Action**	**Approval Number**
7/1/16	PMA Approval	P150017
8/25/16	PMA Supplement- Change vendor of foil lidstock used to seal primary packaging of Cartiva SCI device	S001
9/29/16	PMA Supplement-Approval of protocol for ODE lead PMA Post Approval Study	S002
11/1/16	PMA Supplement- Approval of 8- and 20-unit shipping configurations for smaller orders	S003
1/6/17	PMA Supplement- Change is supplier of a component used in manufacture of Cartiva SCI	S004
3/1/17	PMA Supplement/Label Change- Modifications to Surgical implantation Technique Guide	S005
11/9/17	PMA Supplement- Expansion of Manufacturing facility	S006
1/29/18	Cartiva Instruments Reclassified as Class II device	Q180170

8/28/18	PMA Supplement-Approval of manufacturing site for instruments to Arcamed LLC	S007
7/2/18	PMA Supplement- Approval of an alternate raw material provider	S008
7/2/18	PMA Supplement- Add additional clean room for manufacture of Cartiva	S009
7/11/19	PMA Supplement- Approval of addition of 6 mm and 12 mm sizes of Cartiva SCI to the previously approved 8 mm and 10 mm device.	S010
7/12/19	PMA Supplement/Label change based on findings of PAS	S011
3/22/19	PMA Supplement-Approval to add clarifying statement regarding need for irrigation during drilling within Instructions for Use and the Surgical Implantation Technique for Cartiva	S012
2/9/20	PMA Supplement- add manufacturing site at Steris Synergy Health in Saxonburg, PA	S013
11/26/19	PMA Supplement-Expanded release criteria of final finished device to accept those that have a homogenously opaque appearance	S014

140. The FDA does permit 510(k) transfers with the caveat that two companies may not manufacture the same device under a single 510(k) clearance. Therefore, if a 510(k) holder wishes

to license the right to manufacture a device but also wishes to continue its own manufacturing activity, the FDAs policy is to require the licensee to obtain a new 510(k) clearance.

141. When the holder of an approved PMA enters into an agreement to permit another firm to manufacture and distribute a device under the licensee's private label, FDA approval may be obtained by either of two procedures: (i) the PMA holder may submit a supplement to the approved PMA; or (ii) the licensee may submit an original PMA that includes, or includes by authorized reference to the holder's approved PMA, all appropriate information required by 21 C.F.R. § 814.20 (required information for PMA applications). There is no evidence on the FDA medical device database that the Defective Device implanted in Plaintiff was manufactured or marketed with FDA approval for the new owners of Cartiva.

142. As a direct and proximate result of Defendant's violations of one or more of these federal statutory and regulatory standards of care, the Cartiva implant was used on the Plaintiff and 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. As a direct result, Plaintiff endured pain and suffering, including, but not limited to, scarring and disfigurement, and has required additional and debilitating surgeries and has incurred significant medical expenses in the past and will incur additional surgery and 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.

143. This cause of action is based entirely on the contention that Defendant 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 Defendant's violations of the applicable federal regulations.

144. Under Pennsylvania law, Defendant's violations of the aforementioned federal statutes and regulations establish a *prima facie* case of negligence.

145. Thus, under Pennsylvania common law, a money damages remedy exists for violation of the Act and regulations promulgated thereunder which results in an unreasonably dangerous product proximately causing injuries, and there is no need for the Pennsylvania Legislature to act in order to create such a remedy.

146. 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. As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder and not preempted.[22]

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

148. Defendant created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to Plaintiff, in particular, and Defendant is therefore liable for the injuries sustained by the Plaintiff.

COUNT III

MISBRANDED AND ADULTERATED DEVICE

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

150. 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 Defendant and placed into the interstate stream of commerce.

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

152. It was the duty of Defendant 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 submit a PMA supplement to warn of risk of implant shrinkage, migration and bone loss for review and approval as required by the FDA. 21 C.F.R. §814.39 and PMA approval order for Cartiva. Despite Defendant's knowledge of higher failure rates than previously reported to the FDA, Defendant chose to do nothing. It is the Defendant, not the FDA, who had a duty to report the failure rates and manufacturing problems to the FDA. The burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement 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.

B. Defendant sold, distributed and permitted use of its devices 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 Defendant would not produce a medical device with impurities or inconsistencies. Defendant also had a duty to provide a label that was truthful about the risks associated with the Cartiva implant and Defendant has failed to do so;

C. 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. The Cartiva PMA approval order provided the device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. In direct violation of the PMA order, Defendant's Direction For Use merely states "The Cartiva SCI device should only be used by experienced surgeons who have undergone training in the use of this device". There is no limitation on the physician experience-specialty type, years of experience nor do the instructions provide any details about the type of training required. The PMA approval order further states the FDA has determined that these restrictions on sale and distribution are 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. As mentioned herein, Defendant had a duty to print on the label and marketing of the Cartiva implant all relevant warnings, precautions, side effects, instructions for use and contraindications and has failed to issue any warnings beyond the generalizations provided in the label; and,

D. 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, Defendant has knowledge that failure rates are higher than reported to the FDA, yet Defendant has taken no action to protect the public, including Plaintiff, from harm caused by the defective Cartiva implant; and,

E. Defendant has 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 Defendant has relied solely on the Motion 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 Defendant.

153. As a direct and proximate result of Defendant's 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, including an osteophytectomy in August of 2019, along with the removal of the implant and subsequent surgery to "fuse" her big toe bones together, all of which was 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 both past and future; mental anguish and emotional distress, both past and future, including, but not limited to, annoyance and aggravation.

154. This cause of action is based entirely on the contention that Defendant 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 Defendant's violations of the applicable federal regulations.

155. 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.

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

COUNT IV

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

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

158. The Cartiva implant and corresponding Cartiva instruments used on Plaintiff was designed, manufactured and distributed by Defendant and placed into the stream of interstate commerce by Defendant.

159. Said components were defective in design and/or manufacture.

160. Said defects existed when the components left the hands of Defendant making the components unreasonably dangerous beyond the contemplation of the ordinary user.

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

162. Further, Defendant 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 of the Cartiva SCI, such as was experienced by Plaintiff.

163. 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 Defendant's Cartiva implant and corresponding instruments designed, manufactured, distributed, sold and/or placed into the stream of commerce by the Defendant, 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 Seventy Five Thousand Dollars ($75,000.00).

164. 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 Defendant, Plaintiff suffered the aforesaid damages and, as such, Plaintiff demands that punitive damages be awarded against Defendant.

COUNT V

BREACH OF EXPRESS WARRANTY

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

166. Defendant knew that its Cartiva implant had problems, including but not limited to shrinkage and migration out of joint space into the bone. Defendant advertised Cartiva implants as a non-invasive procedure, designed to reduce quickly restore toe mobility with a simple procedure. None of Defendant's 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.

167. Plaintiff relied on the skill and judgment of the Defendant that the device was adequately tested and rendered safe to use for its intended purpose.

168. Plaintiff became interested in and underwent the Cartiva implant procedure based on the Defendant's representation about the procedure.

169. 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.

170. As the direct and proximate result of Defendant's 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.

171. As the direct and proximate result of Defendant's 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.

COUNT VI

BREACH OF IMPLIED WARRANTY

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

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

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

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

176. That said representations and warranties aforementioned were false, misleading, and inaccurate in that its Cartiva devices were unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

177. Plaintiff and/or members of the medical community and/or healthcare professionals did rely on said implied warranties of merchantability and fitness for a particular use and purpose.

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

179. Defendant's Cartiva devices were injected into the stream of commerce by Defendant 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.

180. Defendant herein breached the aforesaid implied warranties, as its Cartiva devices were neither merchantable nor fit for their intended purposes and uses.

181. 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.

182. 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.

COUNT VII

FAILURE TO WARN

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

184. Defendant is, and at all times mentioned in this Complaint was, engaged in the business of designing, manufacturing, assembling, and selling a medical device product known as Cartiva implant devices with the purpose of gaining profits from the distribution thereof.

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

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

187. Defendant knew that implant migration into the bone was not preventable and is unavoidable if undergoing the Cartiva SCI procedure.

188. Defendant had superior knowledge about implant migration because it was in possession and had access to facts and information about the condition that was not available to anyone else. As the manufacturer of the device, Defendant was a centralized hub of information about the device's adverse effects, including migration. It had received thousands of reports of users developing the condition, had access to those person's medical records and information

regarding diagnosis, treatment, and occurrence rate, which it did not disclose to the medical community.

189. Defendant had a duty to provide adequate warnings about implant shrinkage and migration, a dangerous adverse effect of its Cartiva SCI system, to Plaintiff's provider.

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

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 Defendant 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 effect;

e. Did not use concrete terms like "shrinkage" and "implant migration" 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.

191. Defendant is liable for Plaintiff's damages because its product was defective due to its failure to adequately warn Cartiva SCI providers about the danger of the Cartiva Implant system.

192. As the direct and proximate result of Defendant's 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.

COUNT VIII

PUNITIVE/EXEMPLARY DAMAGES

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

194. Defendant's conduct in deceiving Cartiva system 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.

195. Defendant, as a corporation, 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.

196. Defendant and it's agent's malicious and fraudulent conduct must be punished to deter future harm to others. Therefore, exemplary damages are appropriate under that the circumstances.

PRAYER FOR RELIEF

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

198. So far as the law and this Court allows, Plaintiff demands judgment against Defendant 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. Consequential damages;

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

G. Disgorgement of profits obtained through unjust enrichment;

H. Restitution;

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

J. Treble damages for Defendant's violations of the Act;

K. Reasonable attorneys' fees where recoverable;

L. Costs of this action;

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

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

DEMAND FOR JURY TRIAL

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

Respectfully submitted,

/s/ D. Aaron Rihn
D. Aaron Rihn, Esquire
PA ID No.: 85752
ROBERT PEIRCE & ASSOCIATES, P.C.
437 Grant Street, Suite 1100
Pittsburgh, PA 15219
412-281-7229 (phone)
412-281-4229 (fax)
arihn@peircelaw.com

Alex C. Davis (pro hac vice pending)
ALEX DAVIS LAW OFFICE PSC
445 Baxter Avenue, Suite 275
Louisville, Kentucky 40204
Phone: (502) 882-6000
Fax: (502) 587-2007
alex@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

Andrea Keller

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

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

D. Aaron Rihn, Robert Peirce & Associates, 437 Grant St., Suite 1100, Pittsburgh, PA, 15219 P: 412 281-7229

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 Cartiva Toe Implant

VII. REQUESTED IN COMPLAINT:

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

DEMAND $ 75,001.00

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

VIII. RELATED CASE(S) IF ANY *(See instructions)*:

JUDGE Hon. Kristine G. Baker DOCKET NUMBER MDL 3172

DATE May 12, 2026

SIGNATURE OF ATTORNEY OF RECORD /s/ D. Aaron Rihn

FOR OFFICE USE ONLY

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

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

Place of Accident, Incident, or Transaction: York, PA

RELATED CASE IF ANY: Case Number:_____ Judge:_____

1. Does this case involve property included in an earlier numbered suit? Yes ☐
2. Does this case involve a transaction or occurrence which was the subject of an earlier numbered suit? Yes ☐
3. Does this case involve the validity or infringement of a patent which was the subject of an earlier numbered suit? Yes ☐
4. Is this case a second or successive habeas corpus petition, social security appeal, or pro se case filed by the same individual? Yes ☐
5. Is this case related to an earlier numbered suit even though none of the above categories apply? If yes, attach an explanation. Yes ☐

I certify that, to the best of my knowledge and belief, the within case ☐ **is** / ☑ **is not** related to any pending or previously terminated action in this court.

Civil Litigation Categories

A. Federal Question Cases:

- ☐ 1. Indemnity Contract, Marine Contract, and All Other Contracts)
- ☐ 2. FELA
- ☐ 3. Jones Act-Personal Injury
- ☐ 4. Antitrust
- ☐ 5. Wage and Hour Class Action/Collective Action
- ☐ 6. Patent
- ☐ 7. Copyright/Trademark
- ☐ 8. Employment
- ☐ 9. Labor-Management Relations
- ☐ 10. Civil Rights
- ☐ 11. Habeas Corpus
- ☐ 12. Securities Cases
- ☐ 13. Social Security Review Cases
- ☐ 14. Qui Tam Cases
- ☐ 15. Cases Seeking Systemic Relief ***see certification below***
- ☐ 16. All Other Federal Question Cases. *(Please specify)*:_____

B. Diversity Jurisdiction Cases:

- ☐ 1. Insurance Contract and Other Contracts
- ☐ 2. Airplane Personal Injury
- ☐ 3. Assault, Defamation
- ☐ 4. Marine Personal Injury
- ☐ 5. Motor Vehicle Personal Injury
- ☐ 6. Other Personal Injury (*Please specify*):_____
- ☑ 7. Products Liability
- ☐ 8. All Other Diversity Cases: *(Please specify)*_____

I certify that, to the best of my knowledge and belief, that the remedy sought in this case ☐ **does** / ☑ **does not** have implications beyond the parties before the court and ☐ **does** / ☑ **does not** seek to bar or mandate statewide or nationwide enforcement of a state or federal law including a rule, regulation, policy, or order of the executive branch or a state or federal agency, whether by declaratory judgment and/or any form of injunctive relief.

ARBITRATION CERTIFICATION (CHECK ONLY ONE BOX BELOW)

I certify that, to the best of my knowledge and belief:

☑ Pursuant to Local Civil Rule 53.2(3), this case is not eligible for arbitration either because (1) it seeks relief other than money damages; (2) the money damages sought are in excess of $150,000 exclusive of interest and costs; (3) it is a social security case, includes a prisoner as a party, or alleges a violation of a right secured by the U.S. Constitution, or (4) jurisdiction is based in whole or in part on 28 U.S.C. § 1343.

☐ None of the restrictions in Local Civil Rule 53.2 apply and this case is eligible for arbitration.

NOTE: A trial de novo will be by jury only if there has been compliance with F.R.C.P. 38.