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

Lisa Paull

(b) County of Residence of First Listed Plaintiff Bonner County, ID
(EXCEPT IN U.S. PLAINTIFF CASES)

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

D. Toby McLaughlin, Sandpoint Law, PC
312 S. First Ave., Ste. A,Sandpoint, ID 83864

DEFENDANTS

Cartiva Inc., Wright Medical Group NV, Stryker BV

County of Residence of First Listed Defendant Fulton County, GA
(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
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- ☐ 376 Qui Tam (31 USC 3729(a))
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- ☐ 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
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- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
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- ☐ 896 Arbitration
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REAL PROPERTY
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- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
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- ☐ 290 All Other Real Property

CIVIL RIGHTS
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- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
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- ☐ 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 USC §1332

Brief description of cause:
Injury from medical product liability

VII. REQUESTED IN COMPLAINT:

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

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

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

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Idaho

Lisa Paull

Plaintiff(s)

v.

Cartiva Inc., Wright Medical Group NV, Stryker BV

Defendant(s)

Civil Action No. 2:26-cv-00277

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Cartiva, Inc.
6120 Windward Parkway, Suite 220
Alpharetta, Georgia 30005

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

D. Toby McLaughlin
Sandpoint Law, P.C.
312 South First Avenue, Suite A
Sandpoint, ID 83864
service@sandpointlaw.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:26-cv-00277

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Idaho

Lisa Paull

Plaintiff(s)

v.

Cartiva Inc., Wright Medical Group NV, Stryker BV

Defendant(s)

Civil Action No. 2:26-cv-00277

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Stryker BV
2825 Airview Boulevard
Kalamazoo, Michigan 49002

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

D. Toby McLaughlin
Sandpoint Law, P.C.
312 South First Avenue, Suite A
Sandpoint, ID 83864
service@sandpointlaw.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:26-cv-00277

PROOF OF SERVICE

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❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Idaho

Lisa Paull

Plaintiff(s)

v.

Cartiva Inc., Wright Medical Group NV, Stryker BV

Defendant(s)

Civil Action No. 2:26-cv-00277

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Wright Medical Group, NV
1023 Cherry Road
Memphis, Tennessee 38117

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: D. Toby McLaughlin
Sandpoint Law, P.C.
312 South First Avenue, Suite A
Sandpoint, ID 83864
service@sandpointlaw.com

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 2:26-cv-00277

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

SANDPOINT LAW, P.C.
Toby McLaughlin, ISB No. 7405
312 S. First Ave., Ste. A
Sandpoint, ID 83864
Tel: (208) 263-4748
Fax: (208) 263-7557
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Seth H. Corthell (*pro hac vice pending*)
311 S. Wacker Dr., Suite 2150
Chicago, IL 60606
Tel: (312) 442-0509
dschlessinger@jaszczuk.com
scorthell@jaszczuk.com

Attorneys for Plaintiff Lisa Paull

UNITED STATES DISTRICT COURT
DISTRICT OF IDAHO

LISA PAULL, Plaintiff, v. **CARTIVA, INC.** 6120 Windward Parkway, Suite 220 Alpharetta, Georgia 30005 and **WRIGHT MEDICAL GROUP, N.V.** 1023 Cherry Road Memphis, Tennessee 38117 and **STRYKER, B.V.** 2825 Airview Boulevard Kalamazoo, Michigan 49002 Defendants.	Case No. **COMPLAINT** **JURY DEMAND**

COMPLAINT

NOW COMES THE PLAINTIFF, Lisa Paull, by and through her attorneys Sandpoint Law, P.C., and for her cause of action against the Defendants Cartiva, Inc. ("Cartiva"), Wright Medical Group, N.V. ("Wright"), and Stryker, B.V. ("Stryker"), and alleges as follows:

PREAMBLE

1. This action arises from the implantation and subsequent failure of the Cartiva Synthetic Cartilage Implant ("Cartiva SCI" or "SCI"), a medical device marketed as a synthetic cartilage replacement for the great toe joint. Despite being promoted as a durable, motion-preserving alternative to fusion surgery, the device has significant real-world failure rates and was recalled in October 2024. Plaintiff Lisa Paull, an Idaho resident, received a Cartiva SCI in her right great toe on November 17, 2020. The device failed due to a defect, causing significant pain, swelling, instability, and loss of mobility that detrimentally impacted Lisa's life. As a result of the device's failure, Lisa required revision surgery, including removal of the implant and fusion of the joint.

2. As a further result of the defective product, Lisa has suffered and will continue to suffer pain, functional limitations, and diminished quality of life.

PARTIES

3. Plaintiff Lisa Paull is a citizen and resident of the State of Idaho, residing in Sand Point, Idaho.

4. Defendant Cartiva, Inc. is a corporation headquartered at 6120 Windward Parkway, Suite 220, Alpharetta, Georgia 30005. As a manufacturer of medical devices, Cartiva is, and at all times relevant was, subject to regulations and consensus industry standards

governing the medical device industry, including those promulgated by the United States Food and Drug Administration ("FDA").

5. Defendant Wright Medical Group, N.V. is a corporation with its principal place of business at 1023 Cherry Road, Memphis, Tennessee 38117. Wright acquired Cartiva and continued to manufacture and distribute the Cartiva SCI. As a manufacturer of medical devices, Wright is subject to regulations and consensus industry standards governing the medical device industry, including those promulgated by the FDA.

6. Defendant Stryker, B.V., is a corporation with its principal place of business at 2825 Airview Boulevard, Kalamazoo, Michigan 49002. Stryker assumed responsibility for the Cartiva SCI, including its recall. As a manufacturer of medical devices, Stryker is subject to regulations and consensus industry standards governing the medical device industry, including those promulgated by the FDA.

7. At all relevant times, Defendants developed, tested, assembled, manufactured, packaged, labeled, prepared, marketed, distributed, supplied, and/or sold the Cartiva SCI, either directly or indirectly, to healthcare providers and patients residing in Idaho, including Lisa.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction under 28 U.S.C. § 1332, as the amount in controversy exceeds $75,000 and the parties are citizens of different states.

9. Venue is proper in this District under 28 U.S.C. § 1391, because Lisa resides here, a substantial portion of the events giving rise to the claims occurred here, and Defendants conduct business in Idaho.

FACTUAL ALLEGATIONS

10. This case arises out of Defendants' individual and collective violations of various sections of the Federal Code of Regulations, along with parallel state law claims, with those violations actually and proximately causing damages suffered by Lisa as a result.

11. Great toe arthritis affects about 2.2 million people in the United States. As arthritis deteriorates the joint's cartilage, a person develops painful bone-on-bone friction. The condition is treated surgically via two methods: (1) arthrodesis (also known as "fusion"); or (2) implantation of synthetic cartilage, which purportedly acts like a cushion to prevent bone-on-bone pain.

The Cartiva SCI

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

13. Defendants tout the implantation of the Cartiva SCI 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.

14. Defendants represented that the Cartiva SCI mimicked the properties of natural cartilage and would provide long-term durability and function.

15. The Cartiva SCI is used 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.

16. The surgeon uses instrumentation to drill an appropriately sized cavity in the metatarsal head and deploy the Cartiva SCI into the prepared cavity. Defendants allege joint

resurfacing with a Cartiva SCI is simple, does not require significant removal of healthy tissue, and typically results in nominal surgical trauma and rapid recovery.

17. Because it is not vascularized, cartilage does not restore itself or otherwise recover quickly from injury. As a result, replacement of cartilage with polyvinyl alcohol-based hydrogels ("PVA"), *e.g.*, the Cartiva SCI, is a joint replacement alternative to traditional fusion treatment.

18. The design of these implants relies on "hard-on-hard" and "hard-on-soft" interactions. That design is dissimilar to the "soft-on-soft" interactions that occur in natural cartilage.

19. PVA is biocompatible and exhibits favorable swelling behavior. However, the properties of the resulting hydrogel may be modified by changes in the manufacturing process or by incorporating additional materials to achieve performance superior to the current design.

Fusion Treatment Option

20. In contrast to the procedure utilizing a Cartiva SCI, a fusion is a procedure where the phalangeal and metatarsal bones are cut and shaped to fit (fuse) together to relieve toe joint pain.

21. 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 restricts the ability to move the great toe but eliminates the patient's pain.

Degradation of the Cartiva SCI

22. SCI implants, including the Cartiva SCI, are susceptible to degradation of the PVA membrane, which is accompanied by implant loosening, surface marring, and deformation.

These failure modes were reported in an independent study (the "Rosas Study").[1] This degradation directly and proximately results in implant failure and the need for subsequent fusion and other revision procedures, and it causes bone loss, pain, and loss of mobility.

23. This degradation is neither expected nor intended as part of the Cartiva SCI manufacturing process. Instead, it reflects a mechanical defect that rendered the Cartiva SCI not reasonably safe for its intended use.

24. The importance of swelling behavior is closely related to the mechanical and tribological properties of Cartiva SCI's PVA hydrogel in addition to how swelling behavior impacts the risk of implant failure.

25. In 2007, PVA hydrogels were used for treatment of knee cartilage defects in adult rabbits. Testing and study results revealed growth over the implant and implant shrinkage.[2] PVA hydrogels can react to osmotic gradients and swell and de-swell accordingly, even in hydrated conditions. This volumetric change of PVA hydrogel may induce detachment from the tissue or implant and interfacial debonding.[3]

26. Because Cartiva SCIs are made up of PVA, which is soluble in water, crosslinking is a key step for PVA hydrogel formation. Without a stable structure, the PVA hydrogel cannot withstand the swelling pressure exerted by fluid intake and could dissolve.[4]

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

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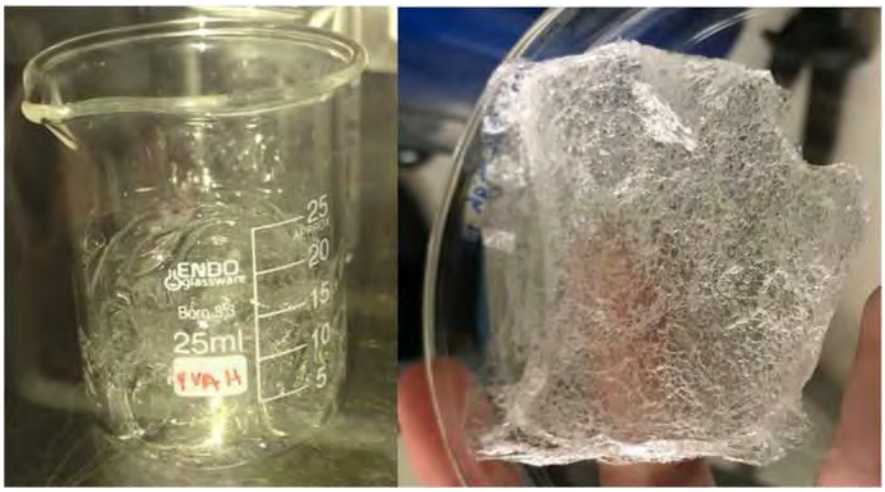
[1] See Rosas K, Hurley ET, Kennedy JG. Early Failures of Polyvinyl Alcohol Hydrogel Implant for the Treatment of Hallux Rigidus. Foot & Ankle Orthopaedics. October 2020. doi:10.1177/2473011420S0041, available at https://pmc.ncbi.nlm.nih.gov/articles/PMC8702944/ (last accessed March 26, 2026).
[2] Maher 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.
[3] Carolina Borges, Rogério Colaço & Ana Paula Serro (2019) Poly(vinyl alcohol)-based hydrogels for joint prosthesis, Annals of Medicine, 51:sup1, 105, DOI: 10.1080/07853890.2018.1562711
[4] Peppas NA. Hydrogels in Medicine and Pharmacy. Boca Raton: CRC Press; 1989.

28. As shown below, PVA hydrogels are problematic because the method of manufacturing may result in air bubbles, fragility, improper crystallite binding, disintegration, striation (grooves or ridges), or clumping.

Partially disintegrated freeze-thawed PVA gel

Striations on gel caused by rapid cooling and oxygen exposure of pre-gel solution.



Vacuum on gelation of PVA results in air bubbles being trapped inside the hydrogel.

Semi-irreversible contracture of thick PVA hydrogel.

29. And manufacturing methods are even more problematic in the case of thicker hydrogels such as the Cartiva SCI. That is because thicker gels are susceptible to larger variation, and just small temperature or aeration changes can contribute to these variations. Steady temperature and aeration are much more difficult to maintain on a large scale in a manufacturing environment like Defendants' production of the Cartiva SCI.

30. Defendants violated federal regulations by making an adulterated device because their manufacturing of the Cartiva SCI failed to meet established performance standards, or, alternatively, their methods, facilities, or controls used to manufacture, package, or store the device did not conform with federal regulations. Those violations proximately and directly caused Lisa's injuries and damages. *See* 21 U.S.C. § 351. As a result of these violations, the Cartiva SCI was unsafe because the material utilized degraded rapidly after it was implanted into Lisa's great toe, causing her injuries and damages.

Defendants Hid Negative Data and Results.

31. Defendants are duty-bound to be honest regarding the risks of their devices when marketing and promoting them. Notwithstanding that obligation, Defendants have hidden medical industry knowledge from the FDA and the public that demonstrates the Cartiva SCI's high failure rate as a result of implant migration due to shrinkage.

32. Before getting the Cartiva SCI to the market, Defendants obtained Premarket Approval from the FDA for the Cartiva SCI as a Class III device.

33. The approval was mostly based on the "substantial equivalence" of the Cartiva SCI performance to the gold standard treatment of fusion (discussed above). However, substantial equivalence is usually used for Class II medical devices and avoids a full FDA safety review.

34. One required condition of approval is a post-approval study ("PAS") that shows no greater than a 13.5% complication rate as well as tracking of the number of patients who were converted to fusion surgery.

35. The critical study (termed the "Motion Study") for the Cartiva SCI compared it to the fusion gold standard. It included 202 patients, 152 with implants and 50 with fusion,

assessing pain, function, and safety. It reported zero cases of implant fragmentation, wear or bone loss. The study served as the basis for the Cartiva SCI's PMA approval.[5]

36. In laymen's terms, the Motion study compared the implant procedure to a fusion procedure. But the outcome of the Motion Study (*i.e.*, no migration or other issues with the Cartiva SCI implant) has not been replicated in clinical practice. Rather, in practice the Cartiva SCI failure rate is substantially higher.[6]

37. Nevertheless, Defendants funded a follow-up to the Motion Study to retrospectively evaluate the initial study and again found the success rates of Cartiva SCI implantation and fusion were identical. Again, these purported success rates have not been borne out in clinical practice. Indeed, actual patient results identified in the Rosas Study have reported failure rates of 64% as opposed to the 13.5% failure rate Defendants reported to the FDA.

38. And a more recent analysis of 236 adverse event reports indicated a 74% removal rate for the Cartiva SCI, and concluded the device ". . . represents the unfortunately repetitive rise and fall of new surgical devices accepted too early in the usage life cycle before mid- to -long-term outcomes exist."[7]

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[5] Baumhauer JF, Singh D, Glazebrook M, Blundell C, De Vries G, Le IL, Nielsen D, Pedersen ME, Sakellariou A, Solan M, Wansbrough G, Younger AS, Daniels T; for and on behalf of the CARTIVA Motion Study Group. Prospective, Randomized, Multicenter Clinical Trial Assessing Safety and Efficacy of a Synthetic Cartilage Implant Versus First Metatarsophalangeal Arthrodesis in Advanced Hallux Rigidus. Foot Ankle Int. 2016 May;37(5):457-69. doi: 10.1177/1071100716635560. Epub 2016 Feb 27. PMID: 26922669.

[6] *See, e.g.,* https://www.medtechdive.com/news/wright-medical-shares-tumble-amid-report-of-cartiva-slowdown/558132/ (last accessed March 26, 2026).

[7] Michael Radcliffe, *et al.*, A Review of Adverse Events Related to Synthetic Cartilage Implant for the First Metatarsophalangeal Joint: An Analysis of Manufacturer and User Facility Device Experience database from 2016 to 2023, Foot & Ankle Surgery: Techniques, Reports and Cases, Spring 2024, available at https://www.sciencedirect.com/science/article/pii/S2667396723000940 (last accessed March 26, 2026).

39. The Cartiva SCI was initially viewed as a game-changer for great toe arthritis therapy. The splashy release propped up by the Motion Studies, which purported to show incredible results.

40. Bob Baravarian, DPM, FACFAS, assisted in the launch of the Cartiva SCI and demonstrated its proper use to other surgeons. But his clinic, the University Foot and Ankle Institute began to observe failures caused by the implant migrating into the bone, referred to as subsidence.

41. Dr. Baravarian's findings are not unique. For example, a review of 64 Cartiva SCI procedures performed by Cedars Sinai Medical Center demonstrated a higher level of patient dissatisfaction with implant outcomes than indicated in the Motion Studies. There, 37% of patients underwent revision surgery within an average of 20.9 months. Significantly, the radiographic loss of great toe joint space and progression of arthritis were present for all cases studied. MRIs showed bony channel widening and a smaller implant-evidence of subsidence (*i.e.*, shrinkage) with peri-implant fluid suggesting instability at the implant-bone interface. Also, persistent edema was observed in soft tissues and bone.

42. Based on the findings of the Motion Studies, the FDA approved Defendants' updated label on July 12, 2019 to include implant subsidence. But in securing that approval, Defendants incorrectly claimed most of the serious adverse events were for pain. Further, Defendants incorrectly stated only 9.2% of Cartiva SCI patients and 12% of fusion patients had the implant and/or hardware removed during the study.

43. On information and belief, Defendants have misrepresented the rate of failure to the FDA by mischaracterizing adverse events as pain instead of implant subsidence.

44. Further, on information and belief, Defendants failed to report the Rosas study to the FDA until recently even though the study confirmed high implant failure rates caused by shrinkage as well as lysis and bone erosion around the Cartiva SCI implant. Patient radiographs were assessed postoperatively at weeks 2, 4, and 8, as well as at the final follow-up. Of those patients, shrinkage (subsidence) was found in 64% after 4 weeks and 79% by the final follow-up. 57% presented radiologic lucency around the implant. 40% experienced erosion of the proximal phalanx of great toe. 43% reported no improvement after the surgery at the final follow-up. Three of the 14 patients needed additional surgery, including debridement and fixation of the Cartiva SCI. Additionally, the Rosas study found significant radiologic subsidence with disintegration of bone around the implant, erosion of the proximal countersurface as well as recorded implant wear and tear. These findings bode ill and raise concerns for long-term use of the implant.[8]

45. At least one insurance carrier, Cigna, took note of the wide criticism of the Motion Studies and deemed the use of the Cartiva SCI to be "experimental." In doing so, Cigna cited a report by Hayes, Inc,[9] which concluded individual outcome measures are inconsistent and suggest better outcomes with fusion.

46. Cigna also recognized that clinical practice guidelines suggest a different implant design is recommended which renders the Cartiva SCI 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

[8] These findings are in line with Interventional Procedures Guidance published by the National Institute for Health and Care Excellence ("NICE") which analyzed several case series and concluded there was little evidence that newer implants are sufficiently durable and they pose risks that may require removal of the joint.
[9] 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.

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).

47. Prior to Lisa having the Cartiva SCI implanted, Defendants were aware of higher than reported loss of toe mobility, pain, and high failure rates of the Cartiva SCI due to migration and shrinkage, including but not limited to, over 144 adverse event reports filed with the FDA.

As Failure Rates Mount, Defendants Recall the Device.

48. By October 2024, Defendants could no longer deny reality: the Cartiva SCI was not a reasonably safe product. As such, Defendants issued a recall of the Cartiva SCI device on October 31, 2024 due to reports of alarmingly high rates of revision, removal, displacement, pain, or nerve damage that were higher than previously disclosed in premarket and post-approval studies.

49. The notice of recall advised healthcare providers to quarantine any remaining Cartiva SCIs in their inventory and return them to Stryker. It also asked physicians to continue monitoring their patients, and watch for new or worsening symptoms including pain, and difficulties walking.

50. Recalling a product is an alternative to an FDA-initiated action to remove or correct violative, distributed products by setting forth specific recall procedures for the FDA to monitor recalls and assess the adequacy of a firm's efforts in recall. See 21 CFR § 7.40(a).

51. Upon information and belief Defendants knew or should have known the Cartiva SCI should have been recalled long before October 31, 2024, and that the product violated federal regulations including those prohibiting the production of an adulterated device that proximately and directly caused Lisa's (and many other patients') injuries and damages.

Defendants' Representations of the Cartiva SCI.

52. Defendants' label and patient brochure failed to provide accurate substantive or quantitative prevalence rates of failure or other adverse effects to Lisa prior to her surgery.

53. Defendants represented and portrayed in patient marketing literature implantation of the Cartiva SCI as a quick 35-minute procedure in which a physician replaces the damaged cartilage in your great toe with a new synthetic cartilage that behaves like the natural cartilage of a great toe joint.

54. Defendants also enticed patients, including Lisa, with tales of the relative benefits of the Cartiva SCI over fusion. Specifically, they told patients "movement matters" further stating in marketing materials - "Your great 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."

55. In addition to promises about the increased toe mobility and function, Defendants alleged in marketing that the Cartiva SCI was proven to provide long-term pain reduction and increased foot mobility, with 97% reduction in pain demonstrated at almost six years post-procedure. Such statements exceeded the scope of the FDA approved label.

56. Not mentioned in the Product Brochure are significant adverse consequences of using the Cartiva SCI, including:

a. loss of range of motion of the toe, bone lysis, shrinkage of implant, bone erosion or the inability to walk as a known risk of the Cartiva SCI.

b. the true failure rate due to migration and prevalence of those failures sufficient for her to make an informed decision prior to her surgery. Instead, Defendants' label indicates a 13.5% failure rate. However, in view of continual and ongoing reports and studies, the actual rate of failure of the defective Cartiva device is likely 6-7 times higher than Defendants' reported failure rate, which upon information and belief, Defendants knew of before November 2020.

57. Like many others, Lisa was induced to purchase/use a Cartiva SCI based on such representations about the safety and efficacy of the product. As a result of that reliance, Lisa endured medical expenses, loss of income, and pain and suffering and she will continue to have future expenses to repair the bodily harm caused by the defective Cartiva SCI.

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

59. Indeed, the conditional approval letter relating to the Cartiva SCI 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"

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

61. Defendants violated the conditional approval requirements and consequently the federal regulations in, among other things, making untrue, inaccurate and/or misleading statements regarding Lisa's Cartiva SCI. If Defendants had not made these statements and violated the requirements and regulations, Lisa would have chosen an alternative treatment

option or a different device for implantation into her body.

62. Unfortunately, for patients with Cartiva SCI failure, many in the medical community believe that loss of toe range of motion is a symptom of shrinkage (*i.e.*, implant subsidence), which is a precursor to failure. By any measure, the number of Cartiva SCI failures have reached alarming proportions.

63. During the time Defendants marketed, labeled, and sold the Cartiva SCI to Lisa, Defendants knew or should have known that the likelihood of patients experiencing implant shrinkage was significantly higher than they reported (and higher than any comparable product on the market) and that pain and discomfort were likely consequences of implant shrinkage and migration.

After Obtaining PMA, Defendants Shirked Post-Approval Requirements.

64. The PMA approval order of the Cartiva SCI required Defendants to collect data to assess the following primary and secondary study endpoints:

a. Primary Study Endpoints- The primary endpoint will evaluate the long-term safety of the Cartiva SCI 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.

b. Addressed by:

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

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

c. Provide the following **secondary endpoints:**

i. Evaluation of maintenance of range of motion;

ii. Wear characteristics or device degradation for any Cartiva SCI 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

iv. 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).

65. In addition to *not* following the PMA post-approval orders, Defendants have largely ignored the endpoints the FDA placed in the PMA to protect public safety. The safety data the FDA established did not narrow the Defendants' focus to the Motion study participants. Yet, Defendants have violated the FDA's PMA order by not assessing the safety of each endpoint for each device with reported adverse events, including Lisa's defective device.

66. 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 Lisa.

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

68. Defendants failed to develop practices and procedures to assure compliance with the federal requirements for reporting adverse events, or MDRs, in accordance with 21 U.S.C. § 360.

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

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

71. 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.

Lisa's Cartiva SCI Nightmare.

72. In October 2020, Lisa Paull, after experiencing years of increasing great toe pain, consulted with Dr. Christopher R. Butler who provided options for treatment, including the Cartiva SCI.

73. Lisa, an active NCAA official and personal trainer, proceeded to research the product hoping it could serve as a substitute for fusion, which would limit her mobility.

74. Based on her research and the representations by Defendants, she concluded the Cartiva SCI showed substantial promise to take the place of fusion and allow for her to continue her normal life activities.

75. Specifically, as discussed above, the Cartiva SCI marketing materials indicated to her that the implant was superior to a toe fusion.

76. Based on those representations, Lisa opted for the Cartiva SCI.

77. On or about November 17, 2020, Dr. Butler performed implant surgery.

78. Following the procedure, Lisa has some flexion in the great toe, but it was insufficient to allow her to continue her daily activities as she had before the procedure.

79. Specifically, Lisa was unable to perform most, if not all, activities that required toe flexion.

80. Lisa experienced chronic instability in her right great toe, causing multiple falls that led to injuries to, *inter alia*, her ribs and tailbone.

81. Further, her resulting gait left her with right medial knee pain that prevented her from doing her jobs.

82. This was only the beginning. Subsequently, she consulted with a new doctor who determined her great toe was no longer aligned correctly. He attempted to correct this with a soft brace.

83. This attempt to fix the problem failed. Her toe felt increasingly unstable and by December 2025, a doctor informed Lisa that her body had rejected the implant, that cysts had developed around it, and that she had lost a significant amount of bone.

84. Her options were fusion or a new, different implant, provided she had enough bone remaining for the new implant. However, X-rays showed that she had lost too much bone

and her only option was fusion.

85. On January 13, 2026, Lisa underwent reconstructive surgery on her great toe.

86. To date and as a direct and proximate result of Defendants' actions, Lisa has, *inter alia*, lost any chance to maintain flexion in her great toe, lost out on significant work opportunities (and will likely continue to miss out on them), experienced significant limitations on her ability to perform simple day-to-day activities (she was unable to even drive for a month), has been forced to cancel significant life events, and has been put in extreme emotional distress.

87. These negative consequences of Defendants' actions will continue indefinitely.

Corporate Defendants' Involvement.

88. 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).

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

90. On or about October 10, 2018, Wright Medical Group purchased Cartiva, Inc. for Four Hundred Thirty-Five Million Dollars ($435,000,000). 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 great toe.

91. Despite the initial excitement at product launch, stock analysts quickly caught wind of the reports of Cartiva SCI 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 the offering of Cartiva SCI to patients due to failed implants, Wright Medical Group CEO Bob Palmisano remained upbeat on prospects for Cartiva.

92. 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 great toe arthritis as a $400 million opportunity.

93. The failure rate of the Cartiva SCI was 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."

94. 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).[10]

95. 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 SCI group that would require subsequent conversion to fusion surgery within the first two years of the implant.

96. Defendants alleged the Cartiva SCI was determined to be statistically equivalent to fusion surgery but also offered the promise of better mobility and less surgical downtime.

97. Initial results for the Cartiva SCI were encouraging, however, unbiased reviewers adopted the position that "[m]ore research with larger cohorts and longer follow-up by non-industry sponsored researchers is indicated"[11]—something the FDA had already required the Defendants to do in the PMA approval order.

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

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

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

100. Based on the materials submitted by Defendants, the FDA conditionally approved the Cartiva SCI for commercial distribution.[17] 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.]."

COUNT I
(Strict Liability)

101. Lisa repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

102. On or about November 17, 2020, the Cartiva SCI implanted in Lisa was designed and/or manufactured in violation of the Federal Food, Drug, and Cosmetic Act (the "Act") and the regulations promulgated thereunder, including, but not limited to, improper workmanship and manufacturing errors that resulted in defects in the Cartiva SCI. These defects caused Lisa's implant to shrink and migrate from the original implant site, resulting in pain, loss of mobility, and bone loss.

103. At the time the Cartiva SCI was implanted in Lisa it was not reasonably safe due to non-compliance by Defendants and 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.

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 SCI does not

perform as expected long-term as seen in Rosas and other literature, 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 SCI's latent propensity to migrate from the joint space. Radiologic evidence of implant shrinkage is evident in peer-reviewed literature, but Defendants have not undertaken studies to analyze the implant shrinkage when exposed to deep matrix bone;

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

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

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

h. Failed to appropriately respond to adverse incident reports that strongly indicated the Cartiva SCI was malfunctioning [as defined in 21 C.F.R. § 803.3], or otherwise not responding to its Design Objective and Intent, in violation of 21 C.F.R. § 820.198. Physician complaints report failure rates of 50-64% with Cartiva SCIs and Defendants have 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 SCIs and components in violation of 21 C.F.R. § 820.198. Defendants have failed to investigate and analyze Cartiva SCI failures;

and/or

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

104. The defects existing in the Cartiva SCI implanted in Lisa existed at the time the Defective Device was in Defendants' possession, insofar as (i) one or more were defective because

they deviated in a material way from the manufacturer's or designer's specifications, (ii) such defective condition rendered them unreasonably dangerous to the user, and (iii) such condition proximately caused the damages for which recovery is sought herein.

105. At all relevant times, there existed a feasible alternative design and/or procedure that would have prevented the harm and injury which occurred to Lisa.

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

107. Defendants' violations of the aforementioned federal statutes and regulations establish an inference of products liability that can be asserted in Idaho: defective design, defective manufacturing, and failure-to-warn.

108. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 360k 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.[12] As such, the claims set forth herein contain requirements that are parallel to the Act and regulations promulgated thereunder and not preempted

109. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, the Cartiva SCI implanted in Lisa failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and

[11] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7067982/pdf/main.pdf (last accessed March 27, 2026).

[12] "We concluded that federal manufacturing and labeling requirements applicable across the board to almost all medical devices did not pre-empt the common-law claims of negligence and strict liability at issue in Lohr. *Riegel v. Medtronic, Inc*., 552 U.S. 312, 322 (2008)

endured by Lisa as defined in 21 C.F.R. § 803.3.

110. As a direct and proximate result, Lisa endured pain and suffering, including, but not limited to failure of the Cartiva SCI, migration of the implant with swelling and pain, bone loss, loss of mobility which required an additional fusion surgery and she 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 lost income due to decreased employment opportunities as an official and personal trainer.

COUNT II
(Per Se Negligence)

111. Lisa repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

112. Lisa is in the class of persons that Defendants should reasonably foresee as being subject to the harm caused by defectively designed Cartiva SCI insofar as Lisa was the type of person for whom the Cartiva SCI was intended to be used.

113. At all times herein mentioned, Defendants created, designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and/or distributed their SCI as herein above described that was used by Lisa.

114. Defendants could reasonably have foreseen that their SCI 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 Defendants.

115. The SCI inserted into Lisa on November 17, 2020 was a Class III device while the

instruments used to insert SCIs are all Class II devices designed and/or manufactured by Defendants and placed into the interstate stream of commerce. Defendants marketed, distributed and/or permitted use of the Cartiva SCI in violation of the Act and regulations promulgated pursuant to it.

116. It was the duty of Defendants to comply with the Act, and the regulations promulgated pursuant to it, yet, notwithstanding this duty, Defendants violated the Act 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);

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 the SCI;

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 the SCI;

d. Failed to conduct adequate bio-compatibility studies to determine the Cartiva SCI's latent propensity to loosen, migrate into bone and fail 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 the SCI;

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

h. Failed to appropriately respond to adverse incident reports that strongly indicated the SCI was malfunctioning [as defined in 21 C.F.R. § 803.3], or otherwise not responding to its Design Objective and Intent, in violation of 21 C.F.R. § 820.198 and the PMA approval order for the SCI;

i. Failed to conduct complete device investigations on returned SCIs and components, in violation of 21 C.F.R. § 820.198 and the PMA approval order for the SCI;

and/or

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

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

118. The following is the 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 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 in 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	SCI 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 SCI.	S009
7/11/19	PMA Supplement- Approval of addition of 6 mm and 12 mm sizes of 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 the SCI.	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 homogeneously opaque appearance	S014

119. 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 FDA's policy is to require the licensee to obtain a new 510(k) clearance.

120. 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 Cartiva SCI implanted in Lisa was manufactured or marketed

with FDA approval for Wright or Stryker.

121. As a direct and proximate result of Defendants' violations of one or more of these federal statutory and regulatory standards of care, the Cartiva SCI was used on Lisa and failed and such failure directly caused and/or contributed to the severe and permanent injuries sustained and endured by Lisa, as defined in 21 C.F.R. § 803.3. As a direct result, Lisa endured pain and suffering, including, but not limited to the 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; and lost income due to decreased employment opportunities as an official and personal trainer.

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

123. Defendants' violations of the aforementioned federal statutes and regulations establish a prima facie case of negligence. Defendants 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 Lisa, in particular, and Defendants are therefore liable for the injuries sustained by Lisa.

124. The cause of action set forth in this Claim for Relief is not preempted by 21 U.S.C. § 360k 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.[13]

COUNT III
(Failure to Warn)

125. Lisa repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

126. Defendants designed, manufactured, marketed, distributed, and sold the Cartiva SCI at issue in this action.

127. At the time the product left Defendants' possession and control, it was defective and unreasonably dangerous because Defendants failed to provide adequate warnings and instructions regarding the risks associated with its use.

128. As set forth above, the risks associated with the product were known or reasonably knowable to Defendants in light of the generally recognized and prevailing scientific and medical knowledge available at the time of manufacture and distribution.

129. Defendants failed to provide adequate warnings or instructions to users and consumers, including Lisa, regarding the foreseeable risks associated with the product's use.

130. Had adequate warnings or instructions been provided, Lisa would have altered her conduct, including by not using the Cartiva SCI or by using it differently.

131. As a direct and proximate result of Defendants' failure to warn, the Cartiva SCI was used on Lisa and failed and such failure directly caused and/or contributed to the severe and

[13] In Riegel, the Court noted that § 360k "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to federal requirements." 552 U.S. at 330.

permanent injuries sustained and endured by Lisa. As a direct result, Lisa endured pain and suffering, including, but not limited to the 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; and lost income due to decreased employment opportunities as an official and personal trainer.

132. The product was therefore defective and unreasonably dangerous, and Defendants are liable for Lisa's damages.

COUNT IV
(Common Law Product Liability and Negligence)

133. Lisa repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

134. The Cartiva SCI implanted in Lisa on November 17, 2020 was designed, manufactured and distributed by Defendants and placed into the stream of interstate commerce by Defendants. Said components were defective in design and/or manufacture. Said defects existed when the components left the hands of Defendants making the components unreasonably dangerous beyond the contemplation of the ordinary user.

135. Defendants further failed to provide appropriate warnings regarding the potential dangers associated with the use of said components, including warnings regarding the risk of migration and shrinkage of the SCI, such as was experienced by Lisa.

136. As a direct and proximate result of the design and/or manufacturing defects, failure to warn and breach of express and implied warranties related to Defendants' SCI and

corresponding instruments designed, manufactured, distributed, sold and/or placed into the stream of commerce by the Defendants, Lisa 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; lost income due to decreased employment opportunities as an official and personal trainer; and has suffered damages in an amount in excess of Seventy Five Thousand Dollars ($75,000.00).

COUNT V
(Breach of Express Warranty)

137. Lisa repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

138. Under Idaho commercial law, Idaho Code § 28-2-313, Defendants expressly warranted, as described above and herein, directly to Lisa that the Cartiva SCI was safe and effective for use when it was not. Defendants, through their own statements, expressly warranted that the Cartiva SCI was safe and effective and that the Cartiva SCI when distributed would conform to that express affirmation, and Lisa relied on those express affirmations in her decision to use the Cartiva SCI.

139. Defendants knew that the Cartiva SCI had problems, including but not limited to shrinkage and migration out of joint space into the bone. Defendants advertised Cartiva SCIs as a non-invasive procedure, designed to quickly restore toe mobility with a simple procedure. None of Defendants' advertising, marketing, or informational materials to Lisa, 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.

140. Lisa relied on the skill and judgment of the Defendants that the device was adequately tested and rendered safe to use for its intended purpose.

141. Lisa became interested in and underwent the Cartiva SCI implant procedure based on the Defendants' representation about the procedure.

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

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

144. As the direct and proximate result of Defendants' wrongful conduct, Lisa suffered and continues to suffer economic losses, emotional distress, permanent disfigurement, physical pain, mental anguish, diminished enjoyment of life; lost income due to decreased employment opportunities as an official and personal trainer; and future medical expenses.

COUNT VI
(Breach of Implied Warranty)

145. Lisa repeats, reiterates and re-alleges each and every allegation of this Complaint in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

146. At all times herein mentioned, Defendants manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted and sold the Cartiva SCI and instruments.

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

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

149. Said representations and warranties aforementioned were false, misleading, and inaccurate in that their SCIs were not reasonably safe, improper, not of merchantable quality, and defective.

150. Lisa 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.

151. Lisa and/or her physicians and/or healthcare professionals reasonably relied upon the skill and judgment of Defendants as to whether the Cartiva SCI was of merchantable quality and safe and fit for its intended use.

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

153. Defendants herein breached the aforesaid implied warranties, as the Cartiva SCI

was neither merchantable nor fit for their intended purposes and uses.

154. By reason of the foregoing, Lisa 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, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

155. As a result of the foregoing acts and omissions Lisa requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Lisa has also lost employment opportunities as an official and personal trainer. Lisa is informed and believes and further alleges that Lisa will in the future be required to obtain further medical and/or hospital care, attention, and services and will continue to lose employment opportunities.

PRAYER FOR RELIEF

WHEREFORE, Lisa demands judgment against Defendants on each count set forth herein 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 non-economic damages, including without limitation pain, suffering, and loss of enjoyment of life;

g. Disgorgement of profits obtained through unjust enrichment;

h. Restitution;

i. Treble damages for Defendants' violations of the Act;

j. Reasonable attorneys' fees where recoverable;

k. Costs of this action;

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

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

DEMAND FOR JURY TRIAL

Date: May 7, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been filed electronically using the Court's CM/ECF system and has been served on all parties via email through CM/ECF on this 7th day of May, 2026.

BY: _____