June 20, 2018

Cartiva, Inc.
Tanya Eberle
Senior Director, Regulatory Affairs and Quality Assurance
6120 Windward Parkway Suite 220
Alpharetta, Georgia 30005

Re: K181348
Trade/Device Name: Cartiva® SCI Disposable Instrumentation Set
Regulation Number: 21 CFR 888.4505
Regulation Name: Orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation
Regulatory Class: Class II
Product Code: QBO
Dated: May 18, 2018
Received: May 21, 2018

Dear Ms. Eberle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) No. (if known): K181348

Device Name: Cartiva® SCI Disposable Instrumentation Set

Indications for Use: Orthopedic surgical instrumentation supplied by Cartiva, Inc. is indicated for use in the press-fit fixation of the implantable medical device products manufactured by Cartiva, Inc.

Prescription Use: __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

CARTIVA®

510(k) Summary

SUBMITTER'S INFORMATION

Owner:	Cartiva, Inc.
Address:	6120 Windward Parkway, Suite 220, Alpharetta, GA 30005
Phone:	770-754-3800
Fax Numbers:	770-754-3808
Contact Person:	Tanya Eberle, Sr. Director, Regulatory Affairs

Date Summary Prepared:	May 18, 2018

DEVICE INFORMATION

Name of Device:	Cartiva SCI Disposable Instrumentation Set
Common/Usual Name:	Orthopedic Surgical Instrumentation
Classification Name:	Orthopedic Surgical Instrumentation designed for osteochondral implants with press-fit fixation (Product Code QBO)
Predicate Device(s):	Cartiva SCI Instrumentation (Product Code QBO, Regulation Number 21 CFR 888.4505)
Device Description:	Orthopedic surgical instruments designed for osteochondral implants with press-fit fixation are hand-held devices intended to manipulate bone and cartilage tissue or the implant for the positioning, alignment, defect creation, and placement of press-fit osteochondral implants that utilize no additional means of fixation (e.g., suture fixation, adhesives). This type of device includes instruments specific to the geometry of the implant.
Indication for Use:	Orthopedic surgical instrumentation supplied by Cartiva, Inc. is indicated for use in the press-fit fixation of the implantable medical device products manufactured by Cartiva, Inc.
Technological Characteristics:	The minor changes to the material of the Cartiva SCI Disposable Instrumentation do not do not raise new questions of safety or effectiveness. All technological aspects of press-fit fixation are preserved.
Comparison to Predicate Device:	The Cartiva SCI Disposable Instrumentation Set intended use and performance characteristics are not altered by this modification to allow for a single-use option.

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Performance Data:

Testing of the Cartiva SCI Disposable Instrumentation Set was carried out, including:

Biocompatibility per ISO 10993-1

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)
- Toxicity (ISO 10993-11)
- Pyrogenicity (ISO 10993-11)

Sterility and Shelf Life

- The Cartiva SCI Disposable Instrumentation Sets are terminally sterilized via Gamma radiation.
- Sterilization validation methodology per ISO 11137 and ISO 11737, Method VDmax^{25}.
- Sterility Assurance Level is 10^{-6}.
- Non-pyrogenic claims for the Cartiva SCI Disposable Instrumentation Sets were verified through ISO Materials Mediated Rabbit Pyrogen testing.
- Shelf-Life testing was established as 5 years through accelerated aging per ASTM F 1980. Realtime testing is ongoing to assure stability.

Performance/Functional Testing

- Simulated Use Testing of aged product in beyond use conditions to demonstrate functionality.
- Ship studies per ASTM D4169.

All data demonstrated that the safety and performance of the Cartiva SCI Instrumentation is not affected by the modification to allow for disposable, single-use instrumentation.

A Clinical Evaluation was determined not to be required as the device design, intended use and indication for use are all preserved.

Rationale for Substantial Equivalence:

This modification falls within the FDA regulations for 510(k) review. The indication for use, intended use, principles of operation, and performance have not been altered. The minor change in technological characteristics (material) of the next-generation disposable instrumentation do not raise any new questions of safety or effectiveness and the single use set has been demonstrated to provide the same level of performance as the predicate reusable device. The Cartiva SCI Disposable Instrumentation Set with next-generation instrumentation is substantially equivalent to the predicate device (Cartiva SCI Instrumentation, Product Code QBO, Regulation Number 21 CFR 888.4505).

Conclusion:

The Cartiva SCI next-generation disposable instrumentation, as modified by this 510(k), do not raise any new issues regarding safety or effectiveness, and therefore is suitable for commercial sale.

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