September 4, 2019

Cartiva, Inc.
Shriya Kafle
Regulatory Specialist
6120 Windward Parkway, Suite 220
Alpharetta, Georgia 30005

Re: K192156
Trade/Device Name: Cartiva® SCI Reusable 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: August 8, 2019
Received: August 9, 2019

Dear Shriya Kafle:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192156

Device Name
Cartiva® SCI Reusable Instrumentation Set

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Number: K192156
Date Submitted: August 9, 2019

510(k) Summary

SUBMITTER'S INFORMATION

Owner:	Cartiva, Inc.
Address:	6120 Windward Parkway, Suite 220, Alpharetta, GA 30005
Phone:	770-754-3817
Fax Numbers:	770-754-3808
Contact Person:	Shriya Kafle, Regulatory Specialist

DEVICE INFORMATION

Name of Device:	Cartiva SCI Reusable 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 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 line extension of Cartiva SCI Reusable Instrumentation to add two additional sizes (6mm and 12mm) to the existing reusable instrumentation product line 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 Reusable Instrumentation set use and performance characteristics are not altered by this modification to add two additional sizes, (6mm and 12mm) to the existing Cartiva reusable instrumentation product line.

Performance Data:

Testing of the Cartiva Reusable Instrumentation set was carried out, including:

Biocompatibility per ISO 10993-1

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)

Reprocessing:

- **Cleaning validation:**
  Cleaning validation per AAMI TIR30 and AAMI TIR12

- **Sterilization Validation**
  Sterilization validation per AAMI TIR39, ISO 17665-1 and ANSI/AAMI ST79

Performance/Functional Testing

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

All data demonstrated that the safety and performance of the Cartiva SCI Reusable Instrumentation is not affected by the proposed modification to add two additional sizes, 6mm and 12mm, to the Cartiva existing reusable instrumentation product line.

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 to add the new Cartiva SCI Reusable Instrumentation sizes 6mm and 12mm to the existing Cartiva Reusable Instrumentation portfolio (8mm and 10mm) do not raise any new questions of safety or effectiveness. The new Cartiva SCI Reusable Instrumentation sizes 6mm and 12mm have demonstrated to provide the same level of performance as the predicate device, Cartiva SCI Instrumentation, (Product Code QBO, Regulation Number 21 CFR 888.4505). Therefore, the new Cartiva SCI Reusable Instrumentation Set (6mm and 12mm) is substantially equivalent to the predicate Cartiva SCI Instrumentation, (Product Code QBO, Regulation Number 21 CFR 888.4505).

Conclusion:

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