April 26, 2018

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

Re: Q180170
Reusable Implantation Instruments for the Cartiva Synthetic Cartilage Implant
Evaluation of Accessory Classification Under Section 513(f)(6) – Accessory Classification Request
Regulation Number: 21 CFR 888.4505
Regulation Name: Orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation
Regulatory Classification: Class II
Product Code: QBO
Dated: January 29, 2018
Received: January 31, 2018

Dear Ms. Eberle:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your Accessory Classification request for classification of the Reusable Implantation Instruments for the Cartiva Synthetic Cartilage Implant, a prescription device under 21 CFR 801.109 that is intended to manipulate bone and cartilage tissue or implant materials for the positioning, alignment, defect creation, and placement of press-fit osteochondral implants.

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Reusable Implantation Instruments for the Cartiva Synthetic Cartilage Implant, and substantially equivalent devices of this generic type, into class II under the generic name orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation.

FDA identifies this generic type of device as:

> **Orthopedic surgical instrumentation designed for osteochondral implants with press-fit fixation.** *Identification.* 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.

Section 513(f)(6) of the Federal Food, Drug and Cosmetic Act (the FD&C Act) was added by section 707 of the FDA Reauthorization Act of 2017 (FDARA) on August 18, 2017, and was effective on October 17, 2017 (Pub. L. 115-52). This provision establishes a pathway for manufacturers or importers to request classification of accessories distinct from another device upon written request. The classification is based upon the risks of the accessory when used as intended as well as the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness, notwithstanding the classification of any other device with which such accessory is intended to be used. Until an accessory is reclassified by FDA, the classification of any accessory distinct from another device by regulation or written order issued prior to December 13, 2016 will continue to apply.

Under section 513(f)(6)(D)(ii) of the FD&C Act, a manufacturer or importer may request proper classification of an accessory that has been granted marketing authorization as part of a premarket approval application (PMA), premarket notification (510(k)), or De Novo classification request. FDA must grant or deny the request not later than 85 days after receipt and, if granting, publish a notice in the **Federal Register** within 30 days announcing the classification.

Alternatively, under section 513(f)(6)(C), a person filing a PMA or 510(k) may include a written request for the proper classification of an accessory that has not been classified distinctly from another device based on the risks of the accessory when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness. When the written request is included in a submission for marketing authorization, FDA must grant or deny the request along with the response to the PMA or 510(k). Upon granting, FDA will publish a notice in the **Federal Register** within 30 days announcing the classification.

FDA received your Accessory Classification request on January 31, 2018 to classify the Reusable Implantation Instruments for the Cartiva Synthetic Cartilage Implant into class II under section 513(f)(6)(D)(ii) of the FD&C Act. In order to classify the Reusable Implantation Instruments for the Cartiva Synthetic Cartilage Implant into class I or II, the proposed class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the Accessory Classification request and the amended request for classification into class II in your email dated April 19, 2018, FDA has determined that the Reusable Implantation Instruments for the Cartiva Synthetic Cartilage Implant intended to manipulate bone and cartilage tissue or implant materials for the positioning, alignment, defect creation, and placement of press-fit osteochondral implants can be classified in class II with the establishment of special controls. FDA has determined that class II (special controls) provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risk(s)	**Mitigation Measure(s)**
Adverse tissue reaction	Biocompatibility evaluation
Infection	Reprocessing validation Labeling
Implant malpositioning or migration	Validation of technical specifications Labeling

In combination with the general controls of the FD&C Act, the orthopedic surgical instrumentation for osteochondral implants with press-fit fixation is subject to the following special controls:

(1) Technical specifications regarding geometry of the instruments must be specified and validated to demonstrate that the instruments can safely position and place the implant.
(2) The patient contacting components of the device must be demonstrated to be biocompatible; and
(3) Labeling must include:
    (i) Identification of implant(s) and instruments which have been validated for use together; and
    (ii) Validated methods and instructions for reprocessing any reusable parts.

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. We believe this may be such a device type, and a notice of intent to exempt the device type from premarket notification requirements may appear in the same issue of the **Federal Register** in which we announce this classification order.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Please be advised that FDA's decision to grant this Accessory Classification request does not mean that FDA has determined that your device complies with other requirements of the FD&C Act or any Federal statutes or regulations administered by other Federal agencies. You must comply with all applicable requirements under the FD&C Act, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the **Federal Register**. A copy of this order is on file in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may market your device as described in the Accessory Classification request, provided that your device complies with the general control provisions of the FD&C Act and the special controls identified in this order.

If you have any questions concerning this classification order, please contact Mark Melkerson at 301-796-6383.

Sincerely,

/s/

Angela C. Krueger
Deputy Director
for Engineering and Science Review (Acting)
Office of Device Evaluation
Center for Devices and Radiological Health