June 29, 2020

Integra Lifesciences Corporation
Ascension Orthopedics, Inc.
Cassidy Lemkau
Regulatory Affairs Specialist
11101 Metric Blvd
Austin, Texas 78758

Re: K201507
Trade/Device Name: Cadence Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: June 4, 2020
Received: June 5, 2020

Dear Cassidy Lemkau:

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,

Ting Song, Ph.D., R.A.C.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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)*
K201507

Device Name
Cadence Total Ankle System

Indications for Use *(Describe)*
The Cadence Total Ankle System is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, and allowing for movement at the replaced joint.
The Cadence Total Ankle System is indicated for use to treat:
- Systemic arthritis of the ankle (e.g. rheumatoid arthritis, hemochromatosis)
- Primary arthritis (e.g. degenerative disease)
- Secondary arthritis (e.g. post-traumatic, avascular necrosis, if minimally 2/3 of the talus is preserved)

Cadence Total Ankle System is also indicated for revision surgeries following failed total ankle replacement and non-union/mal-union of ankle arthrodesis. Provided sufficient bone stock is present.
Note – In the United States, this device is intended for cemented use only.
Note – Outside the United States, this device is intended for cemented or cementless use.

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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Integra Lifesciences Corporation – Special 510(k)
Cadence Total Ankle System– Line Extension

510(k) Summary

Sponsor	**Integra Lifesciences Corp.** **Ascension Orthopedics, Inc.** 11101 Metric Blvd. Austin, TX 78758
Establishment Number	3014207283
Point of Contact	Cassidy Lemkau Regulatory Affairs Specialist 11101 Metric Blvd. Austin, TX 78758 402-990-4239
Date	06/06/2020
Trade Name	Cadence Total Ankle System
Common Name	Ankle Implant
Classification Panel	Orthopedic
Classification	Class II
Regulation No.	21 CFR 888.3110
Regulation Name	Ankle joint metal/polymer semi-constrained cemented prosthesis
Product Code	HSN
Predicate Device	K151459 Integra Total Ankle Replacement System

Reference Device	K182878 Integra Salto Total Ankle System
Device Description	The Cadence Total Ankle System is a prosthesis composed of a tibial tray, a talar dome and an insert. The tibial tray and talar dome are secured to patient anatomy. The insert is rigidly fixed to the tibial tray intra-operatively. The insert acts as a bearing along the talar dome, enabling flexion and extension movement at the replaced joint. Each of the three components is available in a variety of sizes and design configurations intended for both primary and revision surgery applications. The Cadence System also consists of various instrumentation to allow for appropriated implantation of the Cadence Prosthesis. The scope of the Cadence System is being extended to include additional options for the talar domes. The new talar dome option features a flat cut design in comparison to the currently commercialized talar dome chamfer cut design. New instrumentation will also be introduced to aid in the implantation of the new flat cut talar dome design.
Intended Use/ Indications for Use	The Cadence Total Ankle System is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, and allowing for movement at the replaced joint. The Cadence Total Ankle System is indicated for use to treat: - Systemic arthritis of the ankle (e.g. rheumatoid arthritis, hemochromatosis) - Primary arthritis (e.g. degenerative disease) - Secondary arthritis (e.g. post-traumatic, avascular necrosis, if minimally 2/3 of the talus is preserved) Cadence Total Ankle System is also indicated for revision surgeries following failed total ankle replacement and non-union/mal-union of ankle arthrodesis. Provided sufficient bone stock is present. Note – In the United States, this device is intended for cemented use only. Note – Outside the United States, this device is intended for cemented or cementless use.

Nonclinical Performance Data	The modified device was subjected to the following verification testing and/or analyses to establish substantial equivalence in comparison to the unmodified device. 1. Constraint 2. Bone Stability 3. Range of Motion 4. Fatigue Strength 5. Contact Area and Pressure Distribution 6. Wear
Clinical Performance Data	Clinical performance data is not required to demonstrate substantial equivalence to the predicate device.
Substantial Equivalence Conclusion	Substantial equivalence of the modified device and predicate device is based on the following: • The modified and predicate device have exactly the same intended use. • Both devices operate using the same fundamental scientific technology. • Both devices share the same functional and technological characteristics via the same operational principles. After evaluation of the risks and performance data, the modified device does not raise any new issues or concerns related to safety or effectiveness.