DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 31, 2015

Ascension Orthopedics
% Mr. Steve Brown
CoorsTek Medical
560 West Golf Course Road
Providence, Utah 84332

Re: K151459
Trade/Device Name: Integra Total Ankle Replacement 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 2, 2015
Received: June 3, 2015

Dear Mr. Brown

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151459

Device Name
Integra Total Ankle Replacement System

Indications for Use *(Describe)*
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)

The 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.

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.

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Section 4: 510(k) SUMMARY

Device Trade Name: Integra Total Ankle Replacement System

Date: May 15, 2015

Sponsor: Integra LifeSciences Corporation

Contact Person:
Integra Life Sciences Corp
Frederic Testa
Director, Regulatory Affairs
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frederic.testa@integralife.com

Manufacturer:
Ascension Orthopedics
8700 Cameron Road, Suite 100
Austin, TX 78754
609-936-3630
frederic.testa@integralife.com

Common Name:	Total Ankle Replacement Device
Device Classification:	Class II
Classification Name:	Ankle joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3110)
Regulation:	Ankle joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3110)

Device Regulation Panel: Orthopedic

Device Product Code: Orthopedic HSN

Device Description:

The Integra® Total Ankle Replacement 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 prosthesis is composed of a tibial component, a talar component and an insert. Both the tibial component and talar component are secured to patient anatomy via bone cement; the intermediate insert is rigidly fixed to the tibial component intra-operatively. When all three components are implanted, the intermediate insert acts as a bearing along the talar component, enabling flexion and extension movement at the replaced joint.

Components are available in a variety of sizes and design configurations intended for both primary and revision applications.

For marketing purposes the Integra Total Ankle Replacement System will be released to market as the Cadence Total Ankle System.

Implants:

Talar Dome Components

The Talar domes are manufactured from cobalt chrome and are offered in 5 sizes with Left and Right hands. They have a highly polished articular surface and a titanium plasma spray under surface.

Tibial Trays

The Tibial Trays are manufactured from titanium alloy and are offered in 9 sizes with Left and Right hands. Sizes 1 through 4 come in both standard and "X" versions with the "X" version having a larger AP dimension. The size 5 only comes in the standard version The trays have a smooth finish top and a titanium plasma spray under surface.

Inserts

The inserts are made of cross-linked polyethylene GUR1020 UHMWPE and are offered in 5 sizes with Left and Right hands. There are 3 versions of the inserts including neutral, Anterior Biased, and Posterior Biased. They all come in thicknesses from 6mm to 12mm in 1 mm increments.

Reusable Instruments:

Tibial Alignment Guides
Tibial and Talar sizing Guides
Tibial and Talar cutting Guides
Talar Reaming guides
Tibial Trays, Talar Domes and insert trials
Tibial and Talar impactors and extractors
Insert Inserter
Retraction instrumentations

Pins, drills and reamers

Materials:

Implants:

The Talar dome components are made out of Cobalt Chrome alloy (CoCr) per NF ISO 5832-4 and ASTM F75, with a porous titanium coating (Ti).

The tibial tray components are made out of titanium alloy (Ti) Ti-6Al-4V ELI Per ASTM F136, with a porous titanium coating (Ti).

The insert is made out of cross-linked polyethylene GUR1020 UHMWPE, per ISO 5834-2 and ASTM F648.

Instrumentation:

The reusable instrumentation is manufactured from biocompatible materials, including stainless steel, Radel, and silicone.

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)

The 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.

Technological Characteristics:

There are no technological characteristics that raise new issues of safety or effectiveness.

Assessment of performance data:

The performance of the Integra Total Ankle Replacement Systemwas verified to be statistically equivalent to that of the predicate device. The predicate construct and Integra Total Ankle Replacement Systemconstruct were tested both dynamically and statically. The stiffness of the 2 systems was compared and was statistically equivalent. A summary of the objective, acceptance criteria, results, and conclusions, as well as the detailed test reports can be found in Section 36.

Legally Marketed Predicate Device:
Wright Medical INBONE™ Total Ankle System (K100886)

Predicate Indications for Use:
The Wright Medical INBONE™ Total Ankle System (K100886) is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The Integra Total Ankle Replacement System is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

The indications are similar to the legally marketed predicate device.

Purpose:
The purpose of this Traditional 510(k) submission is to gain clearance for the Integra Total Ankle Replacement System.

Conclusions:

Based upon the similarities of the Integra Total Ankle Replacement System and the predicate devices studied, the safety and effectiveness of the Integra Total Ankle Replacement System is substantially equivalent to the predicate devices referenced.