



Wright Medical Technology, Inc.
Tara Conrad
Regulatory Affairs Specialist II
1023 Cherry Road
Memphis, Tennessee 38117

April 26, 2018

Re: K172633

Trade/Device Name: INFINITY 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: March 26, 2018
Received: March 27, 2018

Dear Ms. Conrad:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Katherine D. Kavlock -S

for
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 on last page.

510(k) Number (if known)

K172633

Device Name

INFINITY Total Ankle System

Indications for Use (Describe)

The INFINITY Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

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

CAUTION: In the United States, the ankle prosthesis is intended for cement 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the INFINITY™ Total Ankle System.

- (a)(1). Submitted By:** Wright Medical Technology, Inc.
 1023 Cherry Road
 Memphis, TN 38117
- Date:** April 25, 2018
- Contact Person:** Tara Conrad
 Regulatory Affairs Specialist II
 Office (901) 867-4367
 Fax (901) 867-4190
- (a)(2). Proprietary Name:** INFINITY Total Ankle System
- Common Name:** Total Ankle Prosthesis
- Classification Name and Reference:** 21 CFR 888.3110 - Class II
- Device Product Code, Device Panel:** HSN – Orthopedic
- (a)(3). Predicate Device:** K123954, K140749 –INFINITY Total Ankle System
 K141740 - INBONE and INFINITY Total Ankle Systems
 K161742- Aequalis PerFORM Reversed,
 Aequalis PerFORM+ Reversed Glenoid
- (a)(4). Device Description**

The subject INFINITY™ Total Ankle System is a fixed-bearing, bone-sparing ankle replacement prosthesis that restores mobility to a failing ankle joint. The system includes three components (i.e., tibial tray, poly insert, and talar dome) that are assembled together to create the two-piece prosthesis. The talar dome is manufactured using additive manufacturing technology.

- (a)(5). Intended Use**
 INFINITY Total Ankle System is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

Indications for Use

INFINITY Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. INFINITY Total Ankle System is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: In the United States, the ankle prosthesis is intended for cement use only.

(a)(6). Technological Characteristics Comparison

The INFINITY Total Ankle System has identical indications, utilizes similar instrumentation, is made from identical materials, and has identical sterilization methods when compared to the legally marketed predicate devices.

(b)(1). Substantial Equivalence- Non-Clinical Evidence

Non-clinical performance bench testing was performed to demonstrate substantial equivalence to the predicate devices.

- Chemical Analysis
- Abrasion Resistance
- Stereological Evaluation
- Compressive Strength
- Shear and Tensile Strength
- Fatigue Testing
- MRI Safety Analysis
- Direct Metal Laser Sintering (DMLS) Process Validation
 - Operational Qualification-Mechanical validation and Microstructure
 - Performance Qualification- Mechanical validation and Microstructure
 - Powder Bed Position Validation
 - Powder Recycling Validation
- Endotoxin (<20EU/device)

(b)(2). Substantial Equivalence- Clinical Evidence

Clinical Studies were not required to demonstrate substantial equivalence between the subject device and the predicate devices.

(b)(3). Substantial Equivalence- Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate devices. In addition, the subject device is expected to pose minimal risk to patients when placed in an MR environment and is categorized as MR Conditional.