August 9, 2018

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

Re: K181557
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: June 8, 2018
Received: June 13, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181557

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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:	June 8, 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, K172633 –INFINITY Total Ankle System K141740 - INBONE and INFINITY Total Ankle Systems

(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 tibial tray 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.