August 22, 2019

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

Re: K191393
Trade/Device Name: INFINITY Total Ankle System, INBONE 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: May 23, 2019
Received: May 24, 2019

Dear Rachel Roberts:

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,

For: CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*
K191393

Device Name
INFINITY Total Ankle System, INBONE Total Ankle System

Indications for Use *(Describe)*

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

The INBONE Total Ankle System and INFINITY Total Ankle System are 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

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 INBONE™ and INFINITY™ Total Ankle Systems.

(a)(1).	**Submitted By:**	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
	Date:	May 23, 2019
	Contact Person:	Rachel Roberts Regulatory Affairs Specialist II Office (901) 867-9708 Fax (901) 867-4190
(a)(2).	**Proprietary Name:**	INBONE and INFINITY Total Ankle Systems
	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:**	K172633 – INFINITY Total Ankle System K123059 – INBONE Total Ankle System

(a)(4). Device Description

The subject INBONE™ and INFINITY™ Total Ankle Systems are fixed-bearing, bone-sparing ankle replacement prostheses that restore mobility to a failing ankle joint. Both the INFINITY and INBONE systems include three components (tibial trays with or without stems, poly inserts, and talar domes) that are assembled together to create the two-piece prosthesis.

(a)(5). Intended Use

INBONE™ and INFINITY™ Total Ankle Systems are 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

The INBONE™ Total Ankle System and INFINITY™ Total Ankle System are indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. The INBONE™ Total Ankle System and INFINITY™ Total Ankle System are 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 INBONE and INFINITY Total Ankle Systems have 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
- Compressive Strength
- Shear and Tensile Strength
- 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
- Endotoxin (<20EU/device)

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

Clinical Studies were not required to demonstrate equivalence between the subject and 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 place in an MR environment and is categorized as MR Conditional.