APR 2 5 2014

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Wright Medical Technology, Inc.
1023 Cherry Road Memphis, TN 38117
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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 WMT INFINITY® Total Ankle System.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	March 24, 2014
Contact Person:	Jeanine Redden Director, Regulatory Affairs Phone: 901.867.4522 Fax: 901.687.4190
(a)(2). Proprietary Name:	INFINITY™ Total Ankle System
Common Name:	Ankle Prosthesis
Classification Name and Reference:	21 CFR 888.3110 – Class II
Device Product Code, Device Panel:	HSN: Ankle Prosthesis
(a)(3). Predicate Device:	K123954 INFINITY® Total Ankle System

(a)(4). Device Description

The INFINITY® Total Ankle System is a fixed-bearing, bone-sparing total ankle prosthesis that restores mobility to a failing ankle joint. It encompasses three components (i.e., tibial tray, tibial insert, and talar dome) that are assembled together to create a two-piece prosthesis. The device is composed of Titanium Alloy, Cobalt Chrome, Ultra High Molecular Weight Polyethylene and commercially pure Titanium and each component is available in multiple sizes to accommodate variable patient anatomy.

(a)(5). INTENDED USE

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

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

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

(a)(6). Technological Characteristics Comparison

The INFINITY® Total Ankle System is technologically substantially equivalent to the predicates. A summary of the changes is below.

The INFINITY Tibial Tray Line addition maintains, without modification for each corresponding size, all the clinically relevant design features of the INFINITY Total Ankle Tibial Tray. The differences between the subject, INFINITY Tibial Tray line extension, and the predicate, INFINITY Tibial Tray, is the addition of a shorter anterior-posterior (AP) tray length and a neutral posterior curvature posterior. The line addition includes short sizes of sizes 3-6.

The tibial tray line addition uses the identical INFINITY tibial bone interface geometry, three angled proximal peg configuration, peg diameter, and lock detail fits between the tibial insert and tib tray size. Additionally, the subject's anterior profile, medial-lateral (M-L) outer profile, component thickness, and tibial insert assembly features are also identical to the predicate design.

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

Through mechanical analysis the subject devices do not represent a new worst-case. Therefore, no additional mechanical testing was performed to support the subject devices.

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

N/A

(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 system.

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

April 25, 2014

Wright Medical Technology, Incorporated
Ms. Jeanine Redden
Director, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

Re: K140749
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, 2014
Received: March 28, 2014

Dear Ms. Redden:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Ronald P. Jean -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 below.

510(k) Number *(if known)*
K140749

Device Name
INFINITY™ Total Ankle System

Indications for Use *(Describe)*
The INFINITY™ Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

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

CAUTION: The ankle prosthesis 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)

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)*

Ronald P. Jean -S
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