September 11, 2017

Dear Ms. Myles:

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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
Indications for Use

Device Name
INVISION™ Total Ankle Revision System

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

The INVISION Total Ankle Revision 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.
This section applies only to requirements of the Paperwork Reduction Act of 1995.

"DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW."

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
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 INVISION™ Total Ankle Revision System.

(a)(1). Submitted By: Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: March 31, 2017

Contact Person: Val Myles
Regulatory Affairs Specialist
Office (901) 290-5162
Fax (901) 867-4190

(a)(2). Proprietary Name: INVISION™ Total Ankle Revision 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: K142117, K153008 - INVISION Total Ankle Revision System
K141740 - INBONE and INFINITY Total Ankle Systems

(a)(4). Device Description

The INVISION Total Ankle Revision System is a fixed-bearing ankle replacement prosthesis that restores mobility to a failing ankle joint. The system includes multiple tibial and talar components that are assembled together to create the two-piece prosthesis. Based on patient anatomy, a number of component sizes and design configurations can be selected for best fit.

(a)(5). Intended Use

INVISION Total Ankle Revision 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 INVISION Total Ankle Revision System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. The INVISION Total Ankle Revision 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 subject INVISION Total Ankle System includes thicker talar domes and talar plates with additional peg sizes and orientations. The subject 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. Labeling modifications include a statement regarding the compatibility of the device with MR environments and contraindication updates.

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

Engineering analysis and rationale was performed to demonstrate substantial equivalence in shear strength, fatigue strength, and torsional stability. MR testing and analysis related to displacement force, torque, artifact, RF heating testing were also used to demonstrate substantial equivalence. Pyrogenicity testing was also conducted.

**(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 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.