Wright Medical Technology, Inc.
Alayne Melancon
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

July 11, 2018

Re: K180730
Trade/Device Name: INVISION Total Ankle Revision 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 25, 2018
Received: June 1, 2018

Dear Alayne Melancon:

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 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)*

K180730

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.

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 INVISION Total Ankle Revision System.

(a)(1) MANUFACTURER IDENTIFICATION

Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	March 19, 2018
Contact Person:	Alayne Melancon Regulatory Affairs Specialist II Office: (901)290-5986 Fax: (901)867-4190

(a)(2) SUBJECT DEVICE INFORMATION

Proprietary Name:	INVISION™ Total Ankle Revision System
Common Name:	Ankle Joint metal/polymer semi-constrained cemented prosthesis
Classification Name & Reference:	21 CFR 888.3110 – Class II
Device Product Code & Panel:	HSN – Orthopedic

(a)(3) PREDICATE DEVICE INFORMATION

INVISION Total Ankle Revision System – *Primary Predicate*	K171067
INVISION Total Ankle Revision System	K153008
INBONE Total Ankle System	K103374, K133585

(a)(4) DEVICE DESCRIPTON

The INVISION Total Ankle Revision System is a fixed-bearing ankle replacement prosthesis that restores mobility to a failing ankle joint. This modular system is comprised of a tibial stem, tibial tray, talar domes, talar plates, and a poly insert. These components are assembled together to create the two-piece prosthesis. Based on patient anatomy, a number of component sizes and design configurations can be selected.

(a)(5) INTENDED USE

The 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

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 devices are talar fixation line extension components for the talar construct intended to be used with the existing INVISION Total Ankle Revision System talar domes. As such, the subject devices have identical intended use, indications for use, size offerings, and principles of operation to the predicates to maintain the modularity of the system. **Table 1** below shows a comparison of technological characteristics.

Table 1 Subject vs Predicate Technological Comparison

	SUBJECT	PREDICATES	
	INVISION Total Ankle Revision System	INVISION Total Ankle Revision System – K171067, K153008 –	INBONE Total Ankle System – K10086, K103374, K133585 –
Material	Plate: ASTM F136, ASTM F1580 Central Peg/Plug: ASTM F136 Locking Peg/Plug: ASTM F136 +TiN (*peg head only*)	Plate: ASTM F136, ASTM F1580	Dome: ASTM F1537, ASTMF1580 Central Stem: ASTM F136
Plate Sizes	1, 2, 3, 4, 5	Identical	1, 2, 3, 4, 5, 6
Plate Length Options	Standard and Long	Identical	N/A
Orientation	Left and Right	Identical	Universal

(b)(1) **SUBSTANTIAL EQUIVALENCE – NON-CLINICAL EVIDENCE**

The following evaluations were conducted to support the safety and efficacy of the INVISION Total Ankle Revision System:

- Fatigue Testing
- Shear Testing
- Torsion Testing
- Pyrogen
- MR Safety Labeling

(b)(2) **SUBSTANTIAL EQUIVALENCE – CLINICAL EVIDENCE**

N/A

(b)(3) **SUBSTANTIAL EQUIVALENCE – CONCLUSIONS**

The design characteristics of the subject device do not raise any new types of questions of safety or effectiveness and testing shows no new worst case. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.