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

February 22, 2017

Wright Medical Technology, Inc.
Tara Conrad
Regulatory Affairs Specialist II
1023 Cherry Road
Memphis, Tennessee 37117

Re: K162795
Trade/Device Name: PROPHECY INVISION Preoperative Navigation Alignment System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN, OYK
Dated: September 20, 2016
Received: October 4, 2016

Dear Tara 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. 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 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 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,

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K162795

Device Name
PROPHECY® INVISION® Preoperative Navigation Alignment System

Indications for Use *(Describe)*

Wright's PROPHECY® Preoperative Navigation Alignment System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The PROPHECY® Preoperative Navigation Alignment Guides are intended for use with Wright's INBONE® and INFINITY® Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® Preoperative Navigation Alignment Guides are intended for single use only. The PROPHECY® Preoperative Reports are intended for use with Wright's INBONE®, INFINITY® and INVISION® Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

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)*

WRIGHT
FOCUSED EXCELLENCE

Headquarters
Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117
901 867 9971
wmt.com

K162795

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 PROPHECY® INVISION® Preoperative Navigation Alignment System.

1. Submitted By:

Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: January 27, 2017

Contact Person:

Tara Conrad
Regulatory Affairs Specialist II
Office (901) 867-4367
Fax (901) 867-4190

2. Proprietary Name: PROPHECY® INVISION® Preoperative Navigation Alignment System

Common Name: Alignment Guide

Classification Name and Reference: 21 CFR 888.3110 - Class II

Device Product Code, Device Panel: HSN, OYK

3. Predicate Device:

K110306-PROPHECY® INBONE®
K131283-PROPHECY®INFINITY®
K142117-INVISION® Total Ankle System
K153008-INVISION® Total Ankle System

4. Device Description

PROPHECY® Preoperative Navigation Alignment System provides the surgeon a template of the patient's distal tibial and proximal talar anatomy. The PROPHECY® alignment report serves as a template for traditional alignment instrumentation used with Wright's INBONE®, INFINITY®, and INVISION® Total Ankle Systems.

5. Intended Use and Indications for Use

Wright's PROPHECY® Preoperative Navigation Alignment System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the

marking of bone before cutting. The PROPHECY® Preoperative Navigation Alignment Guides are intended for use with Wright's INBONE® and INFINITY® Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® Preoperative Navigation Alignment Guides are intended for single use only. The PROPHECY® Preoperative Reports are intended for use with Wright's INBONE®, INFINITY® and INVISION® Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

6. Technological Characteristics Comparison

The PROPHECY® Preoperative Navigation Alignment system has identical indications, is made from identical materials and software when compared to the legally marketed predicate devices.

7. Substantial Equivalence- Non-Clinical Evidence

The main difference between the subject and predicate PROPHECY® systems is the addition of use with the INVISION® Total Ankle System. The following evaluations were conducted to support the safety and efficacy of the PROPHECY® INVISION® Alignment Report:

- Design repeatability across design engineers
- Software validation

These evaluations concluded the subject alignment guide is substantially equivalent to the predicates.

8. Substantial Equivalence- Clinical Evidence

N/A

9. Substantial Equivalence- Conclusions

The design characteristics of the subject devices 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 systems and are substantially equivalent.