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

Re: K170968  
Trade/Device Name: PROPHECY INVISION Pre-operative Navigation 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: March 24, 2017  
Received: March 31, 2017

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.

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

510(k) Number (if known)
K170968

Device Name
PROPHECY™ INVISION™ Preoperative Navigation 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™, 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. 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)
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."
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 Pre-operative Navigation System.

(a)(1) MANUFACTURER IDENTIFICATION

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

Date: March 24, 2017

Contact Person: Alayne Melancon
Regulatory Affairs Specialist
Office: (901)290-5986
Fax: (901)867-4190

(a)(2) SUBJECT DEVICE INFORMATION

Proprietary Name: PROPHECY INVISION Pre-operative Navigation System
Common Name: Alignment Guide
Classification Name & Reference: 21 CFR 888.3110 – Class II
Device Product Code & Panel: HSN, OYK – Orthopedic

(a)(3) PREDICATE DEVICE INFORMATION

PROPHECY INVISION Pre-operative Navigation Alignment System: K162795
PROPHECY INFINITY Pre-operative Navigation Alignment System: K131283
PROPHECY INBONE Pre-operative Navigation Alignment System: K110360
INVISION Total Ankle System: K142117, K153008
(a)(4) DEVICE DESCRIPTION

Wright Medical’s PROPHECY INVISION Preoperative Navigation Alignment System (K162795) is being expanded to include patient-specific guides for the INVISION Total Ankle System. Like the predicates PROPHECY INFINITY and PROPHECY INBONE guides, the subject patient-specific guides are created to fit the anatomy of the patient’s distal tibia and proximal talus, and when used in combination with the reusable instruments, facilitate positioning of INVISION Total Ankle Implants.

(a)(5) INTENDED 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™, 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. 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.

(a)(6) TECHNOLOGICAL CHARACTERISTICS COMPARISON

The subject PROPHECY INVISION Preoperative Navigation System has identical indications and software components. The materials and design are substantially equivalent to the predicate devices and are summarized in the table below.

<table>
<thead>
<tr>
<th>SUBJECT</th>
<th>PROPHECY INVISION</th>
<th>PROPHECY INFINITY (K131283)</th>
<th>PROPHECY INBONE (K110360)</th>
</tr>
</thead>
</table>
| Patient-Specific Guides | -Tibia Alignment -Guide  
- Tibia spacer Guide  
- Talus Spacer Guide  
- Tibia Stem Guide     | -Tibia Alignment Guide  
- Talus Alignment Guide | -Tibia Alignment Guide  
- Talus Alignment Guide  
- Tibia Stem Guide       |
| Materials                | Patient-specific guides: Duraform Polyamide  
 Accessory instrument: stainless steel, Radel | Patient-specific guides: Duraform Polyamide  
 Accessory instrument: stainless steel | Patient-specific guides: Duraform Polyamide  
 Accessory instrument: stainless steel |

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

The following evaluations were conducted to support the safety and efficacy of the PROPHECY INVISION Pre-operative Navigation System:
- Guide Design Process Validation - Designer Repeatability
- Pre-operative vs Post-operative Analysis of Implant Placement
- Guide Placement Repeatability – Inter-surgeon Variability

(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. 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.