March 10, 2021

Wright Medical Technology, Inc.
Paxia Her
Sr. Regulatory Affairs Specialist
10801 Nesbitt Ave S
Bloomington, Minnesota 55437

Re: K202815
Trade/Device Name: PROPHECY 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: December 10, 2020
Received: December 11, 2020

Dear Paxia Her:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6C: Division of Joint
Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K202815

Device Name

PROPHECY™ 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, in guiding the marking of bone before cutting, and in the pre-surgical planning of the ankle and surrounding anatomy to support the total ankle implant. The PROPHECY™ Preoperative Navigation Alignment Guides and 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. The PROPHECY™ Preoperative Navigation Alignment Guides are intended for single 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 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™ Preoperative Navigation Alignment System.

(a)(1).	**Submitted By:**	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
	Date:	March 10, 2021
	Contact Person:	Paxia Her Sr. Regulatory Affairs Specialist
(a)(2).	**Proprietary Name:**	PROPHECY™ Preoperative Navigation Alignment System
	Common Name:	Alignment Guide
	Classification Name and Reference:	21 CFR 888.3110 - Class II - Ankle joint metal/polymer semi-constrained cemented prosthesis
	Device Product Code, Device Panel:	HSN, OYK
(a)(3).	**Primary Predicate Device:**	K170968 – PROPHECY™ INVISION™ Preoperative Navigation Alignment System
	Additional Predicate Devices:	K162795 – PROPHECY™ INVISION™ Preoperative Navigation Alignment System (Report Only) K131283 – PROPHECY®INFINITY® Preoperative Navigation Alignment System K110360 – PROPHECY® INBONE® Preoperative Navigation Alignment System

(a)(4). Device Description

The PROPHECY™ Preoperative Navigation Alignment System is composed of two components:

- PROPHECY™ Preoperative report
- PROPHECY™ patient-specific guides

The PROPHECY™ Preoperative reports are patient-specific reports created from imaging scans to provide surgeons a template of the patient's distal tibial and proximal talar anatomy and information relevant to the successful implantation of a total ankle replacement. The PROPHECY™ Preoperative Navigation Alignment guides are patient-specific devices that are based on preoperative planning software and assist surgeons in transferring this preoperative plan to the surgery by guiding the marking of bone and/or guiding surgical instruments. The PROPHECY™ patient-specific guides are accompanied by the preoperative report and serve as a template for traditional alignment instrumentation used with Wright Medical's INBONE™, INFINITY™, and INVISION™ Total Ankle Systems.

(a)(5). 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, in guiding the marking of bone before cutting, and in the pre-surgical planning of the ankle and surrounding anatomy to support the total ankle implant. The PROPHECY™ Preoperative Navigation Alignment Guides and 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. The PROPHECY™ Preoperative Navigation Alignment Guides are intended for single use only.

(a)(6). Technological Characteristics Comparison

The PROPHECY™ Preoperative Navigation Alignment System is substantially equivalent in intended use, materials and performance characteristics to the predicate devices.

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

The following evaluations were conducted to support the safety and effectiveness of the PROPHECY™ Navigation Alignment System changes to the PROPHECY™ Preoperative report:

- Board Certified Surgeon content, layout and accuracy verification and validation

These evaluations concluded the subject device is substantially equivalent to the predicates and is adequate to perform as intended.

(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 Special 510(k), the subject devices can be expected to perform at least as well as the predicate devices and are substantially equivalent.