January 27, 2023

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

Re: K222835
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, PBF
Dated: January 9, 2023
Received: January 10, 2023

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 -S

Ting Song, Ph.D.
Assistant Director
DHT6A: 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)*
K222835

Device Name
Prophecy® Preoperative Navigation Alignment System

Indications for Use *(Describe)*
The 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 the 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:	September 9, 2022
	Contact Person:	Paxia Her Staff Regulatory Affairs Specialist
(a)(2).	**Proprietary Name:**	Prophecy® Preoperative Navigation Alignment System
	Common Name:	Alignment guides & 3D planning software
	Classification Name and Reference:	21 CFR 888.3110 - Class II - Ankle joint metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3030 – Class II – Orthopaedic Surgical Planning and Instrument Guides
	Device Product Code, Device Panel:	HSN, OYK, PBF
(a)(3).	**Primary Predicate Device:**	K202815 – Prophecy® Preoperative Navigation Alignment System
	Reference Device:	K203315 – Blueprint™ Patient Specific Instrumentation

(a)(4). Device Description

The Prophecy® Preoperative Navigation Alignment System is composed of three components:

- Prophecy® patient-specific guides
  - The Prophecy® Preoperative Navigation Alignment guides are patient-specific devices that are designed based on preoperative planning software and assist surgeons in transferring their preoperative plan to surgery by guiding the marking of bone and/or guiding surgical instruments.
- Prophecy® 3D Planner
  - The Prophecy® 3D Planner software is a web-based application. The user interface software is intended to be used by orthopedic surgeons, as a preoperative planning and intraoperative viewing software for total ankle replacement surgery.

- Prophecy® Preoperative report
    - 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 offers relevant information for a successful total ankle replacement surgery.

The Prophecy® Preoperative Navigation Alignment System is compatible with the Inbone™, Infinity™, and Invision™ Total Ankle Systems.

(a)(5). Indications for Use

The subject device indication for use is identical to the predicate device.

The 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 the 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 subject device and predicate device have the same key technological characteristics as follows:

- The system processes original patient medical images (i.e., CT scans) and produces patient-specific digital outputs to create a preoperative report and patient specific alignment guides.
- Validated commercially off-the-shelf software applications are used for image segmentation, transfer of patient imaging from a DICOM format to an .STL format, and guide design.
- Requires trained employees/engineers to manipulate data, using software applications.
- Surgeon works with employees/engineers by providing inputs for implant alignment, implant size and implant type modifications.
- Patient-specific alignment guides and bone models are 3D printed via additive manufacturing as the physical output devices.
- Preoperative case reports are produced as an output for planning total ankle replacement surgeries.

The subject device, Prophecy® Preoperative Navigation Alignment System, is substantially equivalent in materials and performance characteristics to the predicate device.

- The modifications do not affect the device's intended use.
- No changes to the patient-specific alignment guides, preoperative report, or other software components are proposed by this submission.

This submission proposes the following modifications to the subject device:

- Addition of the Prophecy® 3D Planner software, which gives surgeons the ability to modify the implant type, implant size and implant orientation via a user interface.
- Changes to the Guide Design Process due to addition of the Prophecy® 3D Planner software.

The technological differences between the subject and predicate devices are supported with verification and validation evaluations. The differences in design specifications do not raise any new questions of safety and effectiveness over the predicate, which is demonstrated in the performance testing and process validation.

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

Performance data and information demonstrating the safety and effectiveness of the Prophecy® Navigation Alignment System with the 3D Planner software is supported by testing that was conducted in-house. This submission includes the following non-clinical testing:

- Software verification testing to ensure all design outputs meet all specified requirements.
- Software validation to ensure software specifications conform to user needs and intended uses.
- Usability test to ensure the software is safe and effective for the intended users, uses and use environments.

The software verification and validation were performed in accordance with FDA Guidance Document *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"* (issued May 11, 2005). The usability was performed in accordance with FDA guidance document *"Applying Human Factors and Usability Engineering to Medical Devices"* (issued February 18, 2016).

All test results met the acceptance criteria, demonstrating the subject device performs as intended and is substantially equivalent to the predicate device.

(b)(2). Substantial Equivalence- Clinical Evidence

Clinical testing was not necessary for the determination of substantial equivalence.

(b)(3). Substantial Equivalence- Conclusions

The subject device and predicate device share identical intended use, general design features and basic fundamental scientific technology. The differences between the subject device and predicate device do not raise any new questions of safety or effectiveness. From the evidence submitted in this Traditional 510(k), the subject device can be expected to perform at least as well as the predicate device and are substantially equivalent.