November 1, 2024

Wright Medical Technology, Inc (Stryker)
Jonathan Dimotta
Staff Specialist, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

Re: K241999
Trade/Device Name: Prophecy Surgical Planning System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Codes: HSN, OYK, PBF
Dated: October 3, 2024
Received: October 3, 2024

Dear Jonathan Dimotta:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2024.11.01 14:25:42 -04'00'

For Lixin Liu
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241999

Device Name

Prophecy Surgical Planning System

Indications for Use *(Describe)*

The Prophecy® Surgical Planning 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® Surgical Planning 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 (e.g. CT scans and X-rays). The Prophecy® Surgical Planning 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.

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.

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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® Surgical Planning System.

(a)(1).	**Submitted By:**	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
	Date:	July 8, 2024
	Contact Person:	Jonathan DiMotta Staff Regulatory Affairs Specialist
(a)(2).	**Proprietary Name:**	Prophecy® Surgical Planning System (previously known as 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 – Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
	Device Product Code, Device Panel:	HSN, OYK, PBF
(a)(3).	**Predicate Device:**	K222835 – Prophecy® Preoperative Navigation Alignment System

(a)(4). Device Description

The Prophecy® Surgical Planning System is composed of three components:

- Prophecy® patient-specific guides
  - The Prophecy® Surgical Planning 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® Surgical Planning System is compatible with the Inbone®, Infinity®, and Invision® Total Ankle Systems.

(a)(5). Indications for Use

The Prophecy® Surgical Planning 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® Surgical Planning 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 (e.g. CT scans and X-rays). The Prophecy® Surgical Planning 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® Surgical Planning 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:

- Updates to Prophecy® 3D Planner software to include new functionality for new users (i.e., Stryker's internal Prophecy® engineers). Specifically, the software update will be used in place of the current off-the-shelf software used in the production of Prophecy® patient-specific guides (i.e. SolidWorks). The updated 3D Planner 2.0.0 software will be able to assist with landmark placement, implant alignment and sizing, and guide design.

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 different 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® Surgical Planning System with the 3D Planner 2.0.0 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 *"Content of Premarket Submissions for Device Software Functions"* (June 14, 2023). The usability testing was performed in accordance with FDA guidance document *"Applying Human Factors and Usability Engineering to Medical Devices"* (issued February 18, 2016). Cybersecurity testing was performed in accordance with "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (issued September 27, 2023).

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 different 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.