June 16, 2026

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

Re: K253159
Trade/Device Name: Prophecy Incompass 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: May 13, 2026
Received: May 13, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.06.16 13:30:56 -04'00'

for Lixin Liu, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253159

Please provide the device trade name(s).

Prophecy Incompass Surgical Planning System

Please provide your Indications for Use below.

Prophecy® Surgical Planning 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®, Invision®, and Incompass™ 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(K) SUMMARY: Prophecy® Incompass™ Surgical Planning System

(a)(1).	**Submitted By:**	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
	Date:	June 12, 2026
	Contact Person:	Jonathan DiMotta Senior Staff Specialist, Regulatory Affairs
	Secondary Contact:	Val Myles Senior Manager, Regulatory Affairs
(a)(2).	**Proprietary Name:**	Prophecy® Incompass™ Surgical Planning 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, PBF, OYK
(a)(3).	**Primary Predicate Device:**	Prophecy Infinity Preoperative Navigation Alignment Guides (K131283)
(a)(4).	**Secondary Predicate Device(s):**	Prophecy Surgical Planning – 3D Planner 2.0.0 (K241999), Prophecy Surgical Planning – Footprint™ (K202815), Incompass Total Ankle System (K250037)

(a)(5). Device Description

The Prophecy Surgical Planning System consists 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® 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. This includes the optional appendix Footprint™.

- Prophecy® Surgical Planning with 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.

(a)(6). Indications for Use

The subject device's indications for use are identical to the predicate device (K241999) with the exception that Incompass™ has been added to the scope.

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®, Invision® and Incompass™ 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)(7). Technological Characteristics Comparison

The Prophecy® Surgical Planning System is identical to the predicate system (K241999) with the exception of being updated to be compatible with the Incompass Total Ankle System (K250037). The subject system is a line extension to the Prophecy® Surgical Planning System which includes new patient-specific guides and updated software. The subject Prophecy® Incompass guides are nearly identical in design to the predicate Prophecy® Infinity guides (K131283) with the exception of Incompass instrument compatibility and a new Anterior Tibia Spacer guide. The updated Prophecy® 3D Planner software is identical to the predicate (K241999) but expands the scope to include Incompass compatibility. Key technological characteristics and indications for use remain the same between subject and predicate devices. The Prophecy® guide design workflow and Footprint™ are identical to predicate submissions.

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 demonstrates the safety and effectiveness of the Prophecy® Incompass™ Surgical Planning System.

The following non-clinical testing was performed on Prophecy Surgical Planning to demonstrate substantial equivalence to the predicate device: software verification and validation, hardware functionality verification and validation, usability, and cybersecurity.

(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 is substantially equivalent.