June 20, 2025

Wright Medical Technology, Inc. (Stryker)
Antonio Ayala
Senior Staff Specialist, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

Re: K250037
Trade/Device Name: Incompass Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: May 20, 2025
Received: May 20, 2025

Dear Antonio Ayala:

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: 2025.06.20 14:17:27 -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

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)*

K250037

Device Name

Incompass Total Ankle System

Indications for Use *(Describe)*

Intended Use:
The Incompass Total Ankle System is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

Indications for Use:
The Incompass Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.
The Incompass Total Ankle is additionally indicated for patients with a failed previous ankle surgery.
CAUTION: In the United States, the ankle prosthesis is intended for cement 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.

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:

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"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."

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510(K) SUMMARY: Incompass™ Total Ankle System

(a)(1).	**Submitted By:**	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
	Date:	June 16, 2025
	Contact Person:	Antonio Ayala Senior Staff Specialist, Regulatory Affairs
	Secondary Contact:	Jonathan DiMotta Senior Staff Specialist, Regulatory Affairs
(a)(2).	**Proprietary Name:**	Incompass™ Total Ankle System
	Common Name:	Total Ankle Prosthesis
	Classification Name and Reference:	21 CFR 888.3110 - Class II - Ankle joint metal/polymer semi-constrained cemented prosthesis
	Device Product Code, Device Panel:	HSN
(a)(3).	**Primary Predicate Device(s):**	The Inbone Total Ankle System, the Infinity Total Ankle System and the Invision Total Ankle Revision System (K193067)
(a)(4).	**Reference Predicate Device(s):**	Infinity Total Ankle System (K191393, K181557, K172633, K140749, K123954), Inbone Total Ankle (K133585, K123059, K110360, K1000886), Topez (Inbone) Total Ankle Replacement (K051023), Agility Total Ankle Prosthesis (K053569), Blueprint Mixed Reality System (K222510), and Perform Humeral System – Stem (K201315)

(a)(5).Device Description

Incompass™ Total Ankle System is a total ankle replacement system consisting of implants and instruments.

Incompass™ Total Ankle System will harmonize the Infinity™ and Inbone™ Total Ankle Systems into one comprehensive system consisting of modular stemmed and low-profile pegged tibial trays, tibial inserts, and talar domes. The harmonized system is facilitated by sharing the same tibial resection geometry between the pegged and the stemmed tibial tray designs.

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(a)(6). Indications for Use

The subject device's indications for use are identical to the predicate device.

- Incompass™ Total Ankle System:
  - **Intended Use:**
    The Incompass™ Total Ankle System is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.
  - **Indications for Use:**
    The Incompass Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.
    The Incompass Total Ankle is additionally indicated for patients with a failed previous ankle surgery.
    CAUTION: In the United States, the ankle prosthesis is intended for cement use only.

(a)(7). Technological Characteristics Comparison

The subject Incompass Total Ankle System is a new system. The subject and predicate indications are identical. There is no change in the fundamental scientific technology shared by both the subject and predicate devices. The subject and predicate implants have similar materials, design features, instrumentation, and performance characteristics.

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 Incompass™ Total Ankle System.

With respect to Incompass implants, non-clinical performance bench testing was performed to demonstrate substantial equivalence to the predicate device in wear, articular stability, lock detail, manufacturing processes, static strength, fatigue strength, fretting, corrosion and MRI safety.

(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.