February 17, 2023

Wright Medical Technology
Anna Bushart
Senior Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K221645
Trade/Device Name: PROstep(TM) MIS 5mm Chamfer Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 6, 2023
Received: February 7, 2023

Dear Anna Bushart:

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221645

Device Name

PROstep™ MIS 5mm Chamfer Screw System

Indications for Use *(Describe)*

The PROstep™ MIS 5mm Chamfer Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Arthrodesis of the first metatarsal cuneiform joint to reposition and stabilize metatarsus primus varus

- Calcaneus/cuboid arthrodesis

- Talar/navicular arthrodesis

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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K221645

510(k) Summary

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 PROstep™ MIS 5mm Chamfer Screw System.

Submitted by:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Contact Person:	Anna Bushart Senior Regulatory Affairs Specialist Phone: 901-605-3318 Fax: 901-867-4190
Date Prepared:	1-June-2022
Proprietary Name:	PROstep™ MIS 5mm Chamfer Screw System
Common Name:	Bone Screw
Regulation Number:	21 CFR 888.3040 – Class II
Product Code – Device Panel:	HWC – Orthopedic
Device Class:	Class II
Primary Predicate:	K162353: PROstep™ MICA™ Screw System
Additional Predicates:	N/A
Reference Device:	K203228: DART-FIRE™ Edge Cannulated Screw System

Description
This Abbreviated, Safety and Performance based 510(k) submission is being supplied to the U.S. FDA to provide authorization to market PROstep™ MIS 5mm Chamfer Screw System.

Indications for Use
The PROstep™ MIS 5mm Chamfer Screw System is indicated for fixation of bone fractures or for bone reconstruction. Examples include:

- Arthrodesis of the first metatarsal cuneiform joint to reposition and stabilize metatarsus primus varus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis

Summary of Technologies

The PROstep™ MIS 5mm Chamfered Screw is designed to facilitate internal fixation for minimally invasive reduction of hallux valgus deformity and subsequent fusion of the first metatarsal cuneiform joint. The subject cannulated screw is made from titanium alloy *(ASTM F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)*) and features multiple lengths. The subject screw is sterile and provided with both sterile and non-sterile instrumentation.

Technological Characteristics Comparison

Compared to the legally marketed primary predicate, the subject The PROstep™ 5mm chamfered screw has a similar design, indications for use, and performance characteristics. The system features the same principles of operation for bone fixation and sterilization method as the predicate system. The subject and predicate are manufactured from the same titanium alloy (ASTM F136) and share similar features such as being fully threaded, self-tapping on both the distal and proximal threads, and availability with a 30° chamfered head. The subject system adds size with longer lengths when compared to the predicate to further accommodate varying patient anatomy.

Non-Clinical Testing

- Mechanical testing was conducted according to ASTM F543 and the related FDA-published Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway
- Pyrogenicity testing was conducted using the bacterial endotoxins test on the subject device per ANSI/AAMI ST 72.
- Engineering analysis was provided to evaluate MR compatibility of the subject device per ASTM F2182 (RF Heating), ASTM F2062 ()/ASTM F2213 (Induced Force /Induced Torque), and ASTM F2119 (Image Artifact).

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject has the same Indications for Use as the predicate device, and similar technological characteristics to the predicate device. Therefore, the information provided in this submission demonstrates substantial equivalence of the subject device to the predicate device.