August 13, 2019

Wright Medical Technology, Inc.
Michael Mullins
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K190970
Trade/Device Name: PROSTEP TBI System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 11, 2019
Received: July 12, 2019

Dear Michael Mullins:

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, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190970

Device Name
PROSTEP™ TBI™ (Tailors Bunion Implant) System

Indications for Use *(Describe)*
The PROSTEP™ TBI™ (Tailor's Bunion Implant) system is indicated for the fixation of 5th metatarsal osteotomies made in the correction of Tailor's Bunion.

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

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™ TBI™ (Tailors Bunion Implant) System.

(a)(1) **MANUFACTURER IDENTIFICATION**

Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	July 11, 2019
Contact Person:	Michael Mullins Regulatory Affairs Specialist II Office: (901) 867-4142 Fax: (901) 867-4190

(a)(2) **SUBJECT DEVICE INFORMATION**

Proprietary Name:	PROSTEP™ TBI™ (Tailors Bunion Implant) System
Common Name:	Plate, Fixation, Bone / Screw, Fixation, Bone
Classification Name & Reference:	21 CFR 888.3030 / 21 CFR 888.3040 – Class II
Device Product Code & Panel:	HRS / HWC – Orthopedic

(a)(3) **PREDICATE DEVICE INFORMATION**

Wright Compression Screw System (*primary*)	K082320
WMT Implantable K-Wires (secondary)	K132895
ORTHOLOC® 3Di Small Bones Plating System (*secondary*)	K163039

(a)(4) **DEVICE DESCRIPTON**

The PROSTEP™ TBI™ (Tailors Bunion Implant) System is intended for use in bone reconstruction and osteotomy of the fifth metatarsal. The implants are provided sterile and consist of one MIS Bunion implant and one ORTHOLOC 3Di screw. Based on patient anatomy and surgeon's needs, different component sizes can be selected.

(a)(5) **INTENDED USE**

The PROSTEP™ TBI™ (Tailor's Bunion Implant) system is indicated for the fixation of 5th metatarsal osteotomies made in the correction of Tailor's Bunion.

(a)(6) **TECHNOLOGICAL CHARACTERISTICS COMPARISON**

The subject device is a construct that uses cleared components and a new component to address first metatarsal hallux valgus. The subject devices intended use/indications for use is contained within the predicate. **Table 1** below shows a comparison of technological characteristics. The principles of operation of the subject uses screw and intramedullary fixation where the predicate uses screw fixation. The subject and predicate have same materials and use similar internal fixation methods. Both subject and predicate use screws to achieve fixation in fifth metatarsal osteotomies.

Table 1 Subject vs Predicate Technological Comparison

<table>
<tr><th></th><th>SUBJECT</th><th>PREDICATE (primary)</th></tr>
<tr><td></td><td>Tailor's Bunion System</td><td>Wright Compression Screws – K082320</td></tr>
<tr><td>Material</td><td>ASTM F136 (Titanium Alloy)</td><td>ASTM F136 (Titanium Alloy)</td></tr>
<tr><td rowspan="2">Implant</td><td>Tailor's Bunion: Small, Medium, Large</td><td rowspan="2">Diameter: 2.0mm
Length: 10-24mm</td></tr>
<tr><td>ORTHOLOC 3Di Screw (K163039-reference predicate):
Diameter: 2.4 mm
Length: 12mm</td></tr>
</table>

(b)(1) **SUBSTANTIAL EQUIVALENCE – NON-CLINICAL EVIDENCE**

The subject was evaluated to the predicate through construct fatigue testing to support the safety and effectiveness of the subject device system. Additionally, bacterial endotoxin testing was done on a representative part.

(b)(2) **SUBSTANTIAL EQUIVALENCE – CLINICAL EVIDENCE**
N/A

(b)(3) **SUBSTANTIAL EQUIVALENCE – CONCLUSIONS**

The design characteristics of the subject device do not raise any new types of questions of safety or effectiveness and testing shows no new worst case. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate and are substantially equivalent.