DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 21, 2014

Wright Medical Technology, Inc.
Ms. Jeanine Redden
Director, Regulatory Affairs
1023 Cherry Road
Memphis, Tennessee 38117

Re: K142121
Trade/Device Name: ORTHOLOC® Calcaneal Plating 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
Dated: July 31, 2014
Received: August 4, 2014

Dear Ms. Jeanine Redden:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142121

Device Name
ORTHOLOC® Calcaneal Plating System

Indications for Use *(Describe)*
Wright's ORTHOLOC® Calcaneal Plating System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of bones in the feet and ankles. The system can be used in both adult and pediatric patients.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

WRIGHT
FOCUSED EXCELLENCE

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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 ORTHOLOC® Calcaneal Plating System.

1. Submitted By: Wright Medical Technology, Inc.
1023 Cherry Road
Memphis, TN 38117

Date: August 12, 2014

Contact Person: Jeanine Redden
Director, Regulatory Affairs
Phone: 901.867.4255
Fax: 901.687.4190

2. Proprietary Name: ORTHOLOC® Calcaneal Plating System

Common Name: Plate, Fixation, Bone

Classification Name and Reference: 21 CFR 888.3030- Class II, Single/multiple component metallic bone fixation appliances and accessories

Device Product Code, Device Panel: HRS - Orthopedic

3. Predicate Device: K061808 DARCO® Locking Bone Plate System
K091243 ORTHOLOC® Ankle Plating System

4. Device Description

The ORTHOLOC® Calcaneal Plating System consists of 2 styles of plates (Tab and Perimeter) and features 3.5mm diameter locking and non-locking screws that range from 10-60mm each. The Tab plates are offered in three different sizes: small, medium, and large, and feature multiple tabs that can be manipulated or cut to accommodate for various patient anatomy. The Perimeter plates come in two sizes: small and large and also feature removable sections. The ORTHOLOC® hole design on the plates allow for the screws to be inserted from either side. This allows each plate to be used in either a right or a left orientation.

5. Intended Use

Wright's ORTHOLOC® Calcaneal Plating System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of bones in the feet and ankles. The system can be used in both adult and pediatric patients.

6. Technological Characteristics Comparison

The ORTHOLOC® Calcaneal Plating System compared the legally marketed predicate device has limited indications, utilizes similar instrumentation, is made of stronger material, and has identical sterilization methods.

7. Substantial Equivalence- Non-Clinical Evidence

Mechanical testing, including Static Bend Testing and Screw through Plate testing, has shown that the performance of the subject plating system is statistically equivalent or greater than the predicate plating system.

8. Substantial Equivalence- Clinical Evidence

N/A

9. Substantial Equivalence- Conclusions

The design characteristics of the subject devices do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.