



Food and Drug Administration
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April 24, 2017

Wright Medical Technology, Inc.
Ms. Rachel Roberts
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, Tennessee 38117

Re: K163650

Trade/Device Name: ORTHOLOC® 3Di Ankle Fusion Plating System Line Extension
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: March 16, 2017
Received: March 20, 2017

Dear Ms. Roberts:

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" (21 CFR 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,

Mark N. Melkerson -S

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)

K163650

Device Name

ORTHOLOC® 3Di Ankle Fusion Plating System Line Extension

Indications for Use (Describe)

The ORTHOLOC® 3Di Ankle Fusion Plating System is intended to facilitate arthrodesis of the ankle including tibiototalcalcaneal and tibiotalar joints and tibiocalcaneal arthrodesis, in conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.

ORTHOLOC® Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

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)

K163650
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 ORTHOLOC® 3Di Ankle Fusion Plating System – Line Extension.

(a)(1). Submitted By:	Wright Medical Technology, Inc. 1023 Cherry Road Memphis, TN 38117
Date:	March 17, 2017
Contact Person:	Rachel Roberts Regulatory Affairs Specialist Office - (901) 867-9708 Fax – (901) 867-4190
(a)(2). Proprietary Name:	ORTHOLOC® 3Di Ankle Fusion Plating System – Line Extension
Common Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification Name and Reference:	21 CFR 888.3030 – Class II 21 CFR 888.3040 – Class II
Device Product Code, Device Panel:	HRS – Orthopedic HWC – Orthopedic
(a)(3). Predicate Device:	K121425: ORTHOLOC® 3Di Ankle Fusion Plating System

(a)(4). Device Description

The subject Universal Anterior Plate is designed to facilitate arthrodesis of the ankle and is composed of titanium alloy. The plate features poly-axial locking screw holes and one compression slot. It accepts screws of multiple diameters and lengths.

K163650

(a)(5). INTENDED USE

The ORTHOLOC® 3Di Ankle Fusion Plating System is intended to facilitate arthrodesis of the ankle including tibiototalcalcaneal and tibiotalar joints and tibiocalcaneal arthrodesis, in conjunction with osteotomies and fractures of the distal tibia, talus, and calcaneus.

ORTHOLOC® Bone Screws are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation, appropriate for the size of the device.

(a)(6). Technological Characteristics Comparison

The subject ORTHOLOC 3Di Universal Anterior Plate is substantially equivalent to the predicate devices in materials and design. The plate incorporated the predicate 3Di locking technology with an additional size of screws which allow for low profile fixation in the talus.

(b)(1). Substantial Equivalence – Non-Clinical Evidence

Finite element analysis and cross-sectional analysis demonstrated substantial equivalence. Through this testing it was determined that the addition of the Universal Anterior Plate is substantially equivalent in bending strength to the predicate and does not introduce a new worse case into the system.

(b)(2). Substantial Equivalence – Clinical Evidence

N/A

(b)(3). Substantial Equivalence – Conclusions

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