DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Janaury 26, 2017

Wright Medical Technology, Inc.
Val Myles
Regulatory Affairs Specialist
1023 Cherry Road
Memphis, TN 38117

Re: K163044
Trade/Device Name: ORTHOLOC® 3Di Ankle Fracture 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: October 21, 2016
Received: October 31, 2016

Dear Ms. Val Myles:

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)*
K163044

Device Name
ORTHOLOC® 3Di Ankle Fracture Plating System

Indications for Use *(Describe)*
Wright's ORTHOLOC® 3Di Ankle Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

ORTHOLOC® 3Di Locking Screws are intended for use with Wright's ORTHOLOC® 3Di Plating Systems of the same base material.

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.

Wright's washers are intended to prevent a screw head from breaking through the cortex of the bone by distributing the forces/load over a large area when used for fracture fixation of bone fragments.

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)*

Headquarters
Wright Medical Technology, Inc.

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K163044

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 Fracture Plating System.

(a)(1). Submitted By: Wright Medical Technology, Inc.

1023 Cherry Road
Memphis, TN 38117

Date: October 21, 2016

Contact Person: Val Myles
Regulatory Affairs Specialist
Office - (901) 290-5162
Fax – (901) 867-4190

(a)(2). Proprietary Name: ORTHOLOC® 3Di Ankle Fracture Plating System

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:

ORTHOLOC® 3Di Ankle Fracture:	K131093
	K102429
Synthes LCP Distal Fibula Plates:	K073460
Synthes Small Fragment DCL:	K000684

(a)(4). Device Description

The ORTHOLOC® 3Di Ankle Plating System consists of plates belonging to 1 of 2 general categories--distal tibia and fibula-based on the contouring of each plate. All plates feature poly-axial locking screw holes while some plates feature compression slots. The plates are made from titanium alloy and are compatible with 2.7mm and 3.5mm ORTHOLOC® 3Di locking screws, 3.5mm and 4.0mm ORTHOLOC® Bone Screws, and 4.0mm Wright Compression Screws.

(a)(5). INTENDED USE

Wright's ORTHOLOC® 3Di Ankle Fracture Plating System is intended for fixation of fractures, osteotomies, and non-unions of the distal tibia and fibula such as:

- Lateral Malleolar Fractures
- Syndesmosis Injuries
- Medial Malleolar Fractures
- Bi-Malleolar Fractures
- Tri-Malleolar Fractures
- Posterior Malleolar Fractures
- Distal Anterior Tibia Fractures
- Vertical Shear Fractures of the Medial Malleolus
- Pilon Fractures
- Distal Tibia Shaft Fractures
- Distal Fibula Shaft Fractures
- Distal Tibia Periarticular Fractures
- Medial Malleolar Avulsion Fractures
- Lateral Malleolar Avulsion Fractures

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(a)(6). Technological Characteristics Comparison

The subject devices included in ORTHOLOC® 3Di Ankle Fracture Plating System are technologically substantially equivalent to predicate devices in material, size, and bending strength.

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

Performance testing, engineering analysis and rationale was performed to demonstrate substantial equivalence in static and fatigue bending strength. An engineering analysis was performed for the subject device screws to demonstrate substantial equivalence with respect to insertion/removal torque, pull-out strength and torsional strength, and bending strength.

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

N/A

(b)(3). Substantial Equivalence – Conclusions

The design characteristics of the subject system 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 devices.