



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

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

December 11, 2015

Re: K152974

Trade/Device Name: ORTHOLOC® 3Di Foot Plating Reconstruction 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: September 26, 2015  
Received: October 13, 2015

Dear 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 yours,

**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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement on last page.

## Indications for Use

510(k) Number (if known)

K152974

Device Name

ORTHOLOC® 3Di Foot Plating Reconstruction System

Indications for Use (Describe)

The ORTHOLOC® 3Di Foot Plating Reconstruction System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. Specific examples include:

Mid / Hindfoot Fusions

- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

First metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic osteotomy
- Proximal Chevron osteotomy
- Distal Chevron osteotomy (Austin)

First metatarsal fracture fixation

Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion)

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux rigidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot Osteotomies

- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)

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)

**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 Foot Plating Reconstruction System – Line Extension.

- (a)(1). Submitted By:** Wright Medical Technology, Inc.  
1023 Cherry Road  
Memphis, TN 38117
- Date:** October 2, 2015
- Contact Person:** Val Myles  
Regulatory Affairs Specialist  
Office - (901) 290-5162  
Fax – (901) 867-4190
- (a)(2). Proprietary Name:** ORTHOLOC® 3Di Foot Plating Reconstruction System – Line Extension
- Common Name:** Plate, Fixation, Bone
- Classification Name and Reference:** 21 CFR 888.3030 – Class II
- Device Product Code, Device Panel:** HRS – Orthopedic
- (a)(3). Predicate Device:** K151442: TOTAL COMPRESSION PLATING SYSTEM  
K132594: CrossCHECK Plating System  
K120359: ORTHOLOC® 3Di Hallux System  
K121651: ORTHOLOC® 3Di Midfoot/Flatfoot System
- (a)(4). Device Description**  
The ORTHOLOC® 3Di Foot Reconstruction System Line Extension (ORTHOLOC® 3Di CrossCHECK Module) is comprised of a variety of titanium plates with shapes and sizes designed for internal fixation of small bone fragments. The implants included in this system are designed to provide highly anatomic and versatile plating options for an array of fusions and stabilizations. The plates include straight, right, and left configurations, as well as locking and non-locking screws.

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

The ORTHOLOC® 3Di Foot Reconstruction System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. Specific examples include:

Mid / Hindfoot Fusions

- LisFranc Arthrodesis and/or Stabilization
- 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
- Intercuneiform Fusions
- Navicular-Cuneiform (NC) Fusion
- Talo-Navicular (TN) Fusion
- Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

First metatarsal osteotomies for hallux valgus correction including:

- Opening base wedge osteotomy
- Closing base wedge osteotomy
- Crescentic osteotomy
- Proximal Chevron osteotomy
- Distal Chevron osteotomy (Austin)

First metatarsal fracture fixation

Arthrodesis of the first metatarsalcuneiform joint (Lapidus Fusion) Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux rigidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

Flatfoot Osteotomies

- Lateral Column Lengthening (Evans Osteotomy)
- Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)

**(a)(6). Technological Characteristics Comparison**

The subject devices included in ORTHOLOC® 3Di Foot Reconstruction System Line Extension are technologically substantially equivalent to predicate devices in material, size, and bending strength.

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

Performance testing and analysis demonstrated substantial equivalence in static bending.

**(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 as well as the predicate devices.