



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

October 31, 2016

The Orthomedix Group, Inc.
% J.D. Webb
Official Correspondent
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K161448
Trade/Device Name: Footmotion 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, HWC
Dated: September 16, 2016
Received: September 20, 2016

Dear J.D. Webb:

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,

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

Form Approved: OMB No. 0910-0120

Expiration Date: December 31, 2013

See PRA Statement on last page.

Indications for Use

510(k) Number (if known)

K161448

Device Name

Footmotion Plating System

Indications for Use (Describe)

The Footmotion Plating System is intended for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

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 for the Footmotion Plating System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) summary is submitted for the Footmotion Plating System.

Summary preparation date: October 18, 2016

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|---|---|
| 1. Submitter: | Contact Person: |
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Telephone: (33) 2 28 21 37 12 | J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199 |
| 2. Trade name: | Footmotion Plating System |
| Common Name: | Plates for foot fractures, osteotomies and arthrodeses
Screws associated
Instrumentation associated |
| Product code: | HRS - Plate, Fixation, Bone
HWC - Screw, Fixation, Bone |
| Classification Name: | Single/multiple component metallic bone fixation appliances and accessories.
(21 CFR part. 888.3030)
Smooth or threaded metallic bone fixation fastener.(21 CFR part. 888.3040) |



NEW CLIP-TECHNICS

3. Primary predicate or legally marketed devices which are substantially equivalent:

- The Anchorage® Bone Plate System of Memometal (K083447),

4. Secondary predicate or legally marketed devices which are substantially equivalent:

- The Ortholoc® 3Di Midfoot/Flatfoot System of Wright Medical Technology (K121651),
- The Plantar Lapidus Plate System 2.7/3.5 of Normed (K152256).

- 5. Description of the device:** The Footmotion Plating System consists of a plate with as many screws as holes (slots) designed for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults. The plates and screws are manufactured from titanium alloy and color anodized.

The Footmotion Plating System will be provided non sterile for sterilization by health care professionals prior to use or provided sterile by gamma sterilization.

Materials: Titanium alloy Ti-6Al-4V ELI (conforms to ASTM F 136-13 and/or ISO 5832-3).

Function: The implants of the Footmotion Plating System are indicated for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.



NEWCLIP-TECHNICS

6. Substantial equivalence claimed to predicate devices:

The Footmotion Plating System is substantially equivalent to the Anchorage® Bone Plate System of Memometal (K083447), the Ortholoc® 3Di Midfoot/Flatfoot System of Wright Medical Technology (K121651) and the Plantar Lapidus Plate System 2.7/3.5 of Normed (K152256) in terms of intended use, design, materials used, mechanical safety and performance.

7. Intended use:

The Footmotion Plating System is indicated for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

8. Non-clinical Test Summary:

The following tests were conducted:

- Comparative fatigue compression tests. (ASTM F382)
- Comparative static tests. (ASTM F382)
- Torsional tests. (ASTM F543)
- Engineering analysis.
- Endotoxin testing is performed using the LAL quantitative kinetic chromogenic method. Testing is performed on worst case representatives from the company's products. The testing demonstrated that the subject devices meet the recommended maximum endotoxin level of 20 EU per device.
- Since water used in the cleaning steps is a possible source of endotoxin, testing is performed on the water and includes bioburden, TOC, THC, and LAL. The maximum limit for endotoxin level is established at 0.25 EU/mL and has never been reached.

9. Clinical Test Summary:

No clinical studies were performed.

10. Conclusions Non-clinical and Clinical:

The Footmotion Plating System is substantially equivalent to the predicate devices in terms of indications for use, design, material, and function.