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

January 26, 2015

NEWCLIP TECHNICS
% Mr. J.D. Webb
Official Correspondent
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K143061
Trade/Device Name: Activ Ankle Locking Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: October 22, 2014
Received: October 24, 2014

Dear Mr. 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" (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,

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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K143061

Device Name
Activ Ankle Locking Plating System

Indications for Use *(Describe)*

The Activ Ankle Locking Plating System is intended for the fixation of fractures, osteotomies and pseudarthrosis of the distal and the diaphyseal fibula and for syndesmotic repair 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)*

4. 510 (k) Summary for the Activ Ankle Locking Plating System

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

Summary preparation date: January 26, 2015

1. Submitter:	**Contact Person:**
NEWCLIP TECHNICS	J.D. Webb
P.A. de la Lande Saint Martin	The OrthoMedix Group, Inc.
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F-44115 Haute-Goulaine - France	Round Rock, TX 78681
Telephone: (33) 2 28 21 37 12	Telephone: 512-388-0199

2. Trade name:	Activ Ankle Locking Plating System
Common Name:	Plates for fibula fractures, osteotomies and pseudarthrosis Screws and washers associated Instrumentation associated
Product code:	HRS/HWC
Classification Name:	Plate, Fixation, Bone (21 CFR part. 888.3030) Screw, Fixation, Bone (21 CFR part. 888.3040)

3. Predicate or legally marketed devices which are substantially equivalent:

- The Synthes Small Fragment Dynamic Compression Locking (DCL) System of Synthes (K000684),
- The Synthes 2.7mm/3.5mm LCP Distal Fibula Plates of Synthes (K073460),
- The Ortholoc® 3Di Ankle Plating System of Wright Medical Technology, Inc. (K131093),
- The Synthes Variable Angle LCP Ankle Trauma System (K120854).

4. Description of the device:

The Activ Ankle Locking Plating System consists of a plate with many screws as holes (slots) designed for fixation of fractures, osteotomies and pseudarthrosis of the distal and diaphyseal fibula and for the syndesmotic repair in adults. The plates and screws are manufactured from titanium alloy and color anodized. Washers are also available for use with syndesmosis screws.

The Activ Ankle Locking 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 (conform to ASTM F 136-12a and/or ISO 5832-3).

Function: The implants of the Activ Ankle Locking Plating System are indicated for fixation of fractures, osteotomies and pseudarthrosis of the distal and the diaphyseal fibula in adults.

5. Substantial equivalence claimed to predicate devices:

The Activ Ankle Locking Plating System is substantially equivalent to the Synthes Small Fragment Dynamic Compression Locking (DCL) System of Synthes (K000684), the Ortholoc® 3Di Ankle Plating System from Wright Medical Technology, Inc. (K131093), the Synthes 2.7mm/3.5mm LCP Distal Fibula Plates of Synthes (K073460), and The Synthes Variable Angle LCP Ankle Trauma System (K120854) in terms of intended use, design, materials used, mechanical safety and performance.

6. Intended use:

The Activ Ankle Locking Plating System is indicated for fixation of fractures, osteotomies and pseudarthrosis of the distal and diaphyseal fibula and for the syndesmotic repair in adults.

7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative fatigue compression tests.
- Comparative static tests.
- Geometric analysis of the subject and predicate screws

8. Clinical Test Summary:

No clinical studies were performed.

9. Conclusions Non-clinical and Clinical:

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