January 16, 2018

Newclip Technics
% J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K173641
Trade/Device Name: Activ Ankle
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: November 17, 2017
Received: November 24, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -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

Indications for Use

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

510(k) Number *(if known)*

K173641

Device Name

Activ Ankle

Indications for Use *(Describe)*

The Activ Ankle range is intended for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

NEWCLIP-TECHNICS

4. 510 (k) Summary for the ACTIV ANKLE range

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

Summary preparation date: October 25, 2017

1. Submitter:

NEWCLIP TECHNICS
P.A. de la Lande Saint Martin
45 rue des Garottières
F-44115 Haute-Goulaine - France
Telephone: (33) 2 28 21 37 12

Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681

Telephone: 512-388-0199

2. Trade name: Activ Ankle

Common Name: Plate, Fixation, Bone / Screw, Fixation, bone

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)

NEWCLIP-TECHNICS

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

- Activ Ankle Locking Plating System of Newclip Technics (K143061)

Secondary predicate or legally marketed devices which are substantially equivalent:

- Ortholoc® 3Di Ankle Fracture System of Wright Medical Technology (K131093)
- Small Fragment Set 3.5 of AAP Implantate AG (K113652)
- Alians Elbow Locking Plating System (K152289)
- Large Screws of Newclip Technics (K172596)

4. Description of the device:

The Activ Ankle range consists of plates with screws designed for fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

Washers are also available for use with screws.

The implants of the Activ Ankle range will be provided non sterile for sterilization by health care professionals prior to use or provided sterile by gamma sterilization.
The instruments of the Activ Ankle range will be provided non sterile for sterilization by health care professionals prior to use.

Single use kits (Initial A) contain implants and instruments, or instruments only provided sterile by gamma sterilization.

Materials:

Titanium alloy Ti-6Al-4V ELI (conform to ASTM F 136 and ISO 5832-3).

Function:

The implants of Activ Ankle range are intended for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

NEWCLIP-TECHNICS

5. Substantial equivalence claimed to predicate devices:

The Activ Ankle range is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performance.

6. Intended use:

The Activ Ankle range is indicated for the fixation of fractures, osteotomies and pseudarthroses of the distal and the diaphyseal fibula, the distal tibia and for the syndesmotic repair in adults.

7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative static bend test. (ASTM F382)
- Comparative fatigue bend test. (ASTM F382)
- Endotoxins testing is performed using LAL quantitative kinetic chromogenic method.

8. Clinical Test Summary:

No clinical studies were performed.

9. Conclusions Non-clinical and Clinical:

Newclip Technics considers the Activ Ankle range to be equivalent to the predicate devices listed above. This conclusion is based upon the device's similarities in principles of operation, technology, materials, and indications for use.