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

April 24, 2017

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

Re: K170012
Trade/Device Name: Foot and Hand Motion
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 5, 2017
Received: April 6, 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.

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 below.

510(k) Number *(if known)*
K170012

Device Name
Foot and Hand Motion

Indications for Use *(Describe)*
The implants of the Foot and Hand Motion are intended for the fixation of bone fractures and osteotomies, and for arthrodeses of the foot and hand 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.

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4. 510 (k) Summary for the FOOT AND HAND MOTION

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) Summary is submitted for the Foot and Hand Motion.

Summary preparation date: April 14, 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: Foot and Hand Motion

Common Name: Fracture fixation screws

Product code: HWC

Classification Name: Screw, Fixation, Bone
(21 CFR part. 888.3040)

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

- FHM System of Newclip Technics (K091118)

Secondary predicate or legally marketed devices which are substantially equivalent:

- SBI Autofix System of Small Bone Innovations (K052576)
- TwistCut-Snap Off Bone screws of MERETE (K051323)
- Large Screws Range of Newclip Technics (K160617)
- Footmotion Plating System of Newclip Technics (K161448)

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4. Description of the device:

The Foot and Hand Motion consists of screws designed for the fixation of bone fractures, for arthrodeses and for osteotomies of foot and hand in adults.

The implants of the Foot and Hand Motion will be provided non sterile for sterilization by health care professionals prior to use or provided sterile by gamma sterilization.
The instruments of the Foot and Hand Motion will be provided non sterile for sterilization by health care professionals prior to use or provided sterile by gamma sterilization (Initial S single use kits).

Materials:

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

Function:

The implants of Foot and Hand Motion are indicated for the fixation of bone fractures, for arthrodeses and for osteotomies of foot and hand in adults.

5. Substantial equivalence claimed to predicate devices:

The Foot and Hand Motion is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performance.

6. Indications for Use:

The implants of the Foot and Hand Motion are intended for the fixation of bone fractures and osteotomies, and for arthrodeses of the foot and hand in adults.

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7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative pullout tests.
- Torsional tests.
- Driving torque tests.
- Engineering analyses
- 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 considers the Foot and Hand Motion 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.