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

June 3, 2016

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

Re: K160617
Trade/Device Name: Large Screws Range
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 1, 2016
Received: April 4, 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,

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)*
K160617

Device Name

LARGE SCREWS range

Indications for Use *(Describe)*

The Large Screws range is intended for the fixation of bone fractures, pseudarthroses, fusions and osteotomies of foot and ankle as well as medium and large bone fragments including radius, humerus, femur, tibia 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)*

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4. 510 (k) Summary for the Large Screws range

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

Summary preparation date: April 13, 2015

1. Submitter:

NEWCLIP TECHNICS
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Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. Trade name: Large Screws range

Common Name: Large 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:

- Asnis III Cannulated Screw System of Howmedica Osteonics Corp. (K000080 and K024060)

Secondary predicate or legally marketed devices which are substantially equivalent:

- Qwix fixation screws and Stabilization screw of Newdeal SAS (K071639 and K050346)

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4. Description of the device:

The Large Screws range consists of screws designed for the fixation of bone fractures, pseudarthroses, fusions and osteotomies of foot and ankle as well as medium and large bone fragments including radius, humerus, femur, tibia in adults.

The Large Screws range 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 Large Screws range are indicated for the fixation of bone fractures, pseudarthroses, fusions and osteotomies of foot and ankle as well as medium and large bone fragments including radius, humerus, femur, tibia in adults.

5. Substantial equivalence claimed to predicate devices:

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

The technological characteristics of the Large Screws are the same as the characteristics of predicate devices in terms of intended use and design. All of these screws have the following characteristics:

- Self-tapping
- Cannulated
- Available in titanium alloy
- Partially or totally threaded
- Available sterile or non-sterile

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- Equivalent size ranges
- Equivalent diameters ranges

6. Indications for use:

The Large Screws range is indicated for the fixation of bone fractures, pseudarthroses, fusions and osteotomies of foot and ankle as well as medium and large bone fragments including radius, humerus, femur, tibia in adults.

7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative torsional tests.
- Comparative pullout engineering analysis.
- Driving torque tests.

8. Clinical Test Summary:

No clinical studies were performed.

9. Conclusions Non-clinical and Clinical:

Newclip Technics considers the Large Screws 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.