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

March 30, 2017

NEWCLIP TECHNICS
Mr. J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd.
Round Rock, Texas 78681

Re: K170310
Trade/Device Name: Alians Clavicle range
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: January 26, 2017
Received: February 1, 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)*

K170310

Device Name

Alians Clavicle range

Indications for Use *(Describe)*

The implants of the Alians Clavicle range are dedicated to the fixation of fractures, mal-unions, non-unions and osteotomies of the clavicle 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 ALIANS CLAVICLE range

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) Summary is submitted for the Alians Clavicle range.

Summary preparation date: January 24, 2017

1. Submitter:

NEWCLIP TECHNICS
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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: Alians Clavicle range

Common Name: Fracture fixation plates and screws

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)

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3. Primary predicate:

- Clavicle Locking Plating System of Newclip Technics (K100944)

Additional predicate:

- Congruent Bone Plate System of Acumed (K102998)

Reference Device:

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

4. Description of the device:

The Alians Clavicle range consists of plates and screws designed for fixation of fractures, mal-unions, non-unions and osteotomies of the clavicle in adults.

The implants of the Alians Clavicle 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 Alians Clavicle range will be provided non sterile for sterilization by health care professionals prior to use.
Single use kits (Initial C) contain implants and instruments provided sterile by gamma sterilization. The Initial C kits contain implants (1 plate + screws), and instrumentation.

Materials:

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

Function:

The implants of Alians Clavicle range are indicated for fixation of fractures, mal-unions, non-unions and osteotomies of the clavicle in adults.

5. Substantial equivalence claimed to predicate devices:

The Alians Clavicle range 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 Alians Clavicle range are dedicated to the fixation of fractures, mal-unions, non-unions and osteotomies of the clavicle in adults.

7. Non-clinical Test Summary:

- Engineering analyses have been conducted in comparison with Clavicle Locking Plating System of Newclip Technics (K100944).
- LAL testing was performed to demonstrate that the subject device meets the endotoxin limit of <20 EU/device.

The analyses show that the Alians Clavicle range is as strong or stronger than the predicate.

8. Clinical Test Summary:

No clinical studies were performed.

9. Conclusions Non-clinical and Clinical:

Newclip considers the Alians Clavicle 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.