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

June 16, 2017

Newclip Technics
% Mr. J.D. Webb
Official Correspondent
The OrthoMedix Group, Incorporated
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K170843
Trade/Device Name: Alians Fragment Specific
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: March 17, 2017
Received: March 21, 2017

Dear Mr. 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,

Vincent J. Devlin -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)*

K170843

Device Name

Alians Fragment Specific

Indications for Use *(Describe)*

The Alians Fragment Specific range is intended for hand and forearm fractures, osteotomies and arthrodeses 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.

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4. 510 (k) Summary for the ALIANS FRAGMENT SPECIFIC range

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

Summary preparation date: January 10, 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: Alians Fragment Specific

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)

NEWCLIP-TECHNICS

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

- APTUS® Wrist 2.5 System of Medartis (K142906)

Secondary predicate or legally marketed devices which are substantially equivalent:

- Trimed Bone Plates of Trimed (K060041)
- 2.4mm VA-LCP Dorsal Distal Radius Plates of Synthes (K102694),
- Universal Distal Radius System of Newclip Technics (K130774).
- Footmotion Plating System of Newclip (K161448)
- Activ Ankle Locking Plating System of Newclip (K143061)

4. Description of the device:

The Alians Fragment Specific range consists of plates and screws designed for hand and forearm fractures, osteotomies and arthrodeses in adults.

The implants of the Alians Fragment Specific 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 Fragment Specific range will be provided non sterile for sterilization by health care professionals prior to use.
Single use kits (Initial FS) contain implants and instruments provided sterile by gamma sterilization.

Materials:

Titanium alloy Ti-6Al-4V (conform to ASTM F136 and ISO 5832-3).
CP-titanium (conform to ASTM F67 and ISO 5832-2).
Stainless steel and other instrument materials

Function:

The implants of Alians Fragment Specific range are indicated for hand and forearm fractures, osteotomies and arthrodeses in adults.

5. Substantial equivalence claimed to predicate devices:

The Alians Fragment Specific 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 Alians Fragment Specific range is intended for hand and forearm fractures, osteotomies and arthrodeses in adults.

7. Non-clinical Test Summary:

The following tests were conducted:

- Comparative static bend test. (ASTM F382)
- Comparative fatigue bend test. (ASTM F382)
- Torsional test (ASTM F543)
- Insertion and removal test (ASTM F543)
- Pull-out tests. (ASTM F543)
- Endotoxins testing was 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 Alians Fragment Specific 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.