December 16, 2021

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

Re: K202803
Trade/Device Name: Activmotion S DTO
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 9, 2021
Received: November 15, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202803

Device Name
Activmotion S DTO

Indications for Use *(Describe)*
The implants of the Activmotion S DTO range are intended for bone reconstruction of the ankle joint in adults, including fixation of fractures and osteotomies of ankle, distal tibia and fibula.

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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K202803

510 (k) Summary for the Activmotion S DTO range

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

Summary preparation date: December 13, 2021

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: Activmotion S DTO

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) (Primary)
Smooth or threaded metallic bone fixation fastener.(21 CFR part. 888.3040)

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

- TIBIAXYS System by NEWDEAL (Integra Lifesciences) (K073375)

Secondary predicate or legally marketed devices which are substantially equivalent:

- LOQTEQ Small Fragment set by AAP IMPLANTATE AG (K113652)

Reference device:

- Activ ankle (K143061, K173641) of Newclip Technics.

4. Description of the device: The Activmotion S DTO range consists of plates and screws designed for bone reconstruction of the ankle joint in adults, including fixation of fractures and osteotomies of ankle, distal tibia and fibula.

The Activmotion S DTO range will be provided sterile by gamma sterilization or non-sterile for sterilization by health care professionals prior to use.

Materials: CP Titanium (conform to ASTM F67 and ISO 5832-2) and Titanium alloy Ti-6Al-4V ELI (conform to ASTM F136 and ISO 5832-3).

Function: The implants of the Activmotion S DTO range are intended for bone reconstruction of the ankle joint in adults, including fixation of fractures and osteotomies of ankle, distal tibia and fibula.

5. Substantial equivalence claimed to predicate devices:

The Activmotion S DTO 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 Activmotion S DTO range are intended for bone reconstruction of the ankle joint in adults, including fixation of fractures and osteotomies of ankle, distal tibia and fibula.

7. Summary of the technological characteristics compared to predicate

Material
The Activmotion S DTO range uses the same material as the predicate devices.

Design
The Activmotion S DTO range and the predicates are equivalent in terms of shape, material, and operating principles.

Sizes
The Activmotion S DTO range and the predicates are equivalent in their dimensions.

8. Non-clinical Test Summary:

The following tests were conducted:

1. Engineering analysis and comparative 4-point-bending tests in static and dynamic condition were conducted to compare the bending strength of the subject device plates to the predicates. Static and dynamic tests were conducted according to according to ASTM F382.

2. Engineering analysis: torsional, driving torque, and pullout tests according to ASTM F543 were performed on the subject screws.

3. Endotoxin testing is performed using LAL quantitative kinetic chromogenic method.

The analysis showed that the Activmotion S DTO range is as safe and as effective as the predicates.

9. Clinical Test Summary:

No clinical studies were performed.

10. Conclusions Non-clinical and clinical:

Based on the indications for use, technological characteristics, and the summary of data submitted, Newclip Technics determined that the Activmotion S DTO range is equivalent to the predicate devices listed above.