November 17, 2020

Newclip Technics
℅ J.D. Webb
Official Correspondent
The OrthoMedix Group, Inc
4313 West 3800 South
West Haven, Utah 84401

Re: K202307
Trade/Device Name: Activ Fuse
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: August 12, 2020
Received: August 14, 2020

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)*
K202307

Device Name
Activ Fuse

Indications for Use *(Describe)*
The implants of the Activ Fuse range are intended for bone reconstruction of the ankle joint in adults including fractures fixation and arthrodeses of the ankle, distal tibia, talus and calcaneus.

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.

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510 (k) Summary for the Activ Fuse range

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

Summary preparation date: July, 2020

1. Submitter:

NEWCLIP TECHNICS
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Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
4313 West 3800 South
West Haven, UT 84401
Telephone: 512-590-5810

2. Trade name: Activ Fuse

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)

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

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

- Ortholoc 3Di Ankle Fusion Plating System (K121425) of WRIGHT MEDIAL TECHNOLOGY INC.

Additional predicate or legally marketed devices which are substantially equivalent:

- Ortholoc 3Di Ankle Fusion Plating System (K163650) of WRIGHT MEDIAL TECHNOLOGY INC.
- Ankle Fusion Plating System (K141735) of ARTHREX
- Arthrex Minimally Invasive Ankle Fusion Plate (K190953) of ARTHREX

4. Description of the device: The Activ Fuse range consists of plates and screws designed for bone reconstruction of the ankle joint in adults including fractures fixation and arthrodeses of the ankle, distal tibia, talus and calcaneus. The system includes a modular plate design for a lateral calcaneal extension.

The Activ Fuse 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 F136 and ISO 5832-3).

Function: The implants of the Activ Fuse range are intended for bone reconstruction of the ankle joint in adults including fractures fixation and arthrodeses of the ankle, distal tibia, talus and calcaneus.

5. Substantial equivalence claimed to predicate devices:

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

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6. Indications for Use:

The implants of the Activ Fuse range are intended for bone reconstruction of the ankle joint in adults including fractures fixation and arthrodeses of the ankle, distal tibia, talus and calcaneus.

7. Summary of the technological characteristics compared to predicate

The Activ Fuse range's intended use and indications for use are similar to the predicate devices

Material
The Activ Fuse range uses the same material as the predicate devices.

Design
The Activ Fuse range and the predicates differ slightly in their geometry, but are equivalent in terms of material and operating principles. The Activ Fuse plate has a modular plate design for a lateral calcaneal extension that the predicate devices do not have.

Sizes
The Activ Fuse range and the predicates are equivalent in their dimensions.

8. Non-clinical Test Summary:

The following tests were conducted:

- Engineering analysis and comparative static and dynamic tests were performed on the subject and predicate plates.
- Engineering analysis and static and dynamic tests were performed on the lateral extension for the calcaneus.
- Engineering analysis were performed on the screws regarding torsional and pullout strength
- Endotoxin testing is performed using LAL quantitative kinetic chromogenic method.

The analysis showed that the Activ Fuse range is as safe and as effective as the predicates.

9. Clinical Test Summary:

No clinical studies were performed.

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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 Activ Fuse range is equivalent to the predicate devices listed above.