July 1, 2022

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

Re: K221395
Trade/Device Name: Footmotion Plating System
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: May 11, 2022
Received: May 13, 2022

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,

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6A: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221395

Device Name
Footmotion Plating System

Indications for Use *(Describe)*
The implants of the Footmotion Plating System are intended for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

4. 510 (k) Summary for the Footmotion Plating System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following 510(k) summary is submitted for the Footmotion Plating System.

Summary preparation date: April 29, 2022

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.
4313 W. 3800 S.
West Haven. UT 84401
Telephone: 512-590-5810

2. Trade name: Footmotion Plating System

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)

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

- Footmotion Plating System of Newclip Technics (K161448 / K171510)

Additional predicate or legally marketed devices which are substantially equivalent:

- Ortholoc® 3Di Midfoot/Flatfoot System of Wright Medical Technology (K121651),
- DARCO Locking Bone Plate System of Wright Medical Technology (K061808),
- A.L.P.S Calcaneal Plating System of Biomet (K132898),
- Gorilla® Plating System of Paragon28 (K190365),
- ActivAnkle (K143061/K173641) of Newclip Technics.

4. Description of the device: The Footmotion Plating System consists of plates and screws, designed for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

The implants of the Footmotion Plating System will be provided non sterile for sterilization by health care professionals prior to use, or provided sterile by gamma sterilization.

The instruments of the Footmotion Plating System will be provided 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 Footmotion Plating System are intended for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

5. Substantial equivalence claimed to predicate devices:

The Footmotion Plating System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performance.

6. Intended use:

The implants of the Footmotion Plating System are intended for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

7. **Summary of the technological characteristics compared to predicate**

Intended Use
The implants of the Footmotion Plating System are intended for arthrodeses, fractures and osteotomies fixation and revision surgeries of the foot in adults.

Indications for Use
All of the devices comply with the indications for use specified in 21 CFR section 888.3030 for metallic bone fixation devices.

Material
The Footmotion Plating System uses the same material as the predicate devices.

Design
The Footmotion Plating System and the predicates are equivalent in terms of shape, material, and operating principles.

Sizes
The Footmotion Plating System and the predicates are equivalent in their dimensions.

8. Non-clinical Test Summary:

The following tests were conducted:
1. 4-point-bending tests per ASTM F382 were conducted to compare the bending strength of the subject device plates to the predicates.
2. ASTM F543 torsional testing was performed on the subject screws. Equation described by Chapman for axial pull-out strength was performed on the subject screws (FDA-Guidance: Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway-2020).

3. Endotoxin testing is performed using LAL quantitative kinetic chromogenic method.
The analysis showed that the Footmotion Plating System is substantially equivalent to cleared 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 Footmotion Plating System is substantially equivalent to the cleared predicate devices listed above.