August 20, 2021

Extremity Medical, LLC.
Brian Smekal
Sr. VP, QA/RA and Compliance
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

Re: K212297
Trade/Device Name: Omni Foot and Ankle 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: July 21, 2021
Received: July 22, 2021

Dear Brian Smekal:

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, MPH
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212297

Device Name
Omni Foot and Ankle Plating System

Indications for Use *(Describe)*
The Omni Foot and Ankle Plating System is intended for use in internal fixation of arthrodesis, osteotomies, fractures and nonunions of the small bones of the foot & ankle including the fore-, mid-, and hind foot and ankle applications.

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 of Safety and Effectiveness:

Omni Foot and Ankle Plating System

Submitter	Extremity Medical, LLC 300 Interpace Parkway, Suite 410 Parsippany, NJ 07054
Contact Person	Brian Smekal, MS, RAC Sr. VP, Quality Assurance, Regulatory Affairs and Compliance Phone: (973) 588-8988 Email: bsmekal@extremitymedical.com
Date Prepared	July 21, 2021
Trade Name	Omni Foot and Ankle Plating System
Classification Name and Number	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories (Primary) 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener
Product Code	HRS (plate, fixation, bone) (Primary) HWC (screw, fixation, bone)
Primary Predicate	K180808 – Omni Foot Plating System
Additional Predicates	K170780 - ARIX Foot System (2.3/2.8) K163044 - ORTHOLOC® 3Di Ankle Fracture Plating System K181067 – AlignX Ankle Fusion System
Device Description	The Omni Foot and Ankle Plating System is a bone fixation system consisting of unalloyed Titanium plates and Titanium Alloy (Ti-6AL-4V) locking and non-locking plate screws, which meet ASTM F67 and ASTM F136, and a set of instruments used for implant site preparation and delivery. The plates are available in various configurations, essentially differing by the lengths and number of holes. The plate screws are provided in diameters of 2.8mm and 3.5mm in lengths from 8mm to 50mm. The System offers 3.5mm cannulated screws and 4.0mm solid screws in various lengths to be used as adjunctive fixation. The 3.5mm cannulated screw can also be used with a specialized locking screw (“Post”) which contains a locking feature at the distal end for compression/stabilization.
Indications for use	The Omni Foot and Ankle Plating System is intended for use in internal fixation of arthrodeses, osteotomies, fractures and nonunions of the small bones of the foot & ankle including the fore-, mid-, and hind foot and ankle applications.

Statement of Technological Comparison	The Omni Foot and Ankle Plating System and predicate devices are equivalent in terms of design, material, mechanical properties and indications for use. The subject and predicate are based on the following same technological elements: • Implants are used temporarily to generate compression across the joint/bone that is being repaired/reconstructed. • Devices are made of the same material (Unalloyed Titanium per ASTM F67 and Ti-6Al-4V ELI per F136).
Non-clinical Testing	The new geometries of the Omni Foot and Ankle plates were compared to the Omni Foot System plates and ARIX System plates by engineering analysis. The 4.0mm solid screws were compared to the predicate Omni 3.5mm cannulated screws and 4.0mm AlignX solid screws by engineering analysis. The results of this analysis indicate that the Omi Foot and Ankle Plating System is equivalent to predicate devices.
Clinical Testing	No clinical testing was performed.
Conclusion	The Omni Foot and Ankle Plating System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, principles of operation, design, and engineering analysis.