Extremity Medical, LLC.
Brian Smekal
Vice President, Regulatory Affairs and Quality Assurance
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

November 6, 2017

Re: K172260
Trade/Device Name: Omni Foot 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: September 19, 2017
Received: September 20, 2017

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. 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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -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)*

K172260

Device Name
Omni Foot Plating System

Indications for Use *(Describe)*
The Omni Foot Plating System is intended for use in internal fixation, reconstruction, or arthrodesis of the 1st Metatarsalphalangeal joint.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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:

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"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."

510(k) Summary of Safety and Effectiveness:

Omni Foot Plating System

Submitter	Extremity Medical, LLC. 300 Interpace Parkway, Suite 410 Parsippany, NJ 07054
Contact Person	Brian Smekal, MS, RAC VP, Regulatory Affairs and Quality Assurance Phone: (973) 588-8988 Email: bsmekal@extremitymedical.com
Date Prepared	October 13, 2017
Trade Name	Omni Foot Plating System
Common Name	Bone plates and screws
Classification Name and Number	21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories; 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener
Product Code	HRS, HWC
Predicate Devices	K161864 – Arix Foot System (Jeil Medical Corporation) K140397 – ParaLock Plating System (Paragon 28) K121349 – Extremity Medical Screw and Washer System
Device Description	The Omni Foot 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 in various lengths to be used as adjunctive fixation. The 3.5mm cannulated screw can also be used with a specialized locking screw (“Peg”) which contains a locking feature at the distal end for compression/stabilization.
Indications for use	The Omni Foot Plating System is intended for use in internal fixation, reconstruction, or arthrodesis of the 1st Metatarsalphalangeal joint.

Statement of Technological Comparison	**Omni Foot System, Bone Plates:** Based on a technical feature comparison, the subject device was found to be similar to all predicate devices with regard to design and materials. The subject plates also have a polyaxial locking feature, identical to the design used in the predicate device (K161864). **Omni Foot System, Bone Screws:** They are identical in design of the Arix Foot System Screw (K161864). **Omni Foot System, Locking Peg:** The Peg device of the Omni System acts like a locking screw while also acting as a bone washer/nut to help produce compression at the MTP joint much like the crossing screw construct of the predicate screw system IO FiX (K121349). In addition, the 4.2mm diameter of the Peg is equivalent in major diameter to the Paragon 28 ParaLock Plating System (K140397).
Non-clinical Testing	The Omni Foot plates were compared to the Arix Foot System plates (K161864) by engineering analysis. Bench tests including pullout, torque and static bend testing were conducted to verify that the proposed 3.5mm screw and Peg device met all design specifications. The results of this testing indicate that the Omi Foot Plating System is equivalent to predicate device.
Clinical Testing	No clinical testing was performed.
Conclusion	The Omni Foot Plating System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, principles of operation, design, engineering analysis and mechanical testing.