November 21, 2019

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

Re: K192592
Trade/Device Name: Axis 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, HTN
Dated: September 19, 2019
Received: September 20, 2019

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,

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)*
K192592

Device Name
Axis Plating System

Indications for Use *(Describe)*
The Axis Plating System is indicated for stabilization and fixation of fractures or osteotomies, reconstruction procedures, nonunions and fusions of bones in the foot and ankle including the metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus; specific examples include: medial and lateral column fusion resulting from neuropathic osteoarthropathy (Charcot).

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."

510(k) Summary

Axis Plating System

Date Prepared	November 20, 2019
510(k) Number	K192592
Submitter	Extremity Medical, LLC. 300 Interpace Parkway, Suite 410 Parsippany, NJ 07054 Phone: (973) 588-8980
Contact Person	Brian Smekal, MS, RAC VP, Regulatory Affairs and Quality Assurance
Trade Name	Axis Plating System
Regulation, Product Code, Classification, and Common Name	888.3030, HRS, Plate, Fixation, Bone 888.3040, HWC, Screw, Fixation, Bone 888.3030, HTN, Washer, Nut Bolt
Primary Predicate	K190365 – Baby Gorilla/Gorilla Plating System
Reference Devices	K180808 – Omni Foot Plating System K140792 – Salvation 3di Plating System
Device Description	The Axis Plating System is a bone fixation system consisting of Titanium Alloy (Ti-6AL-4V) plates, locking and non-locking plate screws, which meet ASTM F136, and a set of instruments used for implant site preparation and delivery. The plates are available in various configurations, essentially differing by geometry and number of holes. The plate screws are provided in diameters of 3.5mm and 4.5mm in lengths from 8mm to 50mm. The System offers 4.0mm cannulated screws and beams in various lengths to be used as adjunctive fixation. The 4.0mm cannulated screws and beams 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 Axis Plating System is indicated for stabilization and fixation of fractures or osteotomies, reconstruction procedures, nonunions and fusions of bones in the foot and ankle including the metatarsals, cuneiforms, cuboid, navicular, calcaneus and talus; specific examples include: medial and lateral column fusion resulting from neuropathic osteoarthropathy (Charcot).
Statement of Technological Comparison	The Axis Plating System is equivalent to predicate device Baby Gorilla/Gorilla Plating System in terms of indications for use, design, and material mechanical properties. The Axis Plating System is equivalent to the predicate device Omni Foot Plating System in design of the Compression Post, materials, mechanical properties and indications for use. The reference device Salvation 3di Plating System (K140792) is used to further support equivalence in terms of plate screw sizes and indications for use.

Non-clinical Testing	Specific testing performed on the Axis system include:
	• Plate Engineering Analysis
	• Screw Engineering Analysis for:
	  o Pullout
	  o Torsion/bending
	  o Torque to failure

Clinical Testing	No clinical testing was performed.
Conclusion	The Axis Plating System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, principles of operation, design, and mechanical test data.