May 28, 2021

Medical, LLC.
Mary Hoffman
Manager, Quality Assurance and Regulatory Affairs
300 Interpace Parkway, Suite 410
Parsippany, New Jersey 07054

Re: K211261
Trade/Device Name: Axis Charcot Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: April 23, 2021
Received: April 26, 2021

Dear Mary Hoffman:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211261

Device Name
Axis Charcot Fixation System

Indications for Use *(Describe)*
The Axis Charcot Fixation System in diameters of 4.5 to 8.5mm is indicated for reconstruction procedures, non-unions 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.

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Special 510(k) Summary of Safety and Effectiveness:

Axis Charcot Fixation System

Submitter	Extremity Medical, LLC 300 Interpace Parkway, Suite 410 Parsippany, NJ 07054
Contact Person	Mary Hoffman, MS Manager, Quality Assurance and Regulatory Affairs Phone: (973) 588-8980 Email: mhoffman@extremitymedical.com
Date Prepared	May 27, 2021
Trade Name	Axis Charcot Fixation System
Classification Name and Number	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener (Primary) 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
Product Code	HWC (screw, fixation, bone) (Primary) HTN (washer, bolt, nut)
Primary Predicates	K171018 – Axis Charcot Fixation System/ 4.5 to 8.5 Screw System
Additional Predicates	K190586 – Paragon 28 Monster Screw System K193366 – Stryker T2 ICF System K140741 – Wright Medical Salvation Beams and Bolts System
Device Description	The Axis Charcot Fixation System consists of 5.5, 6.5 and 7.5mm cannulated, titanium alloy fixation beams and accessories used for midfoot reconstruction. The modified device adds additional sizes, 4.5 and 8.5mm cannulated, titanium alloy fixation beams, previously cleared under Extremity Medical's 4.5 to 8.5 Screw System (K171018). The additional sizes offer the surgeon options for placement based on patient anatomy.
Indications for use	The Axis Charcot Fixation System in diameters of 4.5 to 8.5mm is indicated for reconstruction procedures, non-unions 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 Charcot Fixation System consists of bone screws used for fixation in the foot for arthrodesis procedures. The sizes of screws offered in the Axis System (4.5 to 8.5mm) are equivalent to the predicate devices in terms of design and material mechanical properties, and in indications for use.

Non-clinical Testing	Engineering analyses evaluating mechanical strength of the smallest beam diameter (4.5mm) and pullout strength of the shortest, smallest beam diameter demonstrated that the modified device is substantially equivalent to the predicate devices for the intended use. Additionally, the largest beam diameter (8.5mm) is no worst case than the predicates therefore no additional safety and effectiveness concerns are presented for the subject device in relation to the implant's size for the patient anatomy.
Clinical Testing	No clinical testing was performed.
Conclusion	The Axis Charcot Fixation System is substantially equivalent to its predicate device. This conclusion is based upon indications for use, principles of operation, design, engineering and mechanical test evaluation.