DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Extremity Medical, LLC. July 13, 2017
Brian Smekal
VP, Regulatory Affairs and Quality Assurance
300 Interpace Parkway
Suite 410
Parsippany, New Jersey 07054

Re: K171018
Trade/Device Name: Axis Charcot Fixation System, 4.5 to 8.5mm Screw 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: May 24, 2017
Received: May 25, 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 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 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,

Mark N. Melkerson -S

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)*

K171018

Device Name
Axis Charcot Fixation System, 4.5 to 8.5mm Screw System

Indications for Use *(Describe)*

Axis Charcot Fixation System:
The Axis Charcot Fixation System in diameters of 5.5, 6.5 and 7.5mm 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 osteoarthopathy (Charcot).

4.5 to 8.5 Screw System:
The 4.5 to 8.5mm Screw System is intended for fixation arthrodesis of the metatarsal-cuneiform, navicular-cuneiform, metatarsal-cuboid, talonavicular, and calcaneocuboid joints.

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:

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 of Safety and Effectiveness:

Axis Charcot Fixation System/4.5 to 8.5 Screw 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) 588-8980; Email: bsmekal@extremitymedical.com
Date Prepared	July 11, 2017
Trade Names	Axis Charcot Fixation System 4.5 to 8.5 Screw System
Common Name	Screw, Fixation, Bone Washer, Bolt Nut
Classification Name and Number	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
Product Code	HWC, HTN
Predicate Devices	**Axis Charcot Fixation System** K140741 – Salvation Beams and Bolts System K060736 – Smith & Nephew 6.5 and 8.0mm Cannulated Screws (Reference Device) K151418 – Paragon 28 Monster Screw System K121349 – Extremity Medical Screw and Washer System (Reference Device) **4.5 to 8.5 Screw System** K082934 – Extremity Medical Midfoot Screw System K151418 – Paragon 28 Monster Screw System K121349 – Extremity Medical Screw and Washer System (Reference Device)
Device Description	**Axis Charcot Fixation System** 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. **4.5 to 8.5 Screw System** The 4.5 to 8.5 diameter screws consists of cannulated, titanium alloy fixation screws for use in bone reconstruction, osteotomy, arthrodesis and fracture repair and fixation in the foot.

Indications for use	**Axis Charcot Fixation System** The Axis Charcot Fixation System in diameters of 5.5, 6.5 and 7.5mm 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 osteoarthopathy (Charcot). **4.5 to 8.5 Screw System** The 4.5 to 8.5mm Screw System is intended for fixation arthrodesis of the metatarsal-cuneiform, navicular-cuneiform, metatarsal-cuboid, talonavicular, and calcaneocuboid joints.
Statement of Technological Comparison	**Axis Charcot Fixation System** The Axis System consists of bone screws used for fixation in the foot for arthrodesis procedures. The sizes of screws offered in the Axis System (5.5, 6.5 and 7.5mm) are equivalent to the predicate devices WMT Salvation Beams and Bolts and Smith & Nephew 6.5 and 8.0mm Cannulated Screws in terms of screw size offering and material of manufacture (Ti-6Al-4V). The optional accessory washer/nut enables retention of the screw in bone and help generate and maintain compression across a joint. The differences in design of the clip as compared to predicate washers/nuts do not introduce new issues of safety or effectiveness. **4.5 to 8.5 Screw System** The sizes of screws offered in the 4.5 to 8.5 Screw System are equivalent to the predicate devices Extremity Medical Screw and Washer System and Paragon28 Monster Screw System in terms to screw size offering and material of manufacture (Ti-6Al-4V).
Non-clinical Testing	Bench testing including pull-out and static and dynamic bending and engineering analysis were performed on the Axis Charcot Fixation System and compared to the predicate device.
Clinical Testing	No clinical testing was performed.
Conclusion	**Axis Charcot Fixation System** 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 analysis and mechanical test evaluation. **4.5 to 8.5 Screw System** The 4.5 to 8.5 Screw System is substantially equivalent to its predicate devices. This conclusion is based upon indications for use, principles of operation, design, engineering analysis and mechanical test testing.