July 8, 2020

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

Re: K201556
Trade/Device Name: Intraosseous 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: June 9, 2020
Received: June 10, 2020

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,

for

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)*
K201556

Device Name
Intraosseous Fixation System

Indications for Use *(Describe)*
The Intraosseous Fixation System is intended for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures and nonunions of the small bones and joints of the hand, wrist, foot and ankle, appropriate for the size of the device.

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:

Intraosseous 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	July 8, 2020
Trade Name	Intraosseous Fixation System
Classification Name and Number	21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener (Primary Classification); 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliances and accessories
Product Code	HWC (screw, fixation, bone); HTN (washer, bolt, nut)
Primary Predicate	K121349 – Extremity Medical Screw and Washer System
Additional Predicates	K101700 - Extremity Medical Screw and Washer System K171018 – Axis Charcot Fixation System K124027 – Paragon 28 Monster Screw System
Reference Device	K173347 - STALIF FLX, Intervertebral Fusion Device
Device Description	The Extremity Medical Intraosseous Fixation System is intended for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures and nonunion of the small bones and joints of the hand, wrist, foot, and ankle. The system consists of solid and cannulated screws, with the option of adding Washers; a standard/flat Washer, a Washer Post (referred to as an X-Post) for engaging the head of the Screw, and an X-Clip for engaging the threads of the screw. The X-Post/X-Clip come in varying sizes and lengths. Similarly, the lag screws come in varying diameters and lengths, and are also available in short and long thread configurations. The modified device is a product line extension and improvement to the Screw and Washer System, cleared under K121349, intended to provide modularity to the end user. New components to the system consist of cannulated 3.5 mm screws and implant accessories, X-Posts and X-Clips, to offer surgeons options for placement. Additionally, the system will offer additional thread length options for the 4.5mm screws cleared under K121349 and 6.5mm screws substantially equivalent to those cleared under K121349.
Indications for use	The Intraosseous Fixation System is intended for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures and nonunions of the small bones and joints of the hand, wrist, foot and ankle, appropriate for the size of the device.

Statement of Technological Comparison	The Intraosseous Fixation System and predicate devices are equivalent in terms of design and material mechanical properties, and similar in indications for use. The subject and predicate devices 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 (Ti-6Al-4V ELI per ASTM F3001 and F136). • Implants utilize a crossing relationship to create perpendicular compression through the interaction of a lag screw and washer-style components. The following technological differences exist between the subject and predicate devices: • The predicate device is a one or two part construct, whereas the subject device is a one to three part construct, depending on surgeon preference and patient anatomy. • Use of different instrumentation specific to implantation of the optional accessories (X-Posts and X-Clips). • X-Post and X-Clip geometry modified for reduced profile and required bone removal. Washers introduced to further the versatility of the system. The differences in the design of the subject device as compared to predicates do not introduce new issues of safety or effectiveness.
Non-clinical Testing	An engineering analysis demonstrated that the new washers, X-Posts, X-Clips and screw sizes do not introduce a new worse case in terms of strength. Specific testing performed on the system include an engineering analysis of: • Bending • Torsion • Pullout
Clinical Testing	No clinical testing was performed.
Conclusion	The Intraosseous Fixation System is substantially equivalent to its predicate device. This conclusion is based upon indications for use, principles of operation, design, and mechanical test data.