EPIC Extremity, LLC
Randy Schlemmer
Director of Product Development
120 Marguerite Drive, Suite 301
Cranberry Twp, Pennsylvania 16066

February 13, 2019

Re: K182991
Trade/Device Name: EPIC Extremity Fusion Plate 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
Dated: January 7, 2019
Received: January 9, 2019

Dear Randy Schlemmer:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2019.02.13 10:16:53 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182991

Device Name

EPIC Extremity Fusion Plate System

Indications for Use *(Describe)*

The EPIC Extremity Fusion Plate System is indicated for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet and ankles, including distal tibia. The plates/screws are intended for single use only.

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.

EPIC Extremity Fusion Plate System

Submitter Information

Applicant: EPIC Extremity, LLC
120 Marguerite Dr., Ste 301
Cranberry Twp., PA 16066

Contact Person: Randy Schlemmer
EPIC Extremity, LLC
120 Marguerite Dr., Ste 301
Cranberry Twp., PA 16066
(574)248-0060

Date Prepared: October 15th, 2018

Name of Device: EPIC Extremity Fusion Plate System

Common Name: Bone Fixation Plate

Classification Name Single/Multiple component metallic bone fixation appliances and accessories (per 21 CFR 888.3030) - Class II

Product Code/Panel: HRS/Orthopedics

Predicate Devices: EPIC Extremity Fracture Plate System (K172441)
EPIC Extremity Cannulated Screw System (K153333)
Ortholoc 3DI Ankle Fusion Plating System (K121425) Reference
Ortholoc 3DI Ankle Fusion Plating System
Line Extension (K163650) Reference

Indications for Use:
The EPIC Extremity Fusion Plate System is indicated for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet and ankles, including distal tibia. The plates/screws are intended for single use only.

Device Description
The EPIC Extremity Fusion Plate System consists of multiple plate families of various anatomical sizes and shapes, 4.5mm/5.5mm locking and non-locking screws that mate into the plates, 5.5mm fully and partial threaded cancellous, 5.5mm cannulated partial threaded cancellous bone screws as well as various instruments to assist in implanting the system.

The EPIC Extremity Fusion Plate System is also designed to be used with various instruments to assist in implanting the system from the previously cleared EPIC Extremity Plate System (K153340).

EPIC Extremity Fusion Plate System

Technological Characteristics

The EPIC Extremity Fusion Plate System has the same intended use as the predicate devices. The EPIC Extremity Fusion Plate System has identical indications for use as the predicate devices. The EPIC Extremity Fusion Plate System is manufactured from the same materials as the predicate devices. The EPIC Extremity Fusion Plate System has the following differences from the predicate device:

a. Introduction larger 4.5mm & 5.5mm screw diameters
b. Introduction of cannulated 5.5mm screw diameter
c. Introduction of anatomic specific plate families

Any differences between the EPIC Extremity Fusion Plate System and the predicates are considered minor and do not raise questions concerning safety and effectiveness.

Non-Clinical Performance Data Summary

Cross-sectional analysis demonstrated substantial equivalence. Through this analysis it was determined that the addition of the EPIC Extremity Fusion Plates are substantially equivalent in bending strength to the predicate and does not introduce a new worse case into the system.

Based on the analysis results and the comparisons provided, the EPIC Extremity Fusion Plate System is considered substantially equivalent to the EPIC Extremity Fracture Plate System (K172441), Ortholoc 3DI Ankle Fusion Plating System (K121425), Ortholoc 3DI Ankle Fusion Plating System Line Extension (K163650) and EPIC Extremity Cannulated Screw System (K153333) in material, construction, size, anatomic location and performance characteristics.

Clinical Performance Data Summary

No clinical testing was required.

Non-Clinical and Clinical Performance Data Conclusions

Based on the analysis results and the comparisons provided, the EPIC Extremity Fusion Plate System is considered substantially equivalent to the EPIC Extremity Fracture Plate System (K172441), Ortholoc 3DI Ankle Fusion Plating System (K121425), Ortholoc 3DI Ankle Fusion Plating System Line Extension (K163650) and EPIC Extremity Cannulated Screw System (K153333) in material, construction, size, anatomic location and performance characteristics.