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

November 6, 2017

Re: K172441
Trade/Device Name: EPIC Extremity Fracture 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: August 9, 2017
Received: August 11, 2017

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. 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 (DICE) 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 (DICE) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172441

Device Name
EPIC Extremity Fracture Plate System

Indications for Use *(Describe)*
The EPIC Extremity Fracture Plate System is indicated for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both adult and pediatric patients. 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.

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.

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EPIC Extremity Fracture 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: August 9th 2017

Name of Device: EPIC Extremity Fracture 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 Plate System (K153340).
EPIC Small Staple (K163226) Reference.

Intended Use:

The EPIC Extremity Fracture Plate System is indicated for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both adult and pediatric patients. The plates/screws are intended for single use only.

EPIC Extremity Fracture Plate System

Device Description

The EPIC Extremity Fracture Plate System consists of multiple plate families of various anatomical sizes and shapes, 4.0mm locking and non-locking screws that mate into the plates, 4.0mm fully and partial threaded cancellous bone screws as well as various instruments to assist in implanting the system.

The EPIC Extremity Fracture Plate System is also designed to accept the 2.7mm/3.5mm locking/non-locking screws and various instruments to assist in implanting the system from the previously cleared EPIC Extremity Plate System (K153340).

Technological Characteristics

The EPIC Extremity Fracture Plate System has the same intended use as the predicate devices. The EPIC Extremity Fracture Plate System has similar indications for use as the predicate devices. The EPIC Extremity Fracture Plate System is manufactured from the same materials as the predicate devices.

Non-Clinical Performance Data Summary

1. ASTM F-543

Clinical Performance Data Summary

No clinical testing was required.

Non-Clinical and Clinical Performance Data Conclusions

Based on testing results and the comparisons provided, the EPIC Extremity Fracture Plate System is considered substantially equivalent to the EPIC Extremity Plate System (K153340) in material, construction, and performance characteristics.