DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 28, 2017

Epic Extremity, LLC
Randy Schlemmer
Director Of New Product Development
1000 Hampton Center, Suite A
Morgantown, West Virginia 26505

Re: K163038
Trade/Device Name: EPIC Extremity Snap-off Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 12, 2017
Received: January 17, 2017

Dear Mr. 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 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)*

K163038

Device Name
EPIC Extremity Snap-Off Screw

Indications for Use *(Describe)*

The EPIC Extremity Snap-Off Screw is indicated for use in fixation of bone fractures or bone reconstruction.
Examples include:
*Fixation of small bone fragments
*Weil osteotomy
*Mono-cortical fixation
*Osteotomies and fracture fixation in the foot and hand

The Snap-Off Screw is 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.

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510(k) Summary

Submitter Information

Applicant: EPIC Extremity, LLC
120 Marguerite Drive, Suite 301
Cranberry Twp., PA 16066

Contact Person: Randy Schlemmer
EPIC Extremity
1000 Hampton Center, Suite A
Morgantown, WV 26505
(724)779-4747

Date Prepared: February 27, 2017

Name of Device: EPIC Extremity Snap-Off Screw

Common Name: Snap-Off Screw

Classification Name: Smooth or threaded metallic bone fixation fastener (per 21 CFR 888.3040) – Class II

Product Code/Panel: HWC/Orthopedics/87

Predicate Devices: Charlotte Snap-Off Screw (K043583)
Charlotte Snap-Off Screw (K133713)
EPIC Extremity Cannulated Screw (K15333)

510(k) Summary

Intended Use:

The EPIC Extremity Snap-Off Screw is indicated for use in fixation of bone fractures or bone reconstruction.
Examples include:

- Fixation of small bone fragments
- Weil Osteotomy
- Mono-cortical fixation
- Osteotomies and fracture fixation in the foot and hand

The Snap-Off Screw is intended for single use only.

Device Description

The EPIC Extremity Snap-Off Screw will consist of headed snap off screws of various lengths and instruments to assist in implanting the devices.

Technological Characteristics

The EPIC Extremity Snap-Off Screw

- has the same intended use as the predicate device.
- has similar indications for use as the predicate device.
- is manufactured from the same materials as the predicate device.
- range of sizes of the Snap-Off Screw is similar to the predicate device.

Non-Clinical Performance Data Summary

1. ASTM F-543 (Snap-Off Screw)
    a. Annex A1-Torsional Properties
    b. Annex A2-Driving Torque Parameters
    c. Annex A3-Axial PullOut
    d. Annex A4-Self Tapping Performance
2. Torque to Fail: Snap-Off Feature

Clinical Performance Data Summary

No clinical testing was required.

510(k) Summary

Non-Clinical and Clinical Performance Data Conclusions

Based on testing results and the comparisons provided, the EPIC Extremity Snap-Off Screw is considered substantially equivalent to the Wright Medical Charlotte Snap-Off Screw in material, construction, and performance characteristics.