



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

May 16, 2017

Epic Extremely, LLC
Randy Schlemmer
Director Of New Product Development
120 Marguerite Drive, Suite 301
Cranberry Township, Pennsylvania 16066

Re: K163226

Trade/Device Name: EPIC Extremely Small Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And
Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: April 17, 2017
Received: April 20, 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

Indications for Use

510(k) Number (if known)

K163226

Device Name

EPIC Extremity Small Staple

Indications for Use (Describe)

The EPIC Extremity Small Staple is indicated for use in fixation of bone fractures or bone reconstruction.

Examples include:

- *Wedge osteotomy of the first phalanx (Akin osteotomy)
- *Treatment of hallux valgus in order to correct valgus or pronation of the first ray
- *Wind swept toes

The Small Staple 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.

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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, LLC
120 Marguerite Drive, Suite 301
Cranberry Twp., PA 16066
(574)248-0060

Date Prepared: November 16th, 2016

Name of Device: EPIC Extremity Small Staple

Common Name: Staple, Fixation, Bone

Classification Name: Single/multiple component metallic bone fixation appliances and accessories (per 21 CFR 888.3030) – Class II

Product Code/Panel: JDR/Orthopedics/87

Predicate Devices: **Primary -** Compression Staple and Simple Staple (K043059)
Secondary – Sniper Staple System (K162354)



510(k) Summary

Intended Use:

The EPIC Extremity Small Staple is indicated for use in fixation of bone fractures or bone reconstruction.

Examples Include:

- *Wedge osteotomy of the first phalanx (Akin osteotomy)
- *Treatment of hallux valgus in order to correct valgus or pronation of the first ray
- *Wind swept toes

The Small Staple is intended for single use only.

Device Description

The EPIC Extremity Small Staple will consist of one size and style, and instruments to assist in implanting the device.

Technological Characteristics

The EPIC Extremity Small Staple

- 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 is similar to the predicate device.

Non-Clinical Performance Data Summary

ASTM F-564-10 Static bend testing, fatigue bend testing, and pullout testing of the subject device performance was compared to predicate performance.

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 Small Staple is considered substantially equivalent to the Wright Medical Simple Staple in material, construction, and performance characteristics.