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

January 19, 2016

Epic Extremity, LLC
% Mr. Lee Strnad
President
Intrepid Orthopedics, LLC
3046 Brecksville Road, Suite 4
Richfield, Ohio 44286

Re: K153333
Trade/Device Name: Epic Extremity Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 20, 2015
Received: November 23, 2015

Dear Mr. Strnad:

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 Parts 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" (21CFR 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 yours,

Lori A. Wiggins -S

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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K153333

Device Name
Epic Extremity Cannulated Screw System

Indications for Use *(Describe)*
The Epic Extremity Cannulated Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of bones appropriate for the size of the device.

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.

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# 510(k) Summary

## Submitter Information

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

**Contact Person:** Lee A. Strnad
Management Representative
Intrepid Orthopedics
3046 Brecksville Rd, Ste 4
Richfield, OH 44286
(330) 659-0855

**Date Prepared:** November 10, 2015

**Name of Device:** Epic Extremity Cannulated Screw System

**Common Name:** Bone Screws

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

**Product Code/Panel:** HWC/Orthopedics/87

**Predicate Devices:** Wright Compression Screws (K082320)
aap Cannulated Screw/Darco Headed Screws (K080101)

**Intended Use:**

The Epic Extremity Cannulated Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of bones appropriate for the size of the device.

Screws are intended for single use only.

# 510(k) Summary

**Device Description**

The Epic Extremity Cannulated Screw System will consist of multiple diameter headed and headless cannulated screws of various lengths and instruments to assist in implanting the system.

**Technological Characteristics**

The EPIC Extremity Cannulated Screw System have the same intended use as the predicate devices. The EPIC Extremity Cannulated Screw System have similar indications for use as the predicate devices. The EPIC Extremity Cannulated Screw System are manufactured from the same materials as the predicate devices. EPIC Extremity Cannulated Screw System implants are manufactured from Ti-6Al-4V per ASTM F-136. The range of sizes of the EPIC Extremity Cannulated Screw System are similar to 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 Cannulated Screw System are considered substantially equivalent to the Wright Compression Screw System & aap Cannulated Screw/Darco Headed Screws in material, construction, and performance characteristics.