MAR 1 0 2014

# 5. 510(k) Summary

**Device Trade Name:** VAN Hip Fracture System

**Manufacturer:**
EPIX Orthopaedic, Corp.
191 Pine Lane
Los Altos, CA 94022

**Contact:**
Ms. Michelle McDonough
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
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**Date Prepared:** September 30, 2013

**Common Name:** Intramedullary Fixation Rod

**Classification:** 21 CFR 888.3020, Intramedullary fixation rod.

**Class:** II

**Product Code:** HSB

**Indications For Use:**
The VAN Hip Fracture System is indicated for fixation of fractures of the femur, including intertrochanteric fractures, pertrochanteric fractures, subtrochanteric fractures and combinations of these fractures, pathological fractures in both diaphyseal and trochanteric areas, and nonunion or malunion

**Device Description:**
The VAN Hip Fracture System includes short and long intramedullary nails, lag screws and distal locking cortical bone screws. The nail contains an angle adjust feature that allows for the neck/shaft angle to be adjusted to accommodate anatomical variations in the femoral neck angle.

**Predicate Device:**
The VAN Hip Fracture System is substantially equivalent to the Stryker Howmedica Osteonics Gamma 3 Nail System (K032244), Biomet Vari-Angle Hip Screw (VHS) System (K964880), and Disc-O-Tech Fixion Nail (K010988).

**Preclinical Testing:**

Static and dynamic mechanical testing was performed on the VAN Hip Fracture System in accordance with ASTM F384, Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices. The results demonstrate that the VAN Hip Fracture System is substantially equivalent to a predicate device in side-by-side testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 10, 2014

EPIX Orthopaedic, Corp.
% Ms. Michelle McDonough
Senior Associate, Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisors
1331 H Street, NW, 12th Floor
Washington, DC 20005

Re: K133104
Trade/Device Name: VAN Hip Fracture System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 27, 2014
Received: January 28, 2014

Dear Ms. McDonough:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# 4. Indications for Use

510(k) Number (if known): K133104

Device Name: VAN Hip Fracture System

The VAN Hip Fracture System is indicated for fixation of fractures of the femur, including intertrochanteric fractures, pertrochanteric fractures, subtrochanteric fractures and combinations of these fractures, pathological fractures in both diaphyseal and trochanteric areas, and nonunion or malunion.

| Prescription Use √ (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices