K130613



## 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the Smooth or threaded metallic bone fixation fastener device is provided below.

JAN 2 2 2014

**Device Common Name:** Cannulated Bone Screw, Bone Fixation Fasteners

**Device Proprietary Name:** Cannulated Screw and Kirschner (K wire) System

**Submitter:** Laura Cattabriga
7430 Center Bay Drive
N. Bay Village, Florida 33141

**Contact:** Laura Cattabriga
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**Classification**
**Regulation:** 21 CFR **888.3030** Single /multiple component metallic bone fixation appliances and accessories

21 CFR **888.3040:** Smooth or threaded metallic bone fixation fastener

**Panel:** Orthopedic

**Product Code:** **HTN, HWC, HTY**

**Indication for Use:** The Intended Use of the Cannulated Screw and Kirschner (Kwire) System is for the treatment and fixation of bone fractures and osteotomies of various bones including the, acetabulum, pelvis, humerus, radius, ulna, femur, tibia, phalanges, carpals, metacarpals, tarsals, metatarsals and fibula

**Device Description:** Cannulated Screws and Kwires are a self-tapping, self-drilling screw with a cortico/cancellous or cancellous thread that can be guided into position by Kwire placement. Partial or fully threaded screws are available in various different lengths and diameters to provide fixation in various size bones. The screws are made of Stainless Steel. The Kirschner Wires (Kwires) are threaded, spaded or blunt ranging from 0.8mm to 1.4mm of an inch in diameter and 150mm in length and made of 316L Stainless Steel.

**Performance Data:** The Cannulated Screw and Kirschner (K wire) System are substantially equivalent to the predicate devices with respect to design and material and dimensional comparison.

**Substantial Equivalence:**

- Internal Fixation Systems, Inc. Bone Fixation Devices (K071035)
- Internal Fixation Systems, Inc Cannulated Bone Screw (K061620)

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

January 22, 2014

Ms. Laura H. Cattabriga
7430 Center Bay Drive
North Bay Village, Florida 33141

Re: K130613
Trade/Device Name: Cannulated Screw and Kirschner (K wire) System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTY, HTN
Dated: December 17, 2013
Received: December 18, 2013

Dear Ms. Cattabriga:

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" (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 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,

Ronald P. Jean -S for

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

Enclosure

## Indications for Use Statement

**510(k) Number (if known):** K130613

**Device Name: Cannulated Screw and Kirschner (Kwire) System**

**Indications For Use:**

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Prescription Use __X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Elizabeth L. Frank -S

Division of Orthopedic Devices