K092440

NOV - 5 2009

510(k) Summary

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road, #100
Austin, TX 78754-3832

510(k) CONTACT: Debbie Stearns
Phone: (512) 836-5001 x1548

TRADE NAME: Ascension® Cannulated Screw System

COMMON NAME: Cancellous Cannulated Bone Screws

CLASSIFICATION: 21 CFR 888.3040 – Bone Fixation Screw

PRODUCT CODE: HWC

PANEL: Orthopedic

PREDICATE DEVICES:
K991151 and K991197 – Vilex Cannulated Screws
K962823 – Synthes Cannulated Screws
K893512 – DePuy Cannulated Bone Screw
K901616 – Smith & Nephew Cannulated Interference Screw System

DEVICE DESCRIPTION:
The Ascension® Cannulated Screw System consists of various sizes of cannulated screws. The screws are machined, metallic screws with a cannulation that are self-drilling and self-tapping. Each type is offered in a variety of diameters and lengths and is manufactured from stainless steel or titanium. Washers, as well as guide wires, and various orthopedic surgical instruments will be included in the system.

INTENDED USE:
The Ascension Cannulated Screw System is intended for the following:

- Fixation of fractures in long bones
- Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow
- Arthrodesis of the foot, wrist and elbow
- Small and long bone osteotomies

BASIS OF SUBSTANTIAL EQUIVALENCE:
Ascension Orthopedics believes that this system is substantially equivalent to the legally marketed predicate devices based on similarities in design, materials and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Ascension Orthopedics, Inc.
% Ms. Debbie Stearns
Director, Regulatory/Clinical Affairs
8700 Cameron Road, Suite 100
Austin, Texas 78754-3832

Re: K092440
Trade/Device Name: Ascension® 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: October 5, 2009
Received: October 5, 2009

Dear Ms. Stearns:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

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

Enclosure

Indications for Use Statement

510(K) Number: K092440

Device Name: Ascension® Cannulated Screw System

Indications for Use:

The Ascension Cannulated Screw System is intended for the following:

- Fixation of fractures in long bones
- Fixation of small bones, including those in the foot, patella, ankle, wrist and elbow
- Arthrodesis of the foot, wrist and elbow
- Small and long bone osteotomies

Prescription Use ___X___ OR Over-The-Counter Use _____

(Part 21 CFR 801Subpart B) (Part 21 CFR 801Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janeta J. for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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