

K092440

**510(k) Summary**

NOV - 5 2009

**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.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

NOV - 5 2009

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

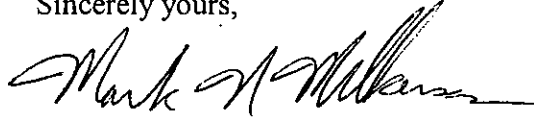
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(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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
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Prescription Use   X  

OR

Over-The-Counter Use

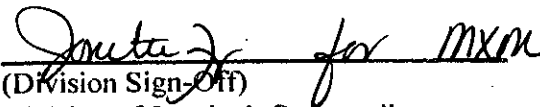
(Part 21 CFR 801 Subpart B)  
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(Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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