K10092 S 1/2

510(k) Summary

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

JUL 12 2010

510(k) CONTACT: Stan Harris
Phone: (512) 836-5001 x1585

TRADE NAME: Ascension® Ankle Fusion Nail System

COMMON NAME: Titanium Intramedullary Nail (Rod)

CLASSIFICATION: 21 CFR 888.3020 – Rod, Fixation, Intramedullary And Accessories

PRODUCT CODE: HSB

PANEL: Orthopedic

PREDICATE DEVICES:
K091976 – Biomet Ankle Arthrodesis Nail, Biomet Phoenix Ankle Nail System
K051590 – Stryker T2 Ankle Arthrodesis Nail

DEVICE DESCRIPTION:
The Ascension® Ankle Fusion Nail System is to be implanted by insertion into the long bones for fixation of fractures, or the fixation of long bones that have been surgically prepared for correction of deformity, or arthodesis.

The Ankle Fusion Nail System consists of nails, screws and an end cap. The standard nails are offered in three diameters and 3 lengths (150mm, 180mm and 210mm). Longer lengths up to 460mm will be made upon request. Fixation screws consist of one diameter and 27 lengths, and an end cap offered in one size. All three implant components will be manufactured from titanium 6AL-4V.

INTENDED USE:
The Ascension® Ankle Fusion Nail System is intended for the following:

- Charcot Foot
- Avascular necrosis of the talus
- Failed total ankle arthroplasty
- Trauma (malunited tibial pilon fracture)
- Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Revision ankle arthrodesis
- Neuroarthropathy
- Rheumatoid arthritis
- Osteoarthritis
- Pseudoarthrosis

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- Post-Traumatic arthrosis
- Previously infected arthrosis
- Severe end stage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

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.

The worst-case cross sectional areas of the device are located at the screw holes and slots. The nail's cross sectional area directly affects the bending strength of the nail. An engineering analysis was completed on the proposed device and the predicate devices. Results demonstrate equivalence in bending strength to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Ascension Orthopedics, Inc.
% Mr. Stan Harris
8700 Cameron Road, Suite 100
Austin, TX 78754-3832

JUL 12 2010

Re: K100925
Trade/Device Name: Ascension Ankle Fusion Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: June 25, 2010
Received: June 28, 2010

Dear Mr. Harris:

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 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,

for

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

Enclosure

3 Indications for Use Statement

510(K) Number: K100925

Device Name: Ascension® Ankle Fusion Nail System

Indications for Use:

The Ascension® Ankle Fusion Nail System is intended for the following:

- Charcot Foot
- Avascular necrosis of the talus
- Failed total ankle arthroplasty
- Trauma (malunited tibial pilon fracture)
- Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Revision ankle arthrodesis
- Neuroarthropathy
- Rheumatoid arthritis
- Osteoarthritis
- Pseudoarthrosis
- Post-Traumatic arthrosis
- Previously infected arthrosis
- Severe end stage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

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)

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

510(k) Number K100925