K092825

510(k) SUMMARY

MAR 16 2010

SUBMMITTER:

SpineCraft, LLC
2215 Enterprise Drive
Westchester, IL 60154-5819

ESTABLISHMENT REGISTRATION No:

3004717358

CONTACT PERSON:

Ami Akallal-Asaad, Director of Regulatory Affairs

DATE PREPARED:

September 8, 2009

CLASSIFICATION NAME:

Spinal Interlaminal Fixation Orthosis - 888.3050
Spinal Pedicle Fixation - 888.3070(b) (1)

PROPRIETARY NAME:

APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers

COMMON NAME:

Spinal Fixation System

PRODUCT CODE:

KWP, MNH, MNI

CLASSIFICATION PANEL:

87

PRODUCT DESCRIPTION:

The APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers is a rod-based system designed to interface with various spinal anatomies. The 5.50mm Rods are available in various lengths and are designed for use with the previously cleared titanium alloy components of the APEX Spine System which can accept a 5.50mm spinal rod, including monoaxial, polyaxial screws, hooks, and connectors. The polyaxial screw washers are available in 2 sizes. The smaller washer size is for use with the APEX Polyaxial Screws with shaft diameter from 4.75mm to 7.00mm and the larger washer size to be used with the APEX Polyaxial Screws with shaft diameters 7.75mm and 8.50mm.

MATERIALS:

The APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers is manufactured from implant grade titanium Alloy (Ti-6Al-4V) conforming to ASTM standard F-136 and ISO 5832-3.

INDICATIONS FOR USE:

The APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective

evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

The APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers is also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

The APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers is also a hook and sacral/iliac screw fixation system of the non-cervical spine indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (fracture and/or dislocation), spinal stenosis, deformities (scoliosis, lordosis and/or kyphosis), tumor, and previous failed fusion (pseudo-arthrosis).

The APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers when used with pedicle screws are indicated for degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies). Levels of fixation are for the thoracic, lumbar and sacral spine.

SUBSTANTIAL EQUIVALENCE:

The APEX Spine System is substantially equivalent to the following predicate devices:

- APEX Spine System: K062513 - SpineCraft
- MONARCH Spine System: K010576, K024348 - DePuy AcroMed, Inc.
- MOSS MIAMI Spinal System: K013296 - DePuy AcroMed, Inc.

The substantial equivalence of the APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers to the above mentioned predicate devices is based upon equivalence in design, material, manufacturing standards, intended use, as well as indications and contraindications. The fundamental scientific technology of this system is identical to previously cleared systems.

PERFORMANCE DATA:

Mechanical and dynamic testing of the APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers was performed. The test results demonstrate that the mechanical performance of the APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers is at least comparable to, if not better than, those of the predicate devices.

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

SpineCraft, LLC
% Ami Akallal-Asaad
Director of Regulatory Affairs
2215 Enterprise Drive
Westchester, Illinois 60154-5819

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Re: K092825
Trade/Device Name: APEX Spine System 5.50mm Titanium Rod and Polyaxial Screw Washers
Regulation Number: 21 CFR 888.3050, 888.3070
Regulation Name: Spinal interlaminal fixation orthosis
Pedicle screw spinal system
Regulatory Class: Class II
Product Code: KWP, MNI, MNH
Dated: February 17, 2010
Received: February 18, 2010

Dear Ami Akallal-Asaad:

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,

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

Enclosure

Indication for Use Statement

510(k) Number (if known): K092825

Device Name: APEX Spine System 5.5mm Rod and Polyaxial Screw Washers

Indication for Use:

The APEX Spine System 5.5mm Rod and Polyaxial Screw Washers intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra; degenerative spondylolisthesis with objective evidence of neurologic impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudoarthrosis).

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Prescription Use: x AND/OR Over-The-Counter Use: _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K092825