K103100

NOV 17 2010

IX. 510(k) Summary

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Eugene Bang Regulatory Affairs Associate Voice: 508-977-3966 Fax: 508-828-3797 Email: ebang@its.jnj.com
DATE PREPARED:	October 11, 2010
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
REGULATION NUMBER:	888.3050, 888.3070
CLASSIFICATION PANEL NAME:	Orthopedics
FDA PANEL NUMBER:	87
PRODUCT CODE:	KWP, MNI
PROPRIETARY NAME:	MOUNTAINEER® OCT Spinal System
PREDICATE DEVICES:	MOUNTAINEER® OCT Spinal System (K080828, K041203)
DEVICE DESCRIPTION:	Addition of the 3.5mm diameter monoaxial screw to the existing MOUNTAINEER® OCT Spinal System. This system also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.
INTENDED USE:	The indications for use for the modified devices described in this submission are the same as those for the MOUNTAINEER OCT Spinal System. The indications are as follows:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput – T3), the MOUNTAINEER Occipito-Cervical-Thoracic (OCT) Spinal System is intended for:

- ddd (neck pain of discogenic origin with degeneration of the disc as confirmed by patient history and radiographic studies)
- spondylolisthesis
- spinal stenosis
- fracture/dislocation
- atlanto/axial fracture with instability
- occipitocervical dislocation
- revision of previous cervical spine surgery
- tumors

The occipital bone screws are limited to occipital fixation only.

The use of the monoaxial and polyaxial screws is limited to placement in the upper thoracic spine (T1-T3) in treating thoracic conditions only. They are not intended to be placed in the cervical spine.

The Songer Cable System, to be used with the MOUNTAINEER OCT Spinal System, allows for wire/cable attachment to the posterior cervical spine.

The MOUNTAINEER OCT Spinal System can also be linked to the ISOLA®, TiMX®, MONARCH®, EXPEDIUM®, VIPER® and MOSS® MIAMI® Systems using the dual wedding band and axial connectors, and via dual diameter rods.

MATERIALS:

Manufactured from ASTM F-136 implant grade titanium alloy.

SUMMARY OF TECHNOLOGICAL DIFFERENCES:

The purpose of this submission is to obtain market clearance for the proposed additional components to the MOUNTAINEER® OCT System which consists of monoaxial screws. These proposed components have the same intended use, design characteristics, materials, performance, and packaging as the predicate devices. The key differences between the subject and predicate devices are:

- The length reduction on overall head height.
- The non-threaded shank diameter is increased to provide additional shank strength.

NON-CLINICAL TEST SUMMARY:

The following mechanical tests were conducted:

- Static cantilever beam in accordance with ASTM F1798 *"Standard Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spine Arthrodesis Implants".*
- Static axial slip in accordance with ASTM F1798 *"Standard Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spine Arthrodesis Implants".*
- Dynamic cantilever beam in accordance with ASTM F1798 *"Standard Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spine Arthrodesis Implants".*

CONCLUSION:

Based on the predicate comparison and testing, the subject device MOUNTAINEER® OCT Spinal System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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DePuy Spine, Inc.
% Mr. Eugene Bang
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02780

Re: K103100
Trade/Device Name: MOUNTAINEER® OCT Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, KWP
Dated: October 11, 2010
Received: October 20, 2010

Dear Mr. Bang:

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

III. Indications for Use

510(k) Number (if known): K103100

Device Name: MOUNTAINEER® OCT Spinal System

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Indications For Use:

The indications for use for the modified devices described in this submission are the same as those for the MOUNTAINEER OCT Spinal System. The indications are as follows:

When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput – T3), the MOUNTAINEER Occipito-Cervical-Thoracic (OCT) Spinal System is intended for:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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

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