K080828

IX. 510(k) Summary

JUN 27 2008

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Lisa A. Gilman
CONTACT TELEPHONE:	(508) 880-8100
DATE PREPARED:	June 19, 2008
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal §888.3050 Orthosis, Spinal Pedicle Fixation §888.3070
CLASSIFICATION PANEL NAME:	Orthopedics
FDA PANEL NUMBER:	87
PRODUCT CODE:	KWP, MNI, MNH
PROPRIETARY NAME:	MOUNTAINEER OCT Spinal System
PREDICATE DEVICES:	MOUNTAINEER OCT Spinal System (K041203, K042508) SUMMIT OCT Spinal System (K002733, K010681, K013222, K022190, K030103)
DEVICE DESCRIPTION:	Expansion of the size offering of MOUNTAINEER OCT Spinal System Minipolyaxial Screws. The MOUNTAINEER OCT Spinal 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 minipolyaxial 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™ 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.

PERFORMANCE DATA:

Performance data were submitted to characterize the additional components of the MOUNTAINEER OCT Spinal System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Spine, Inc.
% Ms. Lisa Gilman
325 Paramount Drive
Raynham, MA 02767

JUN 27 2008

Dear Ms. Gilman:

Re: K080828
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: MNH, MNI, KWP
Dated: June 12, 2008
Received: June 17, 2008

Dear Ms. Gilman:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

III. Indications for Use

510(k) Number (if known): K080828

Device Name: Modified MOUNTAINEER™ OCT Spinal System Components

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 General, Restorative, and Neurological Devices
510(k) Number K080828