K042508

IX. 510(k) Summary

OCT 7 – 2004

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Jennifer Mooney
DATE PREPARED:	September 14, 2004
CLASSIFICATION NAME:	Appliance, Fixation, Spinal Interlaminal Orthosis, Spinal Pedicle Fixation
PROPRIETARY NAME:	Summit OCT Spinal System Mountaineer OCT Spinal System
PREDICATE DEVICES:	Summit OCT Spinal System (K002733, K010681, K013222, K022190, K030103, and K041203) SYNTHES Spine CerviFix System (K984377)
DEVICE DESCRIPTION:	Addition of components to the Summit OCT Spinal System and Mountaineer OCT Spinal System. The Summit OCT Spinal System and Mountaineer OCT Spinal Systems also contain Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.
INTENDED USE:	When intended to promote fusion of the cervical spine and occipito-cervico-thoracic junction (occiput – T3), the Summit Occipito-Cervical-Thoracic (OCT) Spinal System and Mountaineer 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 Summit OCT Spinal System and Mountaineer OCT Spinal System, allows for wire/cable attachment to the posterior cervical spine.

The Summit OCT Spinal System and the Mountaineer OCT Spinal System can also be linked to the ISOLA, TiMX, MONARCH, MOSS MIAMI, and EXPEDIUM 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 Summit OCT Spinal System and Mountaineer OCT Spinal System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2004

Jennifer Mooney
Regulatory Affairs Associate
DePuy Spine, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K042508
Trade/Device Name: Summit OCT Spinal System and Mountaineer OCT Spinal System
Regulation Number: 21 CFR 888.3050, 21 CFR 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, KWP
Dated: September 14, 2004
Received: September 15, 2004

Dear Ms. Mooney:

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.

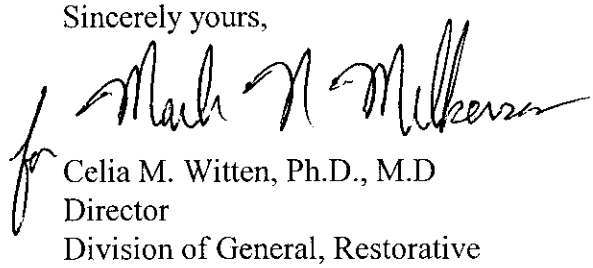
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240)276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D
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): ___ K042508_____

Device Name: Summit OCT Spinal System and Mountaineer OCT Spinal System

Indications For Use:

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

for Mark A. Milhauser

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042508

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