510(K) SUMMARY

A. Submitter Information

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767

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B. Date Prepared **2/04/11**

C. Device Name

Trade/Proprietary Name: MOUNTAINEER OCT Spinal System

Common/Usual Name: Spinal System

Classification Name: Spinal interlaminar fixation orthosis per 21 CFR §888.3050

D. Predicate Device Name

Trade names: DePuy MOUNTAINEER OCT Spinal System (K042508, K080828)

E. Device Description

The MOUNTAINEER OCT Spinal System consists of plates, nuts, bone screws, rods, transverse rod connectors, lateral offset connectors, head-to-head connectors, cable connectors, dual wedding band and axial connectors, set screws, minipolyaxial screws, monoaxial screws, hooks and SONGER® Cables.

The MOUNTAINEER OCT System Titanium Rods (Ti-6AL-4V) are offered in both Straight and Dual Diameter designs. The Straight Rod diameter is 3.5mm and has lengths

ranging from 25mm-100mm in increments of 5mm and lengths ranging from 100mm-400mm in increments of 20mm. The Dual Diameter Rods consists of 3.5 – 4.5mm, 3.5 – 4.75mm, 3.5 – 5.5mm, and 3.5 – 6.35mm diameters with Rod lengths of 420mm and 600mm.

The proposed MOUNTAINEER Cobalt Chromium (Co-Cr) Rods also consist of both Straight and Dual Diameter designs. The Straight Rod diameter is 3.5mm and available in lengths ranging from 25mm to 100mm (increments of 5mm) and 120, 200, 300, 340 and 400mm. The Dual Diameter MOUNTAINEER Co-Cr Rods consist of 3.5 – 4.5mm, 3.5 – 4.75mm, 3.5 – 5.5mm and 3.5 – 6.35mm and available in lengths of 420 and 600mm.

Other than the modifications to the material from Ti-6Al-4V to Co-Cr, no other modifications have been made. The proposed Cobalt Chromium rods are not being made to address a known recall or adverse events. These proposed components have been developed as additions to the existing MOUNTAINEER OCT Spinal System.

F. Intended Use

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.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The proposed devices are identical to the predicate device with the exception of the material being changed from Titanium to Cobalt Chromium. The design, indications for use, and technology remain identical to the predicate system.

G. Materials

Manufactured from ASTM F-1537 Cobalt Chromium.

H. Performance Data

Performance data per ASTM F 1717 were submitted to characterize the subject MOUNTAINEER OCT Spinal System rods addressed in this notification. This testing was compromised of static and fatigue testing on the proposed device. Specifically, static and dynamic compression-bending testing as well as static torsion testing was performed.

I. Conclusion

Both the Performance Testing and Substantial Equivalence Justification demonstrate that the device is as safe, as effective, and performs as well as the predicate device

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

DePuy Spine, Inc.
% Mr. Christopher Rogers
325 Paramount Drive
Raynham, Massachusetts 02767

APR - 7 2011

Re: K110353
Trade/Device Name: Mountaineer OCT Spinal System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: March 11, 2011
Received: March 14, 2011

Dear Mr. Rogers:

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): Unknown

Device Name: MOUNTAINEER OCT Spinal System

Indications For Use:

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___ 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 K110353