VI. 510(k) Summary

SUBMITTER: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02780

JAN - 7 2010

CONTACT PERSON: Daphney Germain

DATE PREPARED: July 1, 2009

CLASSIFICATION NAME: Orthosis, Spine, Plate, Laminoplasty, Metal §888.3050

PROPRIETARY NAME: MOUNTAINEER® Laminoplasty System

PREDICATE DEVICES: Medtronic CENTERPIECE™ Plate Fixation System (K050082)
Synthes ARCH™ Fixation System (K032534)

DEVICE DESCRIPTION: The proposed MOUNTAINEER Laminoplasty System is an implant system that consists of various sizes of plates and screws.

The proposed plates are available in various configurations to address surgeon and patient needs as necessary similar to the predicate devices, the Medtronic CENTERPIECE Plate Fixation System (K050082) and Synthes ARCH Fixation System (K032534). The proposed plates are available in the Inline, Inline Side-By-Side, and Offset Side-By-Side configurations. The proposed plate devices come in a preformed shape with holes for bone screws. The plates also contain a slot in the middle portion of the plate for allograft or autograft material attachment. The allograft or autograft material is secured to the plate using bone screws that are inserted through the middle slot on the top portion of the plate. The Inline, Inline Side-By-Side, and Offset Side-By-Side plates are available in 6mm to 18mm lengths in increments of 2mm. The three configurations are manufactured from commercially pure titanium as specified on the attached engineering drawing.

A Hinge Plate is provided to stabilize a weakened or displaced sectioned lamina. The proposed plate

device comes in a preformed shape with holes for bone screws. The Hinge Plate is attached to both the lamina and lateral mass using bone screws that are inserted through the holes on the top portion of the plate. The Hinge Plate is available in one length. The Hinge Plate is manufactured from commercially pure titanium as specified on the attached engineering drawing.

The screws intended for use with the plates are available in 2.30mm and 2.60mm diameters and in 4mm to 12mm lengths in increments of 2mm. The screws attach the plates to the lamina and lateral mass through the holes incorporated within the plates. The screws are manufactured from titanium alloy as specified on the attached engineering drawing.

The proposed MOUNTAINEER Laminoplasty System includes manual surgical instruments such as drivers, drill bits, graft loading block, plate holders, plate benders, rongeur, trials, and cases that are considered exempt from premarket notification.

INTENDED USE:

The MOUNTAINEER® Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The MOUNTAINEER Laminoplasty System is used to hold or buttress the allograft or autograft material in place in order to prevent the allograft or autograft material from expulsion or impinging the spinal cord.

MATERIALS:

Manufactured from Commercially Pure Titanium and Titanium Alloy.

PERFORMANCE DATA:

Performance data was submitted to characterize the MOUNTAINEER Laminoplasty System. Test data is available in **Exhibit D** (of the original submission).

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

JAN - 7 2010

DePuy Spine, Inc.
% Ms. Daphney Germain
Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K091994
Trade/Device Name: Mountaineer Laminoplasty System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: NQW
Dated: November 5, 2009
Received: November 6, 2009

Dear Ms. Germain:

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 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

IV. Indications for Use

510(k) Number (if known): K091994

Device Name: MOUNTAINEER® Laminoplasty System

Indications For Use:

The MOUNTAINEER® Laminoplasty System is intended for use in the lower cervical and upper thoracic spine (C3 to T3) in laminoplasty procedures. The MOUNTAINEER Laminoplasty System is used to hold or buttress the allograft or autograft material in place in order to prevent the allograft or autograft material from expulsion or impinging the spinal cord.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 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 K091994