Special 510(k) Submission – Additions to EXPEDIUM™ Spine System

510(K) SUMMARY

SEP 1 0 2008

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

Contact Person: Christopher Klaczyk, Regulatory Project Manager
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Date Prepared: July 1, 2008

Device Class: Class III

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

Spinal intervertebral body fixation orthosis
per 21 CFR §888.3060

Pedicle screw spinal fixation
per 21 CFR §888.3070

Classification Panel: Orthopedics

FDA Panel Number: 87

Product Code(s): KWP, MNH, MNI, NKB, KWQ

Proprietary Name: EXPEDIUM™ Spine System

Predicate Devices: EXPEDIUM™ Spine System
(K033901, K063156, K073126, K073364)

Device Description: The subject EXPEDIUM™ Spine System components are designed to accept a 5.5mm rod and are available in various geometries and sizes.

The EXPEDIUM™ Spine System also contains Class I manual surgical instruments, trays and cases and are exempt from premarket notification.

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Intended Use: The EXPEDIUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDIUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Materials: Manufactured from ASTM F 136 implant grade titanium alloy.

Performance Data: Performance data per ASTM F 1798 were submitted to characterize the subject EXPEDIUM™ Spine System components addressed in this notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Depuy Spine, Inc.
% Mr. Christopher Klaczyk
Regulatory Project Manager
325 Paramount Drive
Raynham, Massachusetts 02767

SEP 1 0 2008

Re: K081898
Trade/Device Name: EXPEDIUM™ Spine System
Regulation Number: 21 CFR 888.3070
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class III
Product Code: NKB, MNH, MNI, KWP, KWQ
Dated: August 08, 2008
Received: August 11, 2008

Dear Mr. Klaczyk:

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

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

Enclosure

Special 510(k) Submission – Additions to EXPEDIUM™ Spine System

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K081898

Device Name: EXPEDIUM™ Spine System

Indications For Use:

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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 K081898