AUG 17 2004

K041205
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X. 510(k) Summary

SUBMITTER:	DePuy Spine, Inc. 325 Paramount Drive Raynham, MA 02780
CONTACT PERSON:	Jennifer Mooney
DATE PREPARED:	April 29, 2004
CLASSIFICATION NAME:	Spinal Intervertebral Body Fixation Orthosis
PROPRIETARY NAME:	Expedium™ Anterior Spine System
PREDICATE DEVICES:	Frontier Anterior Scoliosis System (K012916)
DEVICE DESCRIPTION:	The Expedium Anterior Spine System consists of spinal rods, monoaxial screws, staples, washers, and cross connectors. The implants of the Expedium Anterior Spine System have been designed for use in either open or thoracoscopic approaches.

INTENDED USE:

The Expedium Anterior Spine System is intended for anterolateral screw fixation to the T4 to L4 levels of the spine, with all metal at least 1 cm from a major vessel. The Expedium Anterior Spine System may be used in either thoracoscopic procedures or open procedures.

The Expedium Anterior Spine System is indicated for:

1. degenerative disc disease (ddd) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
2. spondylolisthesis
3. trauma (i.e., fracture or dislocation)
4. spinal stenosis
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
6. tumor
7. pseudarthrosis
8. previous failed fusion

MATERIALS:	Manufactured from ASTM F-136 implant grade titanium alloy.
PERFORMANCE DATA:	Performance data were submitted to characterize the Expedium Anterior Spine System components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2004

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

Re: K041205
Trade/Device Name: Expedium™ Anterior Spine System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 4, 2004
Received: August 5, 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 (301) 594-4692. 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

IV. Indications for Use

510(k) Number (if known): K041205

Device Name: Expedium™ Anterior Spine System

Indications For Use:

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5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
6. tumor
7. pseudarthrosis
8. previous failed fusion

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 General, Restorative, and Neurological Devices

[signature]

510(k) Number K041205