K080568

6. 510(K) SUMMARY

MAY - 1 2008

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

Contact Person: Hande Tufan
Senior Regulatory Affairs Associate
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Date Prepared: February 28, 2008

Device Class: Class II

Classification Name: Spinal Vertebral Body Replacement Device

Classification Panel: Orthopedics

FDA Panel Number: 87

Product Code(s): MQP

Proprietary Name: X-MESH™ Expandable Cage System

Predicate Devices: Surgical Titanium Mesh (K030249)
Stackable Cage System (K013382)

Device Description: The X-MESH™ Expandable Cage System comes in three approach-specific shapes for the anterior lateral, direct anterior and posterior approaches. Each cage comes fully assembled with rough, convex endplates containing spikes that help anchor the device in the vertebral endplates, and provide resistance to migration and rotation. This mesh cage contains diamond pattern, side slots and large graft windows for graft material. The cage can be expanded axially and has a setscrew for locking it in position.

Intended Use: The X-MESH™ Expandable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

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The X-MESH™ Expandable Cage System is also indicated for treating fractures of the thoracic and lumbar spine.

The X-MESH™ Expandable Cage System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

The X-MESH™ Expandable Cage System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used include titanium plate or rod systems (i.e., KANEDA™ SR, UNIVERSITY PLATE™, M-2 ANTERIOR PLATE™, ISOLA®, VSP®, MOSS®MIAMI, TiMX™, MONARCH™, EXPEDIUM™, VIPER™, PROFILE™).

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

Performance Data: Performance data were submitted to characterize the subject X-MESH™ Expandable Cage System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 1 2008

DePuy Spine, Inc.
% Mr. Hande Tufan
Senior Regulatory Affairs Associate
325 Paramount Drive
Raynham, MA 02767

Re: K080568
Trade/Device Name: X-MESH™ Expandable Cage System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: April 2, 2008
Received: April 3, 2008

Dear Mr. Tufan:

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) 638-2041or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

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5. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: X-MESH™ Expandable Cage System

Indications For Use:

The X-MESH™ Expandable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

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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 General, Restorative, and Neurological Devices