K090899

510(k) Summary

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

CONTACT PERSON: Hande Tufan

MAY 19 2009

DATE PREPARED: March 31, 2009

CLASSIFICATION NAME: Spinal Vertebral Body Replacement Device
§888.3060

Intervertebral Body Fusion Device
§888.3080

PROPRIETARY NAME: Lateral Cage System

PREDICATE DEVICES: Lateral Cage System (K082128)
Concorde VBR Spinal System (K041722, K052746)
Stackable Cage System (K001340, K013382)

DEVICE DESCRIPTION: The Lateral Cage System consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of allograft and/or autogenous bone graft (autograft), depending on intended use.

The Lateral Cage System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

INTENDED USE: The Lateral 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. This system is also indicated for treating fractures of the thoracic and lumbar spine. The 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. When used as a vertebral body replacement device, this system is intended for use with DePuy Spine supplemental internal fixation.

The Lateral Cage System is also indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous

	levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.
MATERIALS:	Manufactured from Carbon Fiber Reinforced Polymer.
PERFORMANCE DATA:	Performance data were submitted to characterize the Lateral Cage System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Depuy Spine, Inc.
% Ms. Hande Tufan
Sr. Regulatory Affairs Associate
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K090899
Trade Name: Lateral Cage System
Regulation Number: 21 CFR 888.3080
Regulation Names: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, MQP
Dated: March 31, 2009
Received: April 3, 2009

Dear Ms. 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.

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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

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): _____

Device Name: Lateral Cage System

Indications For Use:

The Lateral 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. This system is also indicated for treating fractures of the thoracic and lumbar spine. The 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. When used as a vertebral body replacement device, this system is intended for use with DePuy Spine supplemental internal fixation.

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Prescription Use: _____X_____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090899