IX. 510 (k) Summary

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

JAN 25 2008

CONTACT PERSON: Frank S. Jurczak

DATE PREPARED: December 21, 2007

CLASSIFICATION NAME: 21 CFR 888.3060 Implant, Fixation Device
Spinal Intervertebral Body Fixation Orthosis Device

PROPRIETARY NAME: Bengal Stackable Cage System

PREDICATE DEVICES: Stackable Cage System (K990148, K001340)
Surgical Titanium Mesh System
(K003043, K020522)
DePuy Acromed VBR System (K031635)

INTENDED USE: The VBR Spinal 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.

The VBR Spinal System is also indicated for treating fractures of the thoracic and lumbar spine.

The VBR Spinal 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 VBR Spinal 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™, and PROFILE™).

MATERIALS: Carbon-fiber reinforced polymer (CFRP)
Titanium alloy conforming to ASTM F-136
Tantalum conforming with ASTM 560

DESCRIPTION:

The additional size cages are identical to the previously cleared stackable cages with regards to indications for use, function and material. The design of the cage is slightly different; the footprint of the device has been slightly modified.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

DuPuy Spine, Inc.
% Mr. Frank S. Jurczak
325 Paramount Drive
Raynham, MA 02780

Re: K073649
Trade/Device Name: VBR Spinal System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: December 21, 2007
Received: December 26, 2007

Dear Mr. Jurczak:

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 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

IV. Indications for Use

510(k) Number (if known): _____

Device Name: VBR Spinal System

Indications For Use:

The VBR Spinal 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.

The VBR Spinal System is also indicated for treating fractures of the thoracic and lumbar spine.

The VBR Spinal 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K073649