IX. 510(k) Summary K031635

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

CONTACT PERSON: Lisa A. Gilman

DATE PREPARED: May 21, 2003

CLASSIFICATION NAME: Implant, Fixation Device
Spinal Intervertebral Body Fixation Orthosis Device

PROPRIETARY NAME: DePuy AcroMed VBR System

PREDICATE DEVICES: DePuy AcroMed VBR System (K030833)
Stackable Cage System (K990148)
Surgical Titanium Mesh System (K020522)
Devex Mesh System (K023835)

DEVICE DESCRIPTION: Additional size components in various sizes and footprints.

The DePuy AcroMed VBR System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

INTENDED USE: The DePuy AcroMed VBR System is indicated for use in the thoracolumbar spine (i.e., T1-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 DePuy AcroMed VBR System is also indicated for treating fractures of the thoracic and lumbar spine.

The DePuy AcroMed VBR 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 DePuy AcroMed VBR System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the DePuy AcroMed VBR System include DePuy AcroMed titanium plate or rod systems (i.e., Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, MONARCH, and Profile).

MATERIALS: Carbon-fiber reinforced polymer

PERFORMANCE DATA: Performance data were submitted to characterize the additional components of the DePuy AcroMed VBR System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 23 2003

Mr. Frank Maas
Regulatory Affairs Director
DePuy AcroMed
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K031635
Trade/Device Name: DePuy AcroMed VBR System
Regulation Numbers: 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Codes: MQP
Dated: March 23, 2003
Received: March 28, 2003

Dear Mr. Maas:

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.

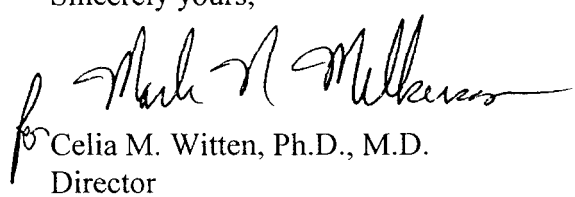
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. 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

III. Indications for Use

510(k) Number (if known): K031635 JUN 2 8 2003

Device Name: DePuy AcroMed VBR System

Indications For Use:

The indications for use for the modified devices described in this submission are the same as those for the DePuy AcroMed VBR System. The indications are as follows:

The DePuy AcroMed VBR System is indicated for use in the thoracolumbar spine (i.e., T1-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 DePuy AcroMed VBR System is also indicated for treating fractures of the thoracic and lumbar spine.

The DePuy AcroMed VBR 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 DePuy AcroMed VBR System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used with the DePuy AcroMed VBR System include DePuy AcroMed titanium plate or rod systems (i.e., Kaneda SR, University Plate, M-2, ISOLA, VSP, Moss Miami, TiMX, MONARCH, and Profile).

for Mark A Melkerson

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

510(k) Number K031635

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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