SEP 3 1999

K990148

STACKABLE CAGE™ SYSTEM
510(k) SUMMARY

COMPANY: DePuy AcroMed™, Inc.

325 Paramount Drive
Raynham, MA 02767-0350 USA

TRADE NAME: Stackable Cage™ System

CLASSIFICATION: 888.3060

Implant, fixation device, spinal intervertebral body fixation orthosis devices

DESCRIPTION:

The Stackable Cage System consists of two components- one or more stackable vertebral body replacement components (stackable cage implants) and a supplemental internal fixation system. The stackable cage implant is made of a polymer/carbon fiber composite material. One or more stackable cage implants may be stacked to the desired height, as determined by the surgeon. A titanium alloy screw can be passed through a center hole in the cages and with a nut provide a rigid and compressed assembly.

The structure of the stackable cage implants has been shown to support anticipated loads with a modulus of elasticity approximating that of cortical bone. The implants have ridges or teeth in both the anterior-posterior and medial-lateral directions, which resist rotation and migration. The stackable cage implants have cavities to accept packing of bone graft. The entire structure is radiolucent so that healing can be assessed by normal radiographic methods. Additionally, radiotherapy can be performed immediately after surgery.

MATERIAL: Carbon-fiber reinforced polymer and titanium alloy

INDICATIONS:

The Stackable 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.

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

PERFORMANCE DATA:

Biomechanical testing, including static axial compression, torsional loading and cantilever beam testing, were conducted.

Clinical data were provided to demonstrate the performance of the device in patients with spine tumors.

SUBSTANTIAL EQUIVALENCE:

The Stackable Cage System is substantially equivalent to the Rezaian Spinal Fixator (K841189). The claim of substantial equivalence is made solely for regulatory purposes and shall not be deemed to be an assertion of equivalence under U.S. and international patent laws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 3 1999

Mr. William Christianson
Vice President, Regulatory Affairs
DePuy AcroMed, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K990148
Trade Name: Stackable Cage™ System
Regulatory Class: II
Product Code: MQP
Dated: June 4, 1999
Received: June 7, 1999

Dear Mr. Christianson:

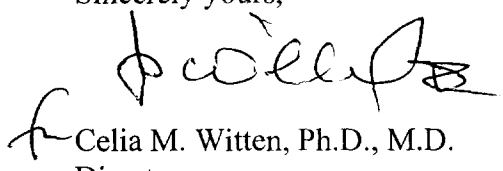
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K990148

DEVICE NAME: Stackable Cage™ System

INDICATIONS FOR USE:

The Stackable 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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Concurrent of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (per 21 CFR 801.109) OR Over-the-Counter-Use _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990148