

DEC 3 1998

K983583



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Cleveland, Ohio 44115

USA

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(K) CONTACT: Lynnette Whitaker
Manager, Clinical and Regulatory Affairs

TRADE NAME: DePuy AcroMed MOSS Miami Spinal System

COMMON NAME: Rod and screw spinal instrumentation

CLASSIFICATION: 888.3050 Spinal interlaminar fixation orthosis
888.3070 Pedicle screw spinal system
888.3060 Spinal intervertebral body fixation orthosis

DEVICE PRODUCT CODE: Product code: 87KWP
87MNH
87MNI
87KWQ

SUBSTANTIALLY EQUIVALENT DEVICES: DePuy Motech MOSS Miami Spinal System (for posterior use)
DePuy Motech MOSS Miami Spinal System - Pedicle Fixation
DePuy Motech MOSS Miami Spinal System - anterior indications
DePuy Motech MOSS Miami 4.0 mm Rod Spinal Subsystem
DePuy Motech Universal Spinal System and Transverse Rod Stabilizer
Biedermann Motech MOSS Miami Spinal System, 6.0mm Rod Subsystem
DePuy Motech Titanium MOSS Miami Spinal System
DePuy Motech MOSS Miami Spinal System Ratchet Rods
DePuy Motech MOSS Miami Titanium Sacral Extenders

DEVICE DESCRIPTION AND INTENDED USE:

The MOSS MIAMI System is available in either Stainless Steel or Titanium. The following components are available in Stainless Steel: longitudinal rods, monoaxial screws, polyaxial screws, reduction screws, hooks, reduction hooks, transverse connectors, axial connectors, staple washers and sacral extenders. The following components are available in Titanium: longitudinal rods, monoaxial screws, polyaxial screws, hooks, transverse connectors, axial connectors, washers, staple washers, and sacral extenders. The design, intended use, and material of these components have been cleared in previous 510(k) submissions.

When used as a posterior, noncervical screw fixation system or as an anterior, thoracic/lumbar screw fixation system, the MOSS Miami Spinal System is intended to treat scoliosis, kyphosis and lordosis, fracture, loss of stability due to tumor, spinal stenosis, spondylolisthesis, a previously failed fusion surgery or degenerative disc disease (i.e. discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

When used as a pedicle screw fixation system of the noncervical spine in skeletally mature patients, the MOSS Miami Spinal System is indicated for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

The MOSS Miami Spinal System is also indicated for pedicle screw fixation in skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) at the L5-S1 vertebral joint, having fusions with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 and below), and for whom the device system is intended to be removed after the development of a solid fusion mass.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The components of the MOSS Miami Spinal System are identical to the components of the other MOSS Miami Spinal Systems which have been cleared by FDA for certain anterior and posterior uses and for pedicle fixation use indications.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 1998

Ms. Lynnette Whitaker
Manager, Clinical and Regulatory Affairs
DePuy Motech AcroMed, Inc.
3303 Carnegie Avenue
Cleveland, Ohio 44115

Re: K983583
MOSS® Miami Spinal System – expanded uses
Regulatory Class: II
Product Codes: MNI, KWP, KWQ, and MNH
Dated: October 9, 1998
Received: October 13, 1998

Dear Ms. Whitaker:

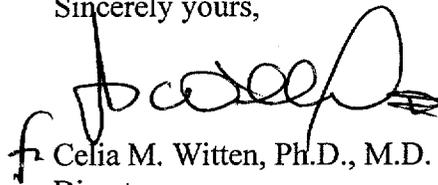
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 requirements, 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" (21CFR 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

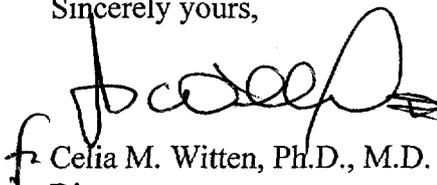
Enclosure

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Enclosure