

SEP 14 1998

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

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

**510(K) CONTACT:** Sally Foust  
Senior Regulatory Submissions Associate  
DePuy Orthopaedics, Inc.  
(219) 372-7455

**TRADE NAME:** DePuy Motech MOSS Miami Spinal System

**COMMON NAME:** Hook, rod and screw spinal instrumentation,  
Screw and rod spinal instrumentation, and  
Pedicule Screws

**CLASSIFICATION:** 888.3050 Spinal interlaminar fixation orthosis  
888.3060 Spinal intervertebral body fixation orthosis,  
and pedicle screws have not been classified

**DEVICE PRODUCT CODE:** 87 KWQ, KWP, MNH

**SUBSTANTIALLY  
EQUIVALENT DEVICES:** DePuy Motech MOSS Miami Spinal Systems:  
K933881, K950697, K953915, K955348, K964024  
AcroMed VSP & ISOLA:  
K944736, K951116, K951657, K952236, K963639

**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.

The MOSS Miami Spinal System is intended for non-cervical use in the spine.

When used with anterior screw fixation or posterior hook, non-pedicule screw fixation 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

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surgery or degenerative disc disease (i.e. discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies).

When used with pedicle screw fixation, the MOSS Miami Spinal System is intended for use in 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.

The line extension covered in this submission are additional screw components to the existing 5mm Stainless Steel and 5.5mm Titanium alloy versions of the MOSS Miami Spinal System. The additional screws consist of Stainless Steel and Titanium 5-7mm diameter polyaxial and monoaxial screws in 5mm increments to provide screws lengths from 25mm to 90mm. The additional screws also consist of Titanium 8mm diameter monoaxial screws in 5mm increments to provide screws lengths from 25mm to 90mm, and the addition of Stainless Steel 8mm monoaxial and polyaxial and of Titanium 8mm polyaxial screws in 14 lengths from 25mm to 90mm in 5mm increments. Additionally, the intended uses of the 7mm monoaxial and polyaxial screws, which were previously cleared as part of the 5mm stainless steel version of this system, were expanded to include anterior use.

#### **BASIS OF SUBSTANTIAL EQUIVALENCE:**

The design, intended use, and materials of the subject additional MOSS Miami Spinal Systems screws have been cleared in previous 510(k) submissions. The additional screws are identical to the screws in the MOSS Miami Spinal Systems which have been cleared by FDA for certain anterior and posterior uses and for certain pedicle fixation use indications. The only differences between the previously cleared screws and those submitted are additional lengths in the Stainless Steel and Titanium 5mm, 6mm, and 7mm diameter monoaxial and polyaxial screw lines; additional lengths in the Titanium 8mm monoaxial screw line; the addition of Stainless Steel 8mm monoaxial and polyaxial and of Titanium 8mm polyaxial screws in 14 lengths from 25mm to 90mm in 5mm increments; and the additional indication of non-cervical anterior use of the Stainless Steel 7mm monoaxial and polyaxial screws.

The subject screw lengths are similar to those available in other spinal implant systems, including the sacral and iliac screws in the AcroMed ISOLA System. The AcroMed ISOLA System is similar in design, material (Stainless Steel and Titanium), and indications and with screws sizes from 25mm to 100mm.

Based on the information provided, DePuy believes that the subject additional screws in the MOSS Miami Spinal Systems and the additional indication of non-cervical anterior use of the Stainless Steel 7mm monoaxial and polyaxial screws are substantially equivalent to other currently legally marketed spinal systems' screws.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SEP 14 1998

Ms. Sally Foust  
Senior Regulatory Submissions Associate  
DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
P.O. Box 988  
Warsaw, Indiana 46581-0988

Re: K982511  
MOSS@ Miami Spinal System - Additional Screws  
Regulatory Class: II  
Product Codes: MNH, KWP, and KWQ  
Dated: July 17, 1998  
Received: July 20, 1998

Dear Ms. Foust:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal, Food, Drug, and Cosmetic Act (Act). This decision is based on your device system being found equivalent only to similar device systems labeled and intended for patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass. You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment for indications other than severe spondylolisthesis, as described above, would cause the device system to be adulterated under 501(f)(1) of the Act.

This device system, when intended for pedicular screw fixation/attachment to the spine for indications other than severe spondylolisthesis, as described above, is a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. All labeling for this device, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system using pedicle screws is intended only for patients: (a) having severe

spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine; and (d) who are having the device removed after the development of a solid fusion mass.

2. You may not label or in anyway promote this device system for pedicular, screw fixation/attachment to the cervical, thoracic or lumbar vertebral column for intended uses other than severe spondylolisthesis, as described above. The package insert must include the following statements:

**WARNINGS:**

- When used as a pedicle screw system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar - first sacral (L5-S1) vertebral joint.
- The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 vertebral joint.
- Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
- Potential risks identified with the use of this device system, which may require additional surgery, include:  
  
device component fracture,  
loss of fixation,  
non-union,  
fracture of the vertebra,  
neurological injury, and  
vascular or visceral injury.

See Warnings, Precautions, and Potential Adverse Events sections of the package insert for a complete list of potential risks.

3. Any pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described by item 1, for this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device for pedicular screw fixation/attachment for intended uses other than severe spondylolisthesis, as described above, must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.
4. Any previous warning statements identified as part of previous 510(k) clearances or required by OC/Labeling and Promotion which stated that a component/system was not approved for screw fixation into the pedicles of the spine must be replaced by the warnings of items 1 and 2 above.

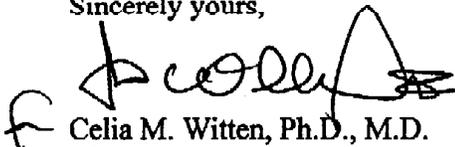
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If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal 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.

FDA advises that the use of your device system with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or those of other manufacturers, may also be required. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

A handwritten signature in black ink, appearing to read 'C. Witten', with a large, 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

510(k) Number 982511

*mm 9/11/98*

Device Name:

DePuy Motec MOSS Miami Spinal System, Additional Screw Components

Indications for Use:

The MOSS Miami Spinal System is intended for non-cervical use in the spine.

When used with anterior screw fixation or posterior hook, non-pedicle screw fixation 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 with pedicle screw fixation, the MOSS Miami Spinal System is intended for use in 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.

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Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number

*982511*

Prescription Use  X

OR

Over-The Counter Use    

(Per 21 CFR 801.109)

*H*