

K974573

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

510(K) CONTACT: Cheryl K. Hastings
Manager, Regulatory Submissions

TRADE NAME: DePuy Motech
MOSS Miami Spinal System

COMMON NAME: Hook, rod and screw spinal instrumentation

CLASSIFICATIONS: 888.3050 Spinal interlaminar fixation orthosis
888.3060 Spinal intervertebral body fixation orthosis
Unclassified

DEVICE PRODUCT CODE: Product codes: 87 KWP, 87 KWQ, 87 MNH

SUBSTANTIALLY EQUIVALENT DEVICES: MOSS Miami Sacral Extenders - K972568

DEVICE DESCRIPTION AND INTENDED 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 back 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 fusion with autogenous bone graft, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw attachment are L3 and below), and for whom the device system is intended to be removed after the development of a solid fusion mass.

The MOSS Miami Spinal System is available in either Stainless Steel or Titanium. The following components are currently available in Stainless Steel: 4 and 5mm diameter longitudinal rods, 5-7mm diameter monoaxial screws, 5-7mm diameter polyaxial screws, hooks, transverse connectors, axial connectors, staple washers, and sacral extenders. The following components are currently available in Titanium: 5.5mm diameter longitudinal rods, 5-8mm diameter monoaxial screws, 5-7mm diameter polyaxial screws, hooks, transverse connectors, axial connectors, washers and staple washers.

This product is an addition to the existing MOSS Miami Spinal System and consists of: a sacral extender available in multiple lengths from 2cm to 20cm manufactured from Ti-6Al-4V alloy. This product uses the same inner screw and outer locking nut as the hooks and screws previously cleared in K955348 for use with the Titanium MOSS Miami Spinal System.

The sacral extender consists of a body and a longitudinal extension "arm". The body is intended to be attached to a 5.5mm MOSS Miami Titanium rod placed transversely through the iliac wings and fixed with sacral screws. The extension arm extends longitudinally and allows attachment of MOSS Miami Titanium screws or hooks. The attachment mechanism between the sacral extender body and the longitudinal rod is the same mechanism as is used for the screws and hooks in the MOSS Miami Spinal System cleared for use in K955348.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The MOSS Miami Titanium Sacral Extender is substantially equivalent to the MOSS Miami Sacral Extender previously cleared in K972568 in that they have similar designs and the same intended use. The only differences between the MOSS Miami Titanium Sacral Extenders described in this submission, and the predicate MOSS Miami Sacral Extenders are: 1) a change in material from stainless steel to titanium alloy and 2) slight dimensional changes (increases in the extender arm diameter and the slot width from 5.0mm to 5.5mm to accommodate use with the MOSS Miami Titanium system).



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1998

Ms. Cheryl K. Hastings
Manager, Regulatory Submissions
DePuy® Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K974573
Titanium Sacral Extender to be used as part
of the MOSS-Miami Spinal System
Regulatory Class: II
Product Codes: MNH, KWP, and KWQ
Dated: December 5, 1997
Received: December 8, 1997

Dear Ms. Hastings:

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.

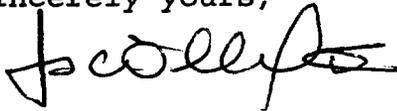
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


f 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) K974573

Device Name DePuy Motech MOSS Miami Titanium Sacral Extender

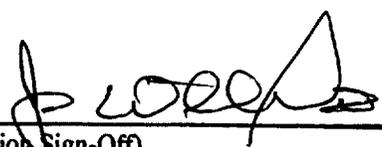
Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K974573

Prescription Use X

OR
(Per 21 CFR 801.109)

Over-The Counter Use