K992168

SEP 23 1999

510(k) Summary

Proprietary name: Moss Miami 6.35mm Polyaxial Screw

Common Name: Polyaxial Pedicle Screw

Classification Name and Reference: Spinal interlaminal fixation orthosis, §888.3050
Pedicle screw spinal fixation §888.3070

Proposed Regulatory Class: Class II

Device Product Code: 87/KWP, 87/MNH, 87/MNI, 87/KWQ

The Moss Miami 6.35mm Polyaxial screws described in this submission are modifications of the previously cleared Moss Miami Polyaxial Screws. The head portion of the screw has been increased to allow the placement of a 6.35mm (1/4 inch) rod. The modified screws are available in the same thread diameters and lengths as the existing screws, namely 6.0mm, 7.0mm, and 8.0mm diameters and 30mm to 55mm lengths.

The 6.35mm polyaxial screws are manufactured from either implant grade titanium alloy or stainless steel that conform to ASTM standards F-136 and F-138, respectively.

Testing was presented to evaluate the performance characteristics of the modified polyaxial screws. Specific tests of the construct included static tests in compression bending and torsion, and fatigue testing in compression bending.

The substantial equivalence of the modified Polyaxial screws is based on an equivalence in intended use, materials, design, and relative indications and contraindications to the existing Moss Miami Polyaxial Screw System (K983583, K953882, K950697 and K933881 (stainless steel) and K983583, K964024, K955348 (titanium alloy).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 1999

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

Re: K992168
Trade Name: Moss Miami 6.35mm Polyaxial Screw to be used with the Moss Miami Spinal System
Regulatory Class: II
Product Code: KWQ, KWP, MNH and MNI
Dated: June 24, 1999
Received: June 28, 1999

Dear Mr. Maas:

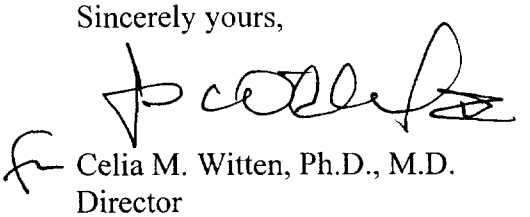
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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

Indications for Use

510(k) Number (if known): K992168

Device Name: Moss Miami Spinal System

Indications for Use:

When used as a posterior, noncervical hook, and/or sacral/iliac 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 –S1), and for whom the device system is intended to be removed after solid fusion is attained.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (per 21 CRF 801.109) OR Over-The-Counter Use _____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992168