MAY 0 8 2002

IX. 510(k) Summary

SUBMITTER: DePuy AcroMed, Inc.
325 Paramount Drive
Raynham, MA 02767

CONTACT PERSON: Lisa A. Gilman

DATE PREPARED: March 29, 2002

CLASSIFICATION NAME: Appliance, Fixation, Spinal Interlaminal
Orthosis, Spinal Pedicle Fixation

PROPRIETARY NAME: MONARCH SPINE SYSTEM COMMERCIALLY PURE TITANIUM SPINAL ROD

PREDICATE DEVICES: MONARCH Spine System Spinal Rod (K010576)

DEVICE DESCRIPTION: The MONARCH Commercially Pure Titanium Spinal Rod is a 6.35mm diameter rod available in various lengths.

INTENDED USE: The MONARCH Spine System when used with pedicle screws is indicated for degenerative spodylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). Levels of fixation are for the thoracic, lumbar and sacral spine.

The MONARCH Spine System is also indicated for pedicle screw fixation for Grade 3 and 4 spondylolisthesis at L5-S1, in skeletally mature patients, utilizing autologous bone graft, having the device fixed or attached to the lumbar or sacral spine and intended to be removed after solid fusion is attained. Levels of attachment for this indication range from L3 to the sacrum.

	The MONARCH Spine System when not used with pedicle screws is intended for posterior hook, wire, and/or sacral/iliac screw fixation from T1 to the ilium/sacrum. The non-pedicle screw indications are spondylolisthesis, degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), deformities (scoliosis, lordosis and kyphosis), tumor, fracture and previous failed fusion.
MATERIALS:	Manufactured from Grade 3 commercially pure (cp) titanium conforming to ASTM F-67.
PERFORMANCE DATA:	Performance data were submitted to characterize the MONARCH Commercially Pure Titanium Spinal Rod.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 8 2002

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

Re: K021148
Trade/Device Name: MONARCH Spinal System Commercially Pure Titanium Spinal Rod
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: April 5, 2002
Received: April 10, 2002

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,

Miriam C. Provost

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

Enclosure

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III. Indications for Use

510(k) Number (if known): K021148

Device Name: MONARCH Spine System Spinal Rod

Indications For Use:

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: _____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021148