

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K973060

NOV - 3 1997

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

510(K) CONTACT: John D. Van Vleet
Manager, Clinical and Regulatory Applications
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988

TRADE NAME: DePuy Motech™ Profile™ Anterior Thoracolumbar
Plate System

COMMON NAME: Anterior Thoracic/Thoracolumbar Plate

CLASSIFICATION: 888.3060: Spinal intervertebral body fixation
orthosis

DEVICE PRODUCT CODE: 87 KWQ

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy Motech MOSS Miami Titanium Spinal
System
DePuy Motech MOSS Miami Spinal System -
4.0mm
Amset Anterior Locking Plate System

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Motech Profile Anterior Thoracolumbar Plate System consists of 10 thoracolumbar and 12 high thoracic plates of various lengths (40-120mm); 9 cancellous screws in varying lengths (20-60mm); 8 cancellous bolts in progressive lengths (25-60mm) with locking nuts and screws; and four bone graft screws of different lengths (15, 20, 25, 30mm).

The anterior thoracolumbar plates are implanted using 2 cancellous bolts placed through the plate's bolt slots and fixed with locking nuts and screws, 2 cancellous screws placed through the plate's threaded screw holes, and an optional graft screw which can be placed through the plates's center slot to provide fixation between the plate and a strut graft if desired.

The high thoracic plates are implanted using 4-6 cancellous screws, placed through the plate's screw holes.

The DePuy Motech Profile Anterior Thoracolumbar Plate System is intended for use in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Motech Profile Anterior Thoracolumbar (ATL) Plates are substantially equivalent to the DePuy Motech MOSS Miami Spinal System Titanium sub-system and 4.0mm sub-system in that all of these systems are intended for anterolateral fixation to the thoracic and thoracolumbar spine (T1-L5) for the same indications. Both the ATL plates and the MOSS Miami Titanium sub-system are manufactured from Ti-6Al-4V alloy. Mechanical testing shows that the fatigue strength of the ATL plates is, at least, equivalent to that of both the MOSS Miami Titanium sub-system and the MOSS Miami 4.0mm sub-system.

The DePuy Motech Profile ATL Plates are also substantially equivalent to the Amset ALPS plates in that both systems are intended for anterior stabilization of the spine and the designs of the systems are similar. The major difference between these systems is that the Amset ALPS plates are manufactured from 316 LVM Stainless Steel.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K973060
Profile™ Anterior Thoracolumbar Plate System
Regulatory Class: II
Product Code: KWQ
Dated: October 17, 1997
Received: October 20, 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). 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 would cause the device system to be adulterated under 501(f)(1) of the Act.

FDA identifies that any device system, if intended for use in pedicular screw fixation/attachment, except for some limited indications, would be found not substantially equivalent and would be 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. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the package insert must include the following statement, "**WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.";
2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for the specific use(s) described in the enclosure only; and
3. Pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column, except for limited indications, of any device system 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 system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

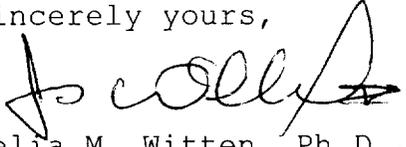
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 the subject device system and/or device components 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 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,


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

INDICATIONS

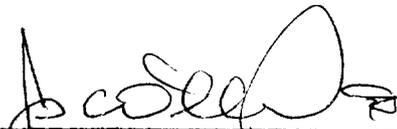
510(k) Number (if known) K973060

Device Name: DePuy Motech™ Profile™ Anterior Thoracolumbar Plate System

Indications for Use:

The DePuy Motech Profile Anterior Thoracolumbar Plate System is intended for use in the treatment of thoracic and thoracolumbar (T1-L5) spine instability as a result of fracture, (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973060

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

