

K971730

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

510(K) CONTACT: Arlene C. Saull, RAC
Manager, Medical Device Submissions
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988

TRADE NAME: DePuy Motech PEAK™ Polyaxial Anterior
Cervical Plate System

COMMON NAME: Anterior Cervical Plate

CLASSIFICATION: 888.3060: Spinal intervertebral body fixation
orthosis

DEVICE PRODUCT CODE: 87 KWQ

**SUBSTANTIALLY
EQUIVALENT DEVICES:** DePuy Motech PEAK Anterior Compression Plate
System

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Motech PEAK Polyaxial Anterior Cervical Plate System consists of 30 different Ti-6Al-4V ELI plates. The plates are available in 4 design segments (1, 2, 3 or 4 "I shaped" segments), each being available in a variety of lengths. The system also includes 3 different Ti-6Al-4V ELI cancellous screws.

The 4.0mm screw is utilized in the plate holes which are located around the periphery of the plate and are intended for fixation between the plate and vertebral bodies that have been spanned by the construct. The 4.35mm screws are intended for use in the same manner as the 4.0mm screws. The 4.35mm bone screw is intended to be used in the event that the surgeon must remove and reinsert a 4.0mm bone screw. The 4.35mm bone screw is larger and therefore would allow a surgeon to regain purchase in the previous screw hole.

The graft screw is optionally used in the case of a corpectomy and subsequent replacement with a strut graft, to obtain fixation between the graft and plate.

The DePuy Motech PEAK Polyaxial Anterior Cervical Plate System is intended for anterior cervical screw fixation in the treatment of anterior cervical spine instability as a

result of fractures (dislocations and subluxations), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), or a failed previous cervical spine surgery.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Motech PEAK Polyaxial Anterior Cervical Plate System is similar in material, design and intended use to the DePuy Motech PEAK Anterior Compression Plate System. Both of these systems consist of Ti-6Al-4V ELI bone plates and screws intended for use in anterior stabilization of various cervical spine instabilities. Mechanical testing indicates that the fatigue strength of the DePuy Motech PEAK Polyaxial Anterior Cervical Plate System is equivalent or better than that of the DePuy Motech PEAK Anterior Compression Plate System.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 1997

Arlene C. Saull, RAC
Senior Submissions Associate
DePuy, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K971730
DePuy Motech PEAK™ Polyaxial Anterior
Cervical Plate System
Regulatory Class: II
Product Code: KWQ
Dated: August 20, 1997
Received: August 21, 1997

Dear Ms. Saull:

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.

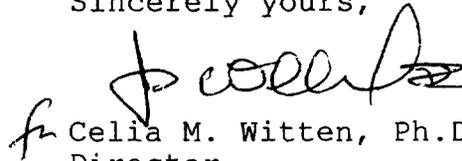
FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new

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,


for 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

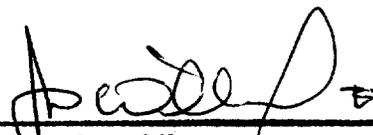
510(k) Number (if known) K971730

Device Name DePuy Motech PEAK™ Polyaxial Anterior Cervical Plate System

Indications for Use:

The DePuy Motech PEAK Polyaxial Anterior Cervical Plate System is intended for anterior cervical screw fixation in the treatment of anterior cervical spine instability as a result of fractures (dislocations and subluxations), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), or a failed previous cervical spine surgery.

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971730

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

