SEP 14 1998

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K982483

NAME OF FIRM:

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(K) CONTACT:

Arlene C. Saull, RAC
Sr. Submissions Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988

TRADE NAME:

Motech PEAK™ Fixation System

COMMON NAME:

Bone Fixation Appliance

CLASSIFICATION:

Class II, per 21 CFR, 888.3030: Single/multiple component metallic bone fixation appliances and accessories.

DEVICE PRODUCT CODE:

87 HRS Plate, Fixation, Bone

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy Motech PEAK™ 3mm Rod Fixation System
ACE Universal Reconstruction Plates

INTENDED USE AND DEVICE DESCRIPTION: (The subject devices are part of the DePuy Motech PEAK 3mm Rod Fixation System.)

The DePuy Motech PEAK 3mm Rod Fixation System is intended for use in treating fractures of the pelvis, acetabulum, clavicle, scapula, and distal humerus. The predicate system consists of 3mm rods in various lengths, rod connectors, pin nut, and bone screws. The subject devices consist of a Transverse Connector Hook used to connect the 3mm rods at right angles or transversely across the fracture; an Inner Screw used to hold the rods and hook connectors together; and the Transverse Connector Assembly that consists of the subject Transverse Hook Connector, subject Inner Set Screw, and the predicate 3mm Fixation Rod (K980368).

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject devices are made from similar material as the predicate DePuy Motech PEAK 3mm Rod Fixation System, and the predicate ACE Universal Reconstruction Plates. Both predicate systems and the subject devices are intended to treat fractures of the pelvis, acetabulum, clavicle, scapula, and distal humerus, using rigid fixation to secure the fracture. Mechanical testing provided with the premarket notification for the DePuy Motech PEAK 3mm Fixation Rod System exceeds that of the ACE 3.5mm Reconstruction Plate System.

END OF 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FORM

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1998

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

Re: K982483
Trade Name: DePuy Motech™ PEAK™ Transverse Connector
Regulatory Class: II
Product Code: HRS
Dated: July 15, 1998
Received: July 17, 1998

Dear Ms. Saull:

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 (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) _____

Device Name PEAK™ Fixation System 3.0mm

The subject devices (inner screw, transverse connector hook and transverse rod connector assembly) are being added to the 3.0mm PEAK Fixation System.

Indications for Use:

The DePuy Motech PEAK 3mm Fixation Rod System is intended for use in treating fractures of the pelvis, acetabulum, clavicle, scapula, and distal humerus.

Concurrence of CDRH, Office of Device Evaluation:

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982483

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