K980368

DePuy®

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

DePuy Inc.
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APR 14 1998

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

510(K) CONTACT: Lynnette Whitaker
Manager, Clinical/RegulatoryAffairs

TRADE NAME: DePuy Motech PEAK 3mm Fixation Rod System

COMMON NAME: Bone Fixation Rod

CLASSIFICATION: 888.3030 Single/multiple component metallic bone fixation appliance and accessories

DEVICE PRODUCT CODE: Product code: 87 HRS

SUBSTANTIALLY EQUIVALENT DEVICES: ACE 3.5 mm Reconstruction Plate

INTENDED USE AND DEVICE DESCRIPTION:
The DePuy Motech PEAK 3mm Fixation Rod System is intended for use in treating fractures of the pelvis, acetabulum, clavicle, scapula, and distal humerus. The system consists of 3 mm rods, ranging in length from 60mm to 180mm, and 3 styles of rod connectors, classified as right, left, and neutral. The rods are secured to the connectors using a pin nut. Screws are used to secure the connectors to the bone.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The DePuy Motech PEAK 3mm Fixation Rod System is similar in material, design and intended use to the ACE 3.5 mm Reconstruction Plate. The systems are intended to treat fractures of the pelvis, acetabulum, clavicle, scapula, and distal humerus, using rigid fixation with bone screws to secure the fracture. Mechanical testing shows that in 4 point bending the rigidity, strength and stiffness of the DePuy Motech PEAK 3mm Fixation Rod System exceeds that of the ACE 3.5 mm Reconstruction Plate System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 1998

Ms. Lynnette Whitaker
Manager, Clinical and Regulatory Affairs
DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K980368
DePuy Motech PEAK™ 3mm Fixation Rod System
Regulatory Class: II
Product Code: HRS
Dated: January 28, 1998
Received: January 30, 1998

Dear Ms. Whitaker:

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 Stephen Rhodes

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

510(k) Number (if known) _____

Device Name DePuy Motech PEAK 3mm Fixation Rod 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

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980368

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