FEB 1 1999

DePuy ACE™

K990120

510(k) SUMMARY

NAME OF FIRM:

DePuy ACE Medical Company
2260 East El Segundo Boulevard
El Segundo, CA 90245

510(k) CONTACT PERSON:

Kathleen Dragovich
Regulatory Affairs Specialist
DePuy ACE Medical Company

TRADE NAME:

DePuy ACE TiMAX™ Medial Pilon Plate

COMMON NAME:

Bone Fixation Plate

CLASSIFICATION:

888.3030 Single/multiple component metallic bone fixation appliances and accessories.

DEVICE CODE:

87HRS

SUBSTANTIALLY EQUIVALENT DEVICE:

DePuy ACE TiMAX™ Pilon Plate

INTENDED USE:

- Pilon fractures - distal tibial intra-articular fractures
- High medial malleolar fractures
- Low boot top type rotational distal extra-articular shaft fractures

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The DePuy ACE TiMAX™ Medial Pilon Plate is a fracture fixation plate intended for use in pilon fractures (distal tibial intra-articular fractures), high medial malleolar fractures, and low boot type rotational distal extra-articular tibial shaft fractures. The plate profile consists of a shaft portion with compression slots, a diamond-shaped structure with three screw holes and a central cutout. There are also two k-wire guide holes for the distal metaphyseal region and a partial hole with countersink in the distal end of the cutout. The plate thickness is 1.6 mm in the shaft region and is decreased to 1 mm in the distal region to facilitate contouring and maintaining anatomic reduction of the fracture.

The plate is supplied with a form along the long axis of the plate and the surgeon is expected to complete the contouring to match the individual patient anatomy. The open architecture of the distal region allows easy contouring by the surgeon to accommodate the anatomical topography of the distal tibia and also to promote fracture healing. The screw holes have been designed to allow low profile interaction with the heads of the following screws: 3.5mm cortical screw and 4.0mm cancellous screw. The plate is a universal plate and can be used on the right or left tibia.

The DePuy ACE TiMAX™ Medial Pilon Plate is manufactured from Titanium 6Al-4V ELI (per ASTM standard F136).

DePuy ACE TiMAX™ Medial Pilon Plate is a minor modification to the DePuy ACE TiMAX™ Pilon Plate and has been shown to have similar strength and bending properties.

Based on the above information, DePuy ACE Medical Company firmly believes that the new DePuy ACE TiMAX™ Medial Pilon Plate is substantially equivalent to the DePuy ACE TiMAX™ Pilon Plate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 1999

Mr. Paul Doner
Director, Regulatory and Clinical Affairs
DePuy Ace Medical Company
2260 East El Segundo Boulevard
El Segundo, California 90245-4694

Re: K990120
DePuy ACE TiMAX™ Medical Pilon Plate
Regulatory Class: II
Product Code: HSB
Dated: January 12, 1999
Received: January 13, 1999

Dear Mr. Doner:

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

DePuy ACE™

510(k) Number (if known) K990120

Device Name: **DePuy ACE TiMAX™ Medial Pilon Plate**

Indications for Use:

- Pilon fractures - distal tibial intra-articular fractures
- High medial malleolar fractures
- Low boot top type rotational distal extra-articular shaft fractures

Concurrence of CDRH, Office of Device Evaluation

Sheila Blunda for C.M.V

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990120

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