K983853

DEC 22 1998

DePuy ACE™

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™ Meta Plate

COMMON NAME:

Plate, Fixation, Bone

CLASSIFICATION NAME:

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

REGULATORY CLASS:

Class II

DEVICE CODE:

87HRS

SUBSTANTIALLY EQUIVALENT DEVICES:

Synthes Cloverleaf Plate, P/N 240.23

INTENDED USE:

- Distal intra-articular tibia fractures
- Proximal tibia fractures
- Proximal and distal humerus fractures

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The DePuy ACE TiMAX™ Meta Plate has a triangular shaped projection at the end of a shaft portion. The shaft portion has compression slots with a pitch of 13mm which matches the small fragment, active compression plate. The plate thickness is 1.6mm in the shaft region and transitions to a thickness of 1mm in the triangular shaped metaphyseal region. A cut-out in the middle of the metaphyseal region provides an open architecture to facilitate contouring by the surgeon, to accommodate the anatomical topography of the distal tibia as well as other indicated anatomical regions, and also to promote fracture healing. The screw holes have been designed to allow low profile interaction with the heads of the 3.5mm cortical screw and the 4.0mm cancellous screw. The plate will be offered in two sizes: small (width=30mm) and large (width=38mm) with various lengths.

The DePuy ACE TiMAX™ Meta Plate is similar in design and function to the Synthes Cloverleaf plate (pre-amendment device).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1998

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

Re: K983853
DePuy ACE TiMAX™ Meta Plate
Regulatory Class: II
Product Code: HRS
Dated: October 27, 1998
Received: October 30, 1998

Dear Mr. Doner:

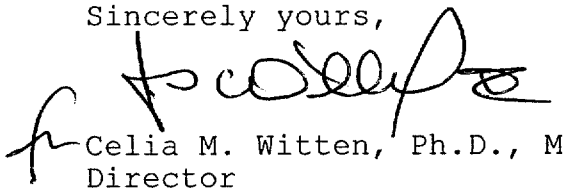
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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) K 983853

Device Name: **DePuy ACE TiMAX™ Meta Plate**

Indication for User:

- Distal intra-articular tibia fractures
- Proximal tibia fractures
- Proximal and distal humerus fractures

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983853

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