JUL 29 1998

DePuy ACE™

K981775

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™ Calcaneal Peri-Articular Plate

COMMON NAME:

Bone Fixation Plate

CLASSIFICATION:

888.3030 Single/multiple component metallic bone fixation appliances and accessories

DEVICE CODE:

87HRS

SUBSTANTIALLY EQUIVALENT DEVICE:

Synthes Calcaneal Plates

INTENDED USE:

The DePuy ACE TiMAX™ Calcaneal Peri-Articular Plates are designed to assist the surgeon in the management of:

- Intra-articular fractures of the calcaneus
- Extra-articular fractures of the calcaneus

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The DePuy ACE TiMAX™ Calcaneal Peri-Articular Plate is a fracture fixation plate intended for both intra-articular and extra-articular fractures of the calcaneus. The plate profile is an enclosed box structure with a smaller anterior section, larger posterior section, a distal to posterior angled strut for additional strength and 12 anatomically relevant screw hole locations. The plate thickness is 1mm and provides a low profile fit to reduce peroneal tendon irritation. The open architecture of the plate allows easy contouring by the surgeon to accommodate the anatomical topography of the calcaneous and also to promote fracture healing. The enclosed box structure has been shown in biomechanical testing to be stronger in intra and extra articular fractures of the calcaneous as well as analysis of the tuberosity shifting laterally and distally due to loading from the talus. The screw holes are also contourable, designed to allow low profile interaction with the heads of the following screws: 3.5mm cortical screw, 4.0mm cancellous screw, and the periarticular screw. The plate has countersinks on both sides to allow universal application of the plate; the same plate may be used on either the right or left side. The plate will be offered in two sizes: small and large. The DePuy ACE TiMAX™ Calcaneal Peri-Articular Plate is manufactured from Titanium 6Al-4V ELI (per ASTM standard F136).

The DePuy ACE TiMAX™ Calcaneal Peri-Articular Plate is similar in design and function to the Synthes Calcaneal Plate (510(k) approval K915818).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1998

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

Re: K981775
DePuy ACE TiMAX™ Calcaneal Peri-Articular Plate
Regulatory Class: II
Product Code: HRS
Dated: May 18, 1998
Received: May 20, 1998

Dear Mr. Doner:

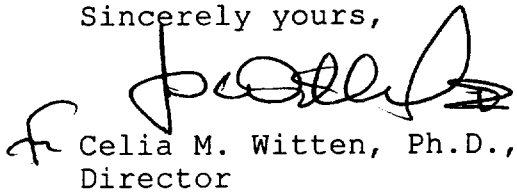
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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) K981775

Device Name: **DePuy ACE TiMAX™ Calcaneal Peri-Articular Plate**

Indications For User:

The DePuy ACE TiMAX™ Calcaneal Peri-Articular Plates are designed to assist the surgeon in the management of:

- Intra-articular fractures of the calcaneus
- Extra-articular fractures of the calcaneus

Concurrence of CDRH, Office of Device Evaluation

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

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981775

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