K993465

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DePuy
a Johnson & Johnson company

JAN 11 2000

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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:

DePuy ACE Calcaneal Peri-Articular Plate

COMMON NAME:

Bone Fixation Plate

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 ACE Calcaneal Peri-Articular Plate
Synthes Calcaneal Plate

INTENDED USE AND DEVICE DESCRIPTION:

The Calcaneal Peri-Articular Plate is designed to assist the surgeon in the management of the following:

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

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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 a number of anatomically relevant screw hole locations. The plate provides a low profile fit to reduce peroneal tendon irritation.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The *subject* devices are essentially identical (except for size) to the *predicate DePuy ACE calcaneal plate* devices cleared by 510(k) on July 29, 1998, in that both are made from the same material; the indications remain the same and the design is essentially the same. The *subject DePuy ACE calcaneal plates* are similar in design and function to the *predicate Synthes Calcaneal Plate* (510(k) K915818). Based on the information provided in this premarket notification, DePuy considers the subject devices to be substantially equivalent to the existing DePuy ACE Calcaneal Plates and the Synthes calcaneal plates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2000

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

Re: K993465
Trade Name: DePuy ACE Calcaneal Peri-Articular Plate
Regulatory Class: II
Product Code: HRS
Dated: October 12, 1999
Received: October 13, 1999

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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS

510(k) Number (if known) K993465

Device Name **DePuy ACE Calcaneal Peri-Articular Plate**

Indications for Use:

The DePuy ACE 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

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Concurrence of CDRH, Office of Device Evaluation:

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993465

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