

3/23/99



K990392

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
310 414-6257

TRADE NAME: DePuy ACE Spider Plate

COMMON NAME: Plate, Fixation, Bone

CLASSIFICATION: 888.3030 Single/Multiple component metallic
bone fixation appliances and accessories

DEVICE CODE: 87HRS

SUBSTANTIALLY EQUIVALENT DEVICES: DePuy ACE Spider Plate
Acumed Suture Washer
DePuy ACE Orthopaedic Washer

INTENDED USE:

- Fixation of Metaphyseal Fractures of the Distal Tibia
- Proximal Metaphyseal Tibial Fractures
- Calcaneus Body Fractures
- Proximal Humeral Head/Shaft Fractures
- Distal Femur Fracture – Comminuted Shaft Fractures
- **Fixation of soft tissue, such as tendon and ligaments, to bone**

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The DePuy ACE Spider Plate has been previously cleared by the FDA for fracture fixation. Intended Uses are being expanded to include **the fixation of soft tissue, such as tendon and ligaments, to bone.**

The DePuy ACE Spider Plate is a low profile, “one-hole plate” design with a family of diameters to account for various fracture locations and spiked projections to engage the metaphyseal bone in any anatomic region. **The DePuy ACE Spider Plate is also indicated for the fixation of soft tissue, such as tendon and ligaments, to bone in orthopaedic procedures.** Five different overall diameters (three small, two large) have been designed to provide adequate clinical flexibility. The top profile has an overall diameter with a central hole for screw fixation; two of the washers have an offset screw hole with an additional k-wire hole. There are eight radiused cutouts producing eight arms that are designed to engage the metaphyseal bone.

The Acumed Suture Washer (K965028) is intended for **soft tissue fixation**, small and large bone fixation and is used in conjunction with a titanium bone screw. The DePuy ACE Spider Plate and the Acumed Suture Washer are similar in design and function. Based on the above, DePuy ACE Medical Company considers the DePuy ACE Spider Plate to be substantially equivalent to the Acumed Suture Washer.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1999

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

Re: K990392
Trade Name: DePuy ACE Spider Plate
Regulatory Class: II
Product Code: HRS
Dated: February 1, 1999
Received: February 9, 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.

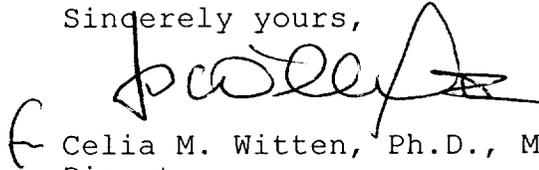
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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

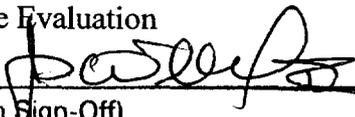
510(k) Number (if known) K990392

Device Name: **DePuy ACE Spider Plate**

Indication for User:

- Fixation of Metaphyseal Fractures of the Distal Tibia
- Proximal Metaphyseal Tibial Fractures
- Calcaneus Body Fractures
- Proximal Humeral Head/Shaft Fractures
- Distal Femur Fracture – Comminuted Shaft Fractures
- **Fixation of soft tissue, such as tendon and ligaments, to bone**

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990392

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter _____