

AUG 26 1997

K972103

510(k) SUMMARY

**NAME OF FIRM:** DePuy ACE Medical Company  
2260 East El Segundo Boulevard  
El Segundo, CA 90245

**510(k) CONTACT PERSON:** Kathleen A. Dragovich  
Regulatory Affairs Specialist  
DePuy ACE Medical Company

**TRADE NAME:** DePuy ACE A.I.M.® Titanium Tibial Nail

**COMMON NAME:** Intramedullary Rod

**CLASSIFICATION:** 888.3020 Rod, Fixation, Intramedullary and Accessories

**DEVICE CODE:** 87HSB

**SUBSTANTIALLY EQUIVALENT DEVICE:** DePuy ACE AIM® Titanium Tibial Nail

**INTENDED USE:**

The DePuy ACE A.I.M.® Titanium Tibial Nail is indicated for internal fixation of tibial fractures including transverse fractures, oblique fractures, spiral fractures, segmental fractures, comminuted fractures, fractures with bone loss, bone transport, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions, metaphyseal fractures and epiphyseal fractures.

**DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:**

The DePuy ACE A.I.M.® Titanium Tibial Nail is an intramedullary fixation rod for the fixation of tibial fractures. The nail has a distal bend of 2° for the nails of 10mm, 11mm, 12mm, and 13mm diameters. The distal bend in the nails of 8mm and 9mm diameters is 5°. The DePuy ACE A.I.M.® Titanium Tibial Nail has diameters from 8.0mm to 13.0mm and lengths from 25.5cm to 43.5cm. The proximal end of the 10mm, 11mm, 12mm, and 13mm nails is 13mm in diameter while the proximal end of the 8mm and 9mm nails is 11mm in diameter. The proximal end of the nail contains two 6mm cross locking screw holes which accept 5.5mm solid cortical bone screws and one 5mm long dynamization slot in the M-L plane. The distal end of the nail contains two 5.0mm holes in the M-L plane which accept 4.5mm solid cortical bone screws and one 5.0mm hole in the A-P plane positioned between the two transverse holes. The 8mm and 9mm nails are solid while the 10mm to 13mm nails are cannulated.

The DePuy ACE A.I.M.® Titanium Tibial Nail is manufactured from Titanium 6A1-4V ELI (ASTM standard F-136).

The new DePuy ACE A.I.M.® Titanium Tibial Nail is the same basic design as the current DePuy ACE A.I.M.® Titanium Tibial Nail, with the exceptions of adding a proximal dynamization slot in the M-L plane, which allows 5mm of length to dynamize across fracture site and that the two oblique proximal screw holes are moved more proximal to yield a longer working length for the nail. Also, there is an additional hole in the distal end of the nail in the A-P plane. This is positioned between the current two distal transverse holes, allowing for oblique locking distally, which is more stable and allows the lagging of anterior fragments of the distal tibia. The additional holes and changes in placement are very similar to that of the Synthes Titanium Cannulated Tibial Nail and the Synthes Titanium Unreamed Tibial Nail.

Biomechanical testing was done using the Synthes product and the DePuy ACE Tibial Nail. On all tests, the DePuy Tibial Nail was either at least as strong or stronger than the Synthes Tibial Nail.

Based on this information, DePuy ACE believes that the modified DePuy ACE A.I.M.® Titanium Tibial Nails are substantially equivalent to the DePuy ACE A.I.M.® Titanium Tibial Nail, the Synthes Reamed Titanium Tibial Nail, and the Synthes Unreamed Titanium Tibial Nail.

66-002



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kathleen A. Dragovich  
Regulatory Affairs Specialist  
DePuy ACE Medical Company  
2260 East El Segundo Boulevard  
El Segundo, California 90245-4694

AUG 26 1997

Re: K972183  
DePuy ACE A.I.M.® Titanium Tibial Nail  
Regulatory Class: II  
Product Code: HSB  
Dated: June 6, 1997  
Received: June 10, 1997

Dear Ms. Dragovich:

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.

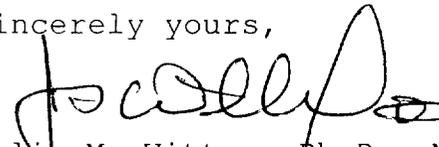
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,

  
f 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) \_\_\_\_\_

Device Name: **DePuy ACE A.I.M.® Titanium Tibial Nail**

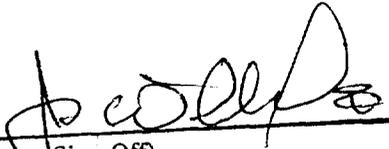
Indication For User:

The DePuy ACE A.I.M.® Titanium Tibial Nail is indicated for internal fixation of tibial fractures including transverse fractures, oblique fractures, spiral fractures, segmental fractures, comminuted fractures, fractures with bone loss, bone transport, open fractures, corrective osteotomies, pathologic fractures, pseudoarthrosis of the tibial shaft, nonunions, malunions, metaphyseal fractures and epiphyseal fractures.

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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 14972183

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