

MAR 10 1998

510(k) SUMMARY



K974781

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

**510(K) CONTACT:** Kathleen Dragovich  
Regulatory Affairs Specialist

**TRADE NAME:** DePuy ACE AIM® Titanium Supracondylar Nail

**COMMON NAME:** Intramedullary Fixation Rod

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

**DEVICE PRODUCT CODE:** 87 HSB

**SUBSTANTIALLY EQUIVALENT DEVICES:**

- ACE Medical AIM® Titanium Supracondylar Nail
- Smith & Nephew Orthopaedics Richards Supracondylar Nail System

**INTENDED USE:**

The AIM® Titanium Supracondylar Nail is intended for use in intramedullary fixation of supracondylar fractures of the femur, including those with severe comminution and intraarticular involvement, osteoporosis, nonunions, malunions, pathologic, and fractures proximal to total knee arthroplasty or prosthesis. **In addition, the AIM® Titanium Supracondylar Nail is indicated for use in tibiototalcalcaneal fusions and treatment of trauma to the hindfoot and distal tibia. Indications include: Revision after failed ankle arthrodesis with subtalar involvement; Absent talus (Tibio Calcaneal Arthrodesis); Post traumatic/primary arthrosis involving both ankle and subtalar joints; A rheumatoid hindfoot; Avascular necrosis of the talus; Previously infected arthrosis, second degree; Failed total arthroplasty.**

**DEVICE DESCRIPTIONS AND SUBSTANTIAL EQUIVALENCE RATIONALES:**

The AIM® Titanium Supracondylar Nail is a straight, cannulated intramedullary nail available in diameters of 10 and 12mm and lengths of 15, 20, 25, and 30cm. Holes in the nail allow for proximal and distal locking. The distal locking screws have a diameter of 6.5mm. The proximal locking screws have a diameter of 4.5mm. An endcap is also provided. The endcap threads into the distal end of the nail to prevent bony ingrowth and facilitate attachment of removal instrumentation. The AIM® Titanium Supracondylar Nail, proximal and distal locking screws, and endcap are all manufactured from Ti-6Al-4V alloy.

The AIM® Titanium Supracondylar Nail has been previously cleared by FDA, intended for intramedullary fixation of supracondylar fractures of the femur. As the DePuy ACE A.I.M. Titanium Supracondylar Nail has tested as stiff or stiffer in comparison to the common method of fixation, crossed lag screws, it is considered to be acceptable for tibiototalcalcaneal arthrodesis.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 10 1998

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

Re: K974781  
DePuy ACE AIM® Titanium Supracondylar Nail  
Regulatory Class: II  
Product Code: HSB  
Dated: December 19, 1997  
Received: December 22, 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.

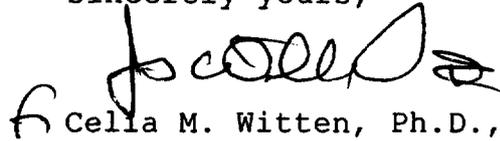
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Ms. Kathleen A. Dragovich

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 Cella 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) K974781

Device Name: DePuy ACE AIM® Titanium Supracondylar Nail

Indication For User:

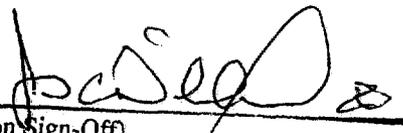
The AIM® Titanium Supracondylar Nail is intended for use in intramedullary fixation of supracondylar fractures of the femur, including those with severe comminution and intra-articular involvement, osteoporosis, nonunions, malunions, pathologic, and fractures proximal to total knee arthroplasty or prosthesis. **In addition, the AIM® Titanium Supracondylar Nail is indicated for use in tibiotalar calcaneal fusions and treatment of trauma to the hindfoot and distal tibia. Indications include: Revision after failed ankle arthrodesis with subtalar involvement; Absent talus (Tibio Calcaneal Arthrodesis); Post traumatic/primary arthrosis involving both ankle and subtalar joints; A rheumatoid hindfoot; Avascular necrosis of the talus; Previously infected arthrosis, second degree; Failed total arthroplasty.**

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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 K974781