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K032097
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SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Ace™ Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Tiffani Rogers Clinical Research Specialist, Clinical/Regulatory Affairs
TRADE NAME:	DePuy Ace™ Versa Nail Tibial Nail
COMMON NAME:	Intramedullary Rod
CLASSIFICATION:	888.3020: Rod, Fixation, Intramedullary and Accessories; Class II
DEVICE PRODUCT CODE:	**87 HSB**
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Ace™ Bio Win Tibial Nail, K013430

DEVICE DESCRIPTION:
The DePuy Ace™ VersaNail Tibial Nail is a cannulated intramedullary nail available in diameters of 8mm, 9mm, 10mm, 11mm, 12mm and 13mm, and lengths of 24.0cm to 43.5cm. There are two holes on the proximal end and three holes on the distal end of the nail that allow for cortical bone screw locking. Screw hole diameters are 5.97mm and 5.00mm at the proximal and distal ends respectively. The proximal end of the nail also features a 13mm medial/lateral (M/L) slot for dynamization, and an 8-degree bend with a bend radius of approximately 2.25mm. The distal end also has a bend radius of approximately 2.25mm and has a bullet tip. The DePuy Ace™ VersaNail Tibial Nail is intended for intramedullary fixation of tibial fractures.

INTENDED USE AND INDICATIONS:
The DePuy Ace™ VersaNail Tibial Nail is indicated for the 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, pseudarthrosis of the tibial shaft, nonunions, malunions, metaphyseal fractures and epiphyseal fractures.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The DePuy Ace™ VersaNail Tibial Nail has the same indications and contraindications as the DePuy Ace™ Bio Win Tibial Nail cleared in K013430 with a similar design. The sole differences between the two designs are: modification of the proximal hole pattern; increase in cannulation; modification of the distal hole pattern; the removal of the optional bioresorbable window available with the DePuy Ace™ Bio Win nail and a smaller size, 24.0cm, will be available for smaller stature adults. The proximal and distal ends of the nail were modified to accommodate the use of a new jig bolt instrument and a ball nose guide wire instead of the exchange tube and nail driving wire used with the DePuy Ace™ Bio Win nail.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 8 2003

Ms. Tiffani D. Rogers
Clinical Research Specialist
Clinical/Regulatory Affairs
Depuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581

Re: K032097
Trade/Device Name: DePuy Ace™ VersaNail Tibial Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: July 1, 2003
Received: July 16, 2003

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K032097

Device Name DePuy Ace™ VersaNail Tibial Nail

Intended Use and Indications:

The Tibial Nail is intended for bone fixation in the management of fractures and reconstructive surgeries.

Non-weight bearing bone fixation is indicated in the following conditions:

- Transverse, oblique, spiral, segmental and comminuted fractures;
- Fractures with bone loss and bone transport;
- Open fractures, pathologic fractures;
- Corrective osteotomies;
- Pseudarthrosis of the tibial shaft;
- Nonunions, malunions, metaphyseal and epiphyseal fractures.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The Counter Use No

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032097