K023115
page 1 of 2

510(k): ACE® VersaNail™

510(k) Summary

DEC 1 8 2002

Name of Sponsor:	**DePuy ACE®, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No.1818910
510(k) Contact:	**Dina L. Weissman, J.D.** Legal consultant, Regulatory Affairs Phone: (574) 371-4905 FAX: (574) 371-4987
Trade Name:	**ACE® VersaNail™**
Common Name:	Intramedullary Fixation Rod
Classification:	**Class II** Device per 21 CFR 888.3020: Rod, Fixation, Intramedullary and Accessories
Device Product Code:	**87HSB**
Substantially Equivalent Devices:	ACE® AIM® Titanium Supracondylar Nail **K974781** ACE® AIM® TTC Fusion Nail **K003797** Biomet Ankle Arthrodesis Nail **K982953** Encore® UltiMax Ankle Fusion Rod **K991790** Smith and Nephew Intramedullary Nail **K983942**
Device Description:	The VersaNail™ is a straight, cannulated intramedullary nail available in diameters of 10 and 12 mm and lengths of 15, 20, 25 and 30 cm. Holes in the nail allow for proximal and distal locking. The VersaNail™, the end cap and the screws are all manufactured from Ti-6AL-4V alloy.
Intended use:	The VersaNail™ is intended for use in tibiotalocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia.

K023115
page 2 of 2

510(k) Summary (continued)

Indications for use:

Indications include: revision after failed ankle arthrodesis with subtalar involvement; absent talus (tibiocalcaneal arthrodesis); post traumatic or primary arthrosis involving both ankle and subtalar joints; rheumatoid hindfoot; avascular necrosis of the talus; previously infected arthrosis, second degree; failed total ankle arthroplasty. **Additional indications also include non-union ankle arthrodesis; osteoarthritis; post-traumatic and degenerative arthritis; neuroarthropathy or neuropathic ankle deformity; neuromuscular disease with severe deformity and Charcot foot.**

This submission covers these additional indications for use: non-union ankle arthrodesis; osteoarthritis; post-traumatic and degenerative arthritis; neuroarthropathy or neuropathic ankle deformity; neuromuscular disease with severe deformity and Charcot foot.

These indications have been cleared previously for the Biomet Ankle Arthrodesis Nail, the Smith and Nephew Intramedullary Nail and/or the Encore® UltiMax Ankle Fusion Rod.

Substantial equivalence:

Based on similarities of design, commonly used materials, identical sterilization processes, and indications for use, DePuy believes the ACE® VersaNail™ to be substantially equivalent to the following FDA cleared devices: the ACE® AIM® Titanium Supracondylar Nail, the ACE® AIM® TTC Fusion Nail, the Biomet Ankle Arthrodesis Nail, the Smith and Nephew Intramedullary Nail and the Encore® UltiMax Ankle Fusion Rod.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2002

Ms. Dina L. Weissman, J.D.
Legal Consultant, Regulatory Affairs
DePuy ACE, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988.

Re: K023115
Trade/Device Name: ACE® VersaNail™
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: September 18, 2002
Received: September 19, 2002

Dear Ms. Weissman:

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) 594-4659. 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" (21CFR Part 807.97). 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): K023115

Device Name: ACE® VersaNail™

Indications for Use:

The VersaNail™ is intended for use in tibiotalocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia. Indications include: revision after failed ankle arthrodesis with subtalar involvement; absent talus (tibiocalcaneal arthrodesis); post traumatic or primary arthrosis involving both ankle and subtalar joints; rheumatoid hindfoot; avascular necrosis of the talus; previously infected arthrosis, second degree; failed total ankle arthroplasty. **Indications also include non-union ankle arthrodesis; osteoarthritis; post-traumatic and degenerative arthritis; neuroarthropathy or neuropathic ankle deformity; neuromuscular disease with severe deformity and Charcot foot.**

Concurrence of CDRH, Office of Device Evaluation

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

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

510(k) Number K023115