NOV 1 4 2003 K033329

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

DePuy ACE®
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT:

Rhonda Myer
Regulatory Affairs

TRADE NAME:

DePuy ACE® Universal and Troch Entry Femoral Nail Systems

COMMON NAME:

Intramedullary Rod

CLASSIFICATION:

888.3030: Single/multiple component metallic bone fixation appliances and accessories; Class II

DEVICE PRODUCT CODE:

87 HSB

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy ACE® AIM Femoral Nail (K871539)
DePuy ACE® Trochanteric Nail System (K010780)
DePuy ACE® Long Trochanteric Nail System (K013563)

DEVICE DESCRIPTION:

The DePuy ACE® Universal Nail is a revision of the ACE® AIM Femoral Nail (K871539). The Universal Nail is a slightly bowed intramedullary nail with proximal holes and distal lateral / medial holes and anterior/ posterior holes. The nail is "universal" in design, as it requires no right or left device configurations. It is designed to be inserted in either an antegrade or retrograde approach. The nail sizes include 8mm through 15mm diameters and lengths of 280mm through 500mm.

The Troch Entry Nail (TEN) is similar in design to the ACE® Trochanteric Nail System (K010780) and the ACE® Long Trochanteric Nail System (K013563). The Troch Entry Nail is a slightly bowed femoral intramedullary nail with proximal and distal holes. It is intended for antegrade insertion only. This nail includes a small proximal bend for insertion just lateral to the tip of the greater trochanter. Due to this bend, the nail designs require a right and left anatomic version. This nail system includes 9mm, 11mm and 13mm diameters in lengths of 280mm through 500mm in right and left versions.

The Nail System includes intramedullary nails, screws, and end caps. All components are manufactured from ASTM F-136 Ti 6Al-4V alloy with titanium type II anodise (TiMax™).

K033329

INTENDED USE AND INDICATIONS:

The DePuy ACE® Universal and Troch Entry Femoral Nail System is intended to treat proximal, middle and distal third fractures, severely comminuted shaft fractures extending beyond the isthmus, spiral, long oblique and segmental fractures, non-unions and malunions, lengthening of the bone, fractures with bone loss, bi-lateral fractures, pseudoarthrosis of the femoral shaft, supracondylar fractures, subtrochanteric fractures, with or without involvement of lesser trochanter, subtrochanteric/intertrochanteric combination fractures, ipsilateral femoral shaft and neck fractures, stable and unstable proximal fractures of the femur, including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone of the trochanteric and diaphyseal areas, proximal or distal non-unions and malunions, leg length discrepancies secondary to femoral inequality, femur reconstruction following tumor resection, stable femoral fractures without necessity for interlocking, long subtrochanteric fractures, and revision procedures involving the replacement of implanted hardware.

In addition to the above indications, the Universal Nail, when used in the retrograde mode, is also indicated for treatment of femoral shaft fractures in obese or multiple trauma patients and supracondylar fractures, including those with severe, extra-articular comminution and/or intra-articular involvement, osteoporosis, non-unions, malunions, pathologic fractures, and those proximal to total knee prosthesis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Ms. Rhonda Myer
Regulatory Affairs
DePuy, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K033329
Trade/Device Name: DePuy ACE® Universal and Troch Entry Femoral Nail Systems
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: II
Product Code: HSB
Dated: October 14, 2003
Received: October 16, 2003

Dear Ms. Myer:

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.

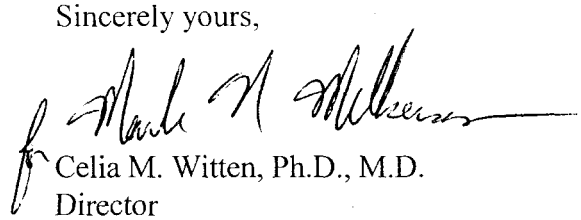
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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. 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 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,



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

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510(k) Number (if known): K033329

Device Name: DePuy ACE® Universal and Troch Entry Femoral Nail System

Intended Use and Indications:

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(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K033329

Concurrence of CDRH, Office of Device Evaluation

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