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510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

NAME OF SPONSOR:	DePuy ACE® 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Regulatory Affairs Telephone: (574) 371-4944 Facsimile: (574) 371-4987 Electronic Mail: Rmyer@dpyus.jnj.com
DATE PREPARED:	November 21, 2003
PROPRIETARY NAME:	ACE® Proximal Humeral Nail System
COMMON NAME:	Intramedullary Fixation Rod
CLASSIFICATION:	Class II Device per 21 CFR 888.3020: Intramedullary Fixation Rod
DEVICE PRODUCT CODE:	87 HSB
SUBSTANTIALLY EQUIVALENT DEVICE:	Acumed Polarus, K951740 Fournitures Hospitaliéres Industrie Telegraph® Humeral Nail, K023241

DEVICE DESCRIPTION:

The ACE® Proximal Humeral Nail System consists of an intramedullary nail, a sleeve, and an end cap and is intended for the fixation of proximal three part humeral fractures. The short, straight nail is available in diameters of 8 and 10 millimeters and length of 150mm. It is designed to be inserted antegrade, in line with the intramedullary canal. The sleeve has been designed to lock all proximal screws to prevent backing out.

INTENDED USE AND INDICATIONS:

Intended Use:

The ACE® Proximal Humeral Nail is a single use device intended for fixation of proximal humeral fractures.

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Indications for Use:

The ACE® Proximal Humeral Nail System is indicated for fixation of proximal humeral fractures. These implants are intended as a guide to normal healing and are not intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the ACE® Proximal Humeral Nail is substantiated by its similarity in intended use, indications for use, materials and design to the Acumed Polarus (K951740) and the Fournitures Hospitaliéres Industrie Telegraph® Humeral Nail (K023241).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 0 2004

Ms. Rhonda Myer
Regulatory Affairs
DePuy Ace
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K033806
Trade/Device Name: ACE® Proximal Humeral Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: December 1, 2003
Received: December 8, 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,

for Mark N Melkerson

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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Indications for Use Statement

510 (k) Number (if known): _____

Device Name: K033806

Indications for Use:

The ACE® Proximal Humeral Nail System is intended for the fixation of proximal humeral fractures.

These implants are intended as a guide to normal healing and are not intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing.

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K033806

(Please do not write below this line – continue on another page if necessary)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X _____ **OR** Over-The-Counter-Use: _____ _____