K013563

DEC 2 7 2001

510(k) Summary

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact:	**Marcia J. Arentz** Senior Regulatory Associate Phone: (219) 371-4944 FAX: (219) 371-4987
Trade Name:	**Long Trochanteric Nail System**
Common Name:	Bone fixation device
Classification:	**Class II** Device per 21 CFR 888.3020: Intramedullary fixation rod Description: Rod, Fixation, Intramedullary and Accessories, Metallic and Non-collapsible
Device Product Code:	Code: **87NDE** or **87HSB** No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for intramedullary nails.
Substantially Equivalent Device:	ACE Trochanteric Nail K010780 ACE AIM Femoral Nail K871539 Synthes Proximal Femoral Nail K973240 Smith & Nephew TriGen Nail K981529
Device Descriptions:	The Trochanteric Long Nail System consists of an intramedullary nail, lag screw, end cap, and optional anti-rotation screw, all manufactured from Titanium (Ti-6Al-4V ELI) which are used to treat fractures of the femur.

510(k) Summary (continued)

Indications for use:

The Trochanteric Nail System is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures. The Trochanteric Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions and malunions and revision procedures.

Substantial equivalence:

The Trochanteric Nail System has the same intended use, is manufactured from the same material and has the same design features as the predicate devices and is therefore substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2001

Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K013563
Trade Name: Trochanteric Long Nail System
Regulation Number: 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: II
Product Code: HSB
Dated: October 21, 2001
Received: October 26, 2001

Dear Ms. Arentz:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 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" (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,

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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510(k) Number (if known):_____

Device Name: Long Trochanteric Nail System

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation

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

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K 01356