SEP - 8 2004

510(k) Summary

K042325

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NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(K) CONTACT:	Steve Kahn RA Director, Trauma and Extremities Telephone: (574) 372-7180 Fax: (574) 371-4987
DATE PREPARED:	July 30, 2004
TRADE NAME:	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:	HSB No performance standards have been established under section 514 of the Federal Food, Drug, and Cosmetic Act for intramedullary nails
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Trochanteric Nail (K010780) DePuy Trochanteric Nail (K013563)

DEVICE DESCRIPTION:

The Trochanteric Nail System consists of an intramedullary nail, lag screw, end cap, and optional anti-rotation screw, all manufactured from titanium alloy (Ti-6Al-4V ELI), which are used to treat fractures in the proximal portion of the femur.

INTENDED USE AND INDICATIONS:

The lag screw provides dynamic compression of the fracture; the anti-rotation screw can be used to prevent the rotation of the bone fracture segments, and the end cap prevents bone ingrowth. It is estimated that the AR screw is required in only five to ten percent of the cases where additional rotational stability of the fracture is required.

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.

BASIS OF SUBSTANTIAL EQUIVALENCE:

Based on the same Intended Use, Indications for Use, materials, sterilization processes and similarities of technological and geometric features, DePuy believes that the subject Trochanteric Nail System components are substantially equivalent to the previously cleared DePuy predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Steve A. Kahn
Regulatory Affairs Director, Trauma and Extremities
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K042325
Trade/Device Name: Trochanteric Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: August 12, 2004
Received: August 27, 2004

Dear Mr. Kahn:

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.

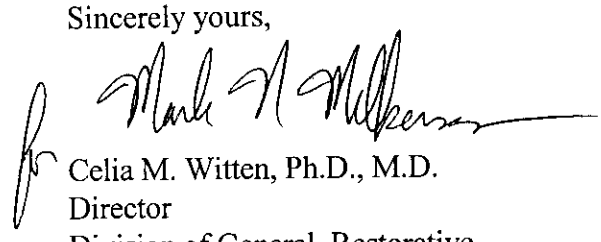
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use
510(k) Number (if known) K042325
Device Name: Trochanteric Nail System

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.

Prescription Use X
(Part 21 CFR 801, Subpart D)

and/or

Over-the-Counter Use ____
(21 CFR 807, Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

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

510(k) Number K042325