K100238

SECTION 5 – 510(K) SUMMARY

MAY 11 2010

Submitted by:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581 Phone: (305) 269-6386 Fax: (305) 269-6441 US representative for Medos International SARL
Contact Person:	Suzana Otaño, Project Manager, Regulatory Affairs
Date Prepared:	January 22, 2010
Proprietary Name:	Hip Fracture Nail System
Common Name:	Intramedullary Fixation Rod
Classification Name:	Rod, Fixation, Intramedullary and accessories (21 CFR § 888.3020)
Predicate Devices:	The Hip Fracture Nail System is substantially equivalent to currently marketed devices: Trochanteric Nail System (K042325) and Gamma3 Nail System (K043431).
Device Description:	The Hip Fracture Nail System consists of an intramedullary nail, lag screw, distal screws, end cap and optional anti-rotation screw all manufactured from titanium alloy and used to treat fractures in the proximal portion of the femur. The system offers 125° and 130° angle nails with 9-15mm distal diameters and a 180-460mm length range.
Indications for Use:	The Hip Fracture 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, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections.

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Technological Characteristics:	The technological characteristics of the Hip Fracture Nail System are similar to the predicate devices including design and material. The Hip Fracture Nail system and predicate systems are manufactured from titanium alloy. Dimensional characteristics are similar among the systems including proximal and distal nail diameters, nail angles and lengths. In addition to the material, the screws are similarly comparable in major and minor OD and length.
Summary of Substantial Equivalence:	The Hip Fracture Nail System is substantially equivalent to currently marketed devices as demonstrated with pre-clinical data. Cyclical testing demonstrated that the new Hip Fracture Nail System achieved higher maximum loads prior to failure when compared to both predicate devices successfully meeting the pre-defined acceptance criteria. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Orthopaedics, Inc.
% Ms. Suzana Otaño
Project manager, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

MAY 11 2010

Re: K100238
Trade/Device Name: Hip Fracture Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: April 28, 2010
Received: April 29, 2010

Dear Ms. Otaño:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K100238

Device Name: **Hip Fracture Nail System**

Indications For Use:

The Hip Fracture 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, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections.

Prescription Use X AND/OR Over-the-Counter _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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