K063509

JAN - 4 2007

510 (k) Summary

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

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Regulatory Affairs Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@dpyus.jnj.com
DATE PREPARED:	November 6, 2006
PROPRIETARY NAME:	Peak Fx Hip Plate
COMMON NAME:	Bone Screw and Plate for Internal Fixation
CLASSIFICATION:	Class II device per 21 CFR 888.3030: Single/Multiple component metallic bone fixation appliances and accessories
DEVICE PRODUCT CODE:	87 KTT
SUBSTANTIALLY EQUIVALENT DEVICES:	**DePuy Captured Hip Screw System (CHS),** K813554, cleared on January 12, 1982

DEVICE DESCRIPTION:

The DePuy Peak Fx Hip Plate System is comprised of plates in various lengths with two to twelve holes, barrel/ lag screw assemblies in various lengths with angles from 125° to 140°, a key and key screw, and a limited collapse cap.

INTENDED USE AND INDICATIONS:

Intended Use:

The DePuy Peak Fx Hip Plate is intended for internal fixation of hip fractures.

Indications for Use:

The Peak Fx Hip Plate is indicated for the following fractures of the proximal femur:

- Basilar neck fractures
- Intertrochanteric fractures
- Subtrochanteric fractures

The Peak Fx Hip Plate is indicated for stable and unstable fractures in which a stable medial buttress can be reconstructed.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the DePuy Peak Fx Hip Plate is shown by its similarity in intended use, indications for use, materials and design to the existing DePuy Captured Hip Screw System (CHS), K813554, cleared on January 12, 1982.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Rhonda Myer
Regulatory Associate, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46582

JAN 04 2007

Re: K063509
Trade/Device Name: Peak Fx Hip Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, HRS
Dated: November 17, 2006
Received: November 20, 2006

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 (240) 276-0210 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988
USA
Tel: +1 (574) 267 8143
Fax: +1 (574) 371 4987

Indications for Use Statement

510 (k) Number (if known): K063509

Device Name: _____

Indications for Use:

The Peak Fx Hip Plate is indicated for the following fractures of the proximal femur:

- Basilar neck fractures
- Intertrochanteric fractures
- Subtrochanteric fractures

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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)

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

510(k) Number K063509