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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 46581-0988 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:	March 29, 2006
PROPRIETARY NAME:	POLYAX™ Locked Plating System
COMMON NAME:	Bone Fixation Device
CLASSIFICATION:	Class II device per 21 CFR 888.3030: Single/Multiple component metallic bone fixation appliances and accessories
DEVICE PRODUCT CODE:	87 HRS
SUBSTANTIALLY EQUIVALENT DEVICES:	**DePuy POLYAX Knee Fracture System,** K003235, cleared on November 6, 2000 **Zimmer Periarticular Locking Plates,** K040593, cleared on April 12, 2004

DEVICE DESCRIPTION:

The DePuy POLYAX Locked Plating System is comprised of anatomically contoured, multi-hole fracture plates and screws. The plates allow for polyaxial screw locking, with provisions for fixed angle locking, variable angle locking and non-locking screw construct options.

INTENDED USE AND INDICATIONS:

Intended Use:

The DePuy POLYAX Locked Plating System is intended to be implanted for the fixation of bone fractures and osteotomies, implanted either percutaneously or by a traditional open method.

Indications for Use:

The **POLYAX™ Locked Plating System** is intended for use in cases requiring stabilization of malunions, non-unions, and osteotomies of the distal femur and proximal tibia and Open Reduction Internal Fixation (ORIF) repair of closed and open fractures of the distal femur and proximal tibia including, but not limited to the following: periarticular fractures, such as simple comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression fractures with associated shaft fractures, and periprosthetic fractures.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of the DePuy POLYAX Locked Plating System is substantiated by its similarity in intended use, indications for use, materials and design to the existing DePuy POLYAX Knee Fracture System, K003235, cleared on November 6, 2000, and to Zimmer Periarticular Locking Plates, K040593, cleared on April 12, 2004

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2006

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

Re: K060969
Trade/Device Name: POLYAX™ Locked Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: April 5, 2006
Received: April 7, 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) 276-0120. 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,

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

Enclosure

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a Johnson & Johnson company

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Indications for Use Statement

510 (k) Number (if known): K060969

Device Name: _____

Indications for Use:

The **POLYAX™ Locked Plating System** is intended for use in cases requiring stabilization of malunions, non-unions, and osteotomies of the distal femur and proximal tibia and Open Reduction Internal Fixation (ORIF) repair of closed and open fractures of the distal femur and proximal tibia including, but not limited to the following: periarticular fractures, such as simple comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression fractures with associated shaft fractures, and periprosthetic fractures.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

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

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