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SECTION 5 – 510(K) SUMMARY

DEC 1 4 2007

Submitted by:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581 Phone: (305) 328-3851 Fax: (305) 270-1382
Contact Person:	Suzana Otaño, Sr. Regulatory Affairs Associate
Date Prepared:	October 2, 2007
Proprietary Name:	Anterolateral and Medial Locking Plating System
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030)

Predicate Devices:

DePuy	K990120	TiMax Medial Pilon Plate
DePuy	K983853	TiMax Meta Plate
DePuy	K905048	3.5mm Cortical Bone Screws
DePuy	K882381	Cancellous Bone Screws

Intended Use:

The Medial Locking Plate is indicated for:
-Pilon Fractures: distal tibial intra-articular fractures
-High medial malleolar fractures
-Low boot type rotational distal extra-articular shaft fractures

while the Anterolateral Locking Plate is indicated for:
-Distal intra-articular tibia fractures
-Proximal tibia fractures
-Proximal and distal humerus fractures

Technological Characteristics:

The technological characteristics of the Anterolateral and Medial Locking Plating System are the same as the predicate device including design and material.

Summary of Substantial Equivalence:

The Anterolateral and Medial Locking Plating System is substantially equivalent to the currently marketed DePuy devices. No new issues of safety or efficacy have been raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

DePuy
% Ms. Suzana Otaño
Sr. Regulatory Affairs Associate
700 Orthopaedics Drive
Warsaw, IN 46581

Re: K072832
Trade/Device Name: Anterolateral and Medial Locking 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: October 2, 2007
Received: October 3, 2007

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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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SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: **Anterolateral and Medial Locking Plating System**

Indications For Use:
The Medial Locking Plate is indicated for:
-Pilon Fractures: distal tibial intra-articular fractures
-High medial malleolar fractures
-Low boot type rotational distal extra-articular shaft fractures

while the Anterolateral Locking Plate is indicated for:
-Distal intra-articular tibia fractures
-Proximal tibia fractures
-Proximal and distal humerus fractures

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 General, Restorative,
and Neurological Devices

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