

K090877 (pg. 1 of 1)

SECTION 5 – 510(k) SUMMARY

Submitted by: DePuy Orthopaedics, Inc.
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JUN 26 2009

Contact Person: Suzana Otaño, Project Manager, Regulatory Affairs

Date Prepared: March 30, 2009

Proprietary Name: Proximal Tibia Plating System

Common Name: Plate, Fixation, Bone

Classification Name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR § 888.3030)

Predicate Devices: The DePuy Proximal Tibia Plating System is substantially equivalent to currently marketed devices.

Intended Use: The DePuy Proximal Tibia Plating System is intended for treatment of nonunions, osteotomies, malunions, osteopenic bone and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic and fractures with associated shaft fractures.

Technological Characteristics: The technological characteristics of the DePuy Proximal Tibia Plating System are similar to the predicate devices including design and material.

Summary of Substantial Equivalence: The DePuy Proximal Tibia Plating System is substantially equivalent to currently marketed devices as demonstrated with pre-clinical data. No new issues of safety or efficacy have been raised.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 26 2009

DePuy Orthopaedics, Inc.
% Ms. Suzana Otaño
Project Manager
700 Orthopaedic Drive
Warsaw, Indiana 46581

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Re: K090877

Trade/Device Name: Proximal Tibia Plating System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Codes: HRS, HWC

Dated: March 30, 2009

Received: March 31, 2009

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 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/CDRHOices/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/cdrh/mdr/> 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 (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

SECTION 4 – INDICATIONS FOR USE STATEMENT

510(k) Number: K090877

Device Name: **Proximal Tibia Plating System**

Indications For Use:

The DePuy Proximal Tibia Plating System is intended for treatment of nonunions, osteotomies, malunions, osteopenic bone and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic and fractures with associated shaft fractures.

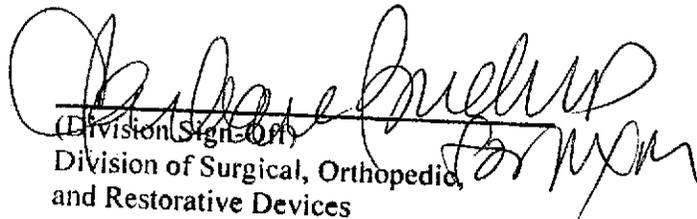
Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter _____
(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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