K093474 #1/1

## SECTION 5 – 510(K) SUMMARY

FEB - 2 2010

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| Submitted by: | DePuy Orthopaedics, Inc.<br>700 Orthopaedic Drive<br>Warsaw, IN 46581<br>Phone: (305) 269-6386<br>Fax: (305) 269-6441 |
| Contact Person: | Suzana Otaño, Project Manager, Regulatory Affairs |
| Date Prepared: | November 4, 2009 |
| Proprietary Name: | DePuy Fracture and Fusion 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 Fracture and Fusion Plating System is substantially equivalent to currently marketed devices. |
| Intended Use: | The DePuy Fracture and Fusion Plating System is intended for use in stabilization and fixation of fractures, revision procedures, fusions, reconstructions (osteotomy) and non-unions of the bones of the hand, foot, wrist, ankle, finger, toe, humerus, olecranon, clavicle, scapula and pelvis, particularly in osteopenic bone. The system can be used in both adult and pediatric patients (adolescents [>12 – 21 years of age]), where the implant would not cross open epiphyseal plates in skeletally immature patients. |
| Technological Characteristics: | The technological characteristics of the DePuy Fracture and Fusion Plating System are similar to the predicate devices including design and material. |
| Summary of Substantial Equivalence: | The DePuy Fracture and Fusion 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

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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

FEB - 2 2010

Re: K093474
Trade/Device Name: DePuy Fracture and Fusion 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, HWC
Dated: November 4, 2009
Received: November 6, 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. 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:** K093474

**Device Name:** **DePuy Fracture and Fusion Plating System**

**Indications For Use:**

The DePuy Fracture and Fusion Plating System is intended for use in stabilization and fixation of fractures, revision procedures, fusions, reconstructions (osteotomy) and non-unions of the bones of the hand, foot, wrist, ankle, finger, toe, humerus, olecranon, clavicle, scapula and pelvis, particularly in osteopenic bone. The system can be used in both adult and pediatric patients (adolescents [>12 – 21 years of age]), where the implant would not cross open epiphyseal plates in skeletally immature patients.

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

510(k) Number K093474