K103408
pg 1/2

510(k) Summary

DEC 16 2010

Submitted by:
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Contact Person: Suzana Otaño, Project Manager, Regulatory Affairs

Date Prepared: November 17, 2010

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Anatomic Locked Plating System Extra Long Plate Line Extension	Plate, Fixation, Bone

Name of Predicate Devices

The device is substantially equivalent to the currently marketed DePuy Anatomic Locked Plating System Extra Long Plate Line Extension System, K082300 and DePuy's Large Fragment Locking Plating System K072423.

Classification

Class II, 21 CFR 888.3030

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act for these devices.

Device Description

The Anatomic Locked Plating System Extra Long Plate Line Extension offers various longer length anatomically contoured plates for use with non-locking, locking and variable angle screws. With conventional non-locking plating, compression of the plate to the bone is a necessary mode of action. However, with locking plating technology, the plate does not need to contact bone or load against the periosteum for construct strength. The locking plate/screw construct provides stability even in osteopenic bone where screw purchase can be more difficult. These posterior lateral plates will be available in 210mm and 250mm lengths.

Indications for Use

The Anatomic Locked Plating System Extra Long Plate Line Extension is intended for fixation of fractures, fusions, osteotomies and non-unions of the clavicle, humerus, radius, ulna, olecranon, metacarpal, metatarsal, malleolus, tibia, fibula, particularly in osteopenic bone.

Technological Characteristics	The technological characteristics of the Anatomic Locked Plating System Extra Long Plate Line Extension are similar to the predicate devices in both design and material. The systems are manufactured from titanium alloy. Dimensional characteristics are similar among the systems including thickness, width and length.
Summary of Substantial Equivalence	The Anatomic Locked Plating System Extra Long Plate Line Extension is substantially equivalent to the predicate devices as confirmed through bench testing. Load and bend testing, as well as validation in cadaveric models, demonstrated that the Extra Long Plate Line Extension performed equivalently to the predicate devices, successfully meeting the pre-determined acceptance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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

DEC 16 2010

Re: K103408
Trade/Device Name: DePuy Anatomic Locked Plating System Extra Long Plate Line Extension
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: November 17, 2010
Received: November 19, 2010

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

510(k) Number: K103408

DEC 16 2010

Device Name: **DePuy Anatomic Locked Plating System Extra Long Plate Line Extension**

Indications For Use:

The **DePuy Anatomic Locked Plating System Extra Long Plate Line Extension** is intended for fixation of fractures, fusions, osteotomies and non-unions of the clavicle, humerus, radius, ulna, olecranon, metacarpal, metatarsal, malleolus, tibia, fibula, particularly in osteopenic bone.

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)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103408