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510(k) Summary FEB 17 2011

Submitted by:
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Contact Person: Suzana Otaño, Project Manager, Regulatory Affairs
Date Prepared: October 5, 2010

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Rockwood Clavicle Pin	Smooth or Threaded Metallic Bone Fixation Fastener

Name of Predicate Devices

The device is substantially equivalent to the currently marketed DePuy Rockwood Clavicle Pin System, K991649.

Classification

Class II, 21 CFR 888.3040, Smooth or Threaded Metallic Bone Fixation Fastener, 87 JDW

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 Rockwood Clavicle Pin System offers various diameter and length stainless steel threaded pins with pre-loaded nuts. The devices are offered in 5" and 6" overall lengths where the 6" pin ranges in diameter from 2.5mm – 4.5mm and the 5" pin has a 2.5mm diameter.

Indications for Use

The Rockwood Clavicle Pin System is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

Technological Characteristics

The technological characteristics of the Rockwood Clavicle Pin System are similar to the current Rockwood Clavicle Pin in both design and material. The pins are stainless steel and design characteristics are the same among the various pins which differ in diameter, threaded length and overall length. The new Rockwood Clavicle Pin provides a shorter 5" overall length in the 2.5mm configuration with corresponding scaled down thread lengths.

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Summary of Substantial Equivalence	The Rockwood Clavicle Pin is substantially equivalent to the predicate device as confirmed through testing. Torque testing and bone model evaluations demonstrated that the new Rockwood Clavicle pin performed equivalently to the predicate device, 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 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 17 2011

Re: K103001
Trade/Device Name: DePuy Rockwood Clavicle Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW
Dated: January 20, 2011
Received: January 21, 2011

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: K103001

Device Name: **DePuy Rockwood Clavicle Pin**

Indications For Use:

The **DePuy Rockwood Clavicle Pin** is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

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. Mckenna

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

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