K102080 (pg 1/2)

NOV 2 3 2010

Section 5: 510 (k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

NAME OF SPONSOR:	DePuy (Ireland) Loughbeg Ringaskiddy Co. Cork Ireland Establishment Registration Number: 9616671
510(K) CONTACT:	Rhonda Myer Senior Regulatory Affairs Associate Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@its.jnj.com
DATE PREPARED:	July 14, 2010
PROPRIETARY NAME:	DePuy RECLAIM Revision Hip System
COMMON NAME:	Hip Stem Prosthesis
CLASSIFICATION AND REGULATION:	Class III per 21 CFR 888.3330: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis (KWA) Class II per 21 CFR 888.3353: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (LZO)
DEVICE PRODUCT CODE AND DESCRIPTION:	**KWA**: prosthesis, hip, semi-constrained (metal uncemented acetabular component) **LZO**: prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy Spectrum Modular System, K033893 DePuy Solution Hip System, K060581

DEVICE DESCRIPTION:
The ReClaim Revision Hip System is a modular tapered hip stem system that is intended for use in revision hip arthroplasty.

INDICATIONS AND INTENDED USE:

Indications:
The DePuy RECLAIM Revision Hip System is indicated for cementless use in the treatment of failed previous hip surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement.

Intended Use:
Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Summary of Technologies/Substantial Equivalence:
The substantial equivalence of the subject RECLAIM Revision Hip System is demonstrated by similarities in intended use, indications for use, materials, geometry, design and performance as compared to the predicate devices. The changes presented in this 510(k) do not present new issues of safety or effectiveness.

Non-clinical Testing:
RECLAIM neck fatigue testing meets the ISO-7206-6:1992 specification when tested to 10 million cycles at 1200 lbf in air. Distal fatigue testing per ISO 7206-4:1989 demonstrated that the subject device achieved higher maximum loads prior to failure when compared to the predicate Spectrum and Solution devices. This testing, coupled with evaluations of the device design and geometry, demonstrated that the subject devices met the applicable performance requirements and are as safe and effective as the predicates.

Clinical Testing:
No clinical testing was required to demonstrate substantial equivalence.

Conclusion:
The subject DePuy RECLAIM Revision Hip System is substantially equivalent to the predicate devices identified in this premarket notification.

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 (Ireland)
% DePuy Orthopaedics, Inc.
Ms. Rhonda Myer
Senior Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46582

NOV 23 2010

Re: K102080
Trade/Device Name: DePuy RECLAIM Revision Hip Stem
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA, LZO
Dated: November 10, 2010
Received: November 12, 2010

Dear Ms. Myer:

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/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 (if known): K102080 (pg 1/1)

NOV 2 3 2010

Device Name: DePuy RECLAIM Revision Hip System

Indications for Use:

The DePuy RECLAIM Revision Hip System is indicated for cementless use in the treatment of failed previous hip surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or other total hip replacement.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

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

510(k) Number K102080