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Section 5 – 510 (k) Summary

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

JAN 30 2008

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
MANUFACTURER:	DePuy International Limited St. Anthony Road Leeds, United Kingdom LS11 8DT Establishment Registration Number: 8010379
510(K) CONTACT:	Dawn Sinclair Regulatory Affairs Associate Telephone: (574) 372-5023 Facsimile: (574) 371-4987 Electronic Mail: Dsincla3@dpyus.jnj.com
510(K) PREPARER:	Rebecca Lennard Independent Contractor Electronic Mail: RLennard@dpyus.jnj.com
DATE PREPARED:	October 29, 2007
PROPRIETARY NAME:	DePuy ASR™ 300 Acetabular Cup System
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	Class III per 21 *CFR* 888.3330, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy ASR™ Modular Acetabular Cup System, K040627 DePuy Pinnacle® Acetabular Cup System, K000306 Porocoat Lunceford Acetabulum, K823145

DEVICE DESCRIPTION:

The subject DePuy ASR™ 300 Acetabular Cup System is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular cup is designed as a cobalt-chrome molybdenum (CoCrMo) alloy one-piece cup. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. The cups feature three spikes for adjunct fixation and are available in ten sizes. The subject device is identical in design to the acetabular cups cleared as part of the DePuy ASR™ Modular Acetabular Cup System in K040627 on August 5, 2005 with the addition of spikes on the outer surface of the cup.

INDICATIONS AND INTENDED USE:

Indications:

The device is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

Porous-coated ASR™ 300 Acetabular Cups are indicated for cementless application.

Intended Use:

The device is part of a modular system for use in total hip replacement in which the acetabular component articulates with a femoral component.

The DePuy ASR™ 300 Acetabular Cup System is compatible with ASR femoral components.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy ASR™ 300 Acetabular Cup System described in this submission is substantially equivalent to the previously cleared DePuy ASR™ Modular Acetabular Cup System (K040627), the Pinnacle Acetabular System (K000306) and the Porocoat Lunceford Acetabulum (K823145) based upon the similarities in design, material composition and intended use/indications for use. The subject device does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2008

DePuy Orthopaedics, Inc.
% Ms. Dawn Sinclair
Regulatory Associate
700 Orthopaedic Drive
P.O. Box 988
Warsaw, IN 46581-0988

Re: K073413
Trade/Device Name: DePuy ASR™ Modular Acetabular Cup System
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
Dated: December 3, 2007
Received: January 4, 2008

Dear Ms. Sinclair:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (if known): K073413

Device Name: DePuy ASR™ 300 Acetabular Cup System

Indications for Use:

The device is indicated for use in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

Porous-coated ASR™ 300 Acetabular Cups are indicated for cementless application.

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.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Barbara Paschke for mpm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073413