K080991 # 1/3

510(k) Summary

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

JUL - 2 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
DATE PREPARED:	February 25, 2008
PROPRIETARY NAME:	DePuy ASR™ XL Modular 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(S):	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy ASR™ Modular Acetabular Cup System (K040627) DePuy ASR™ 300 Acetabular Cup System (K073413) Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes) (K021349) DePuy Ultima® Unipolar Head and Adapter Sleeves (K965156) DePuy ASR™ Taper Sleeve Adapter (K070359) Corail AMT™ Hip Prosthesis (K042992) DePuy Tri-Lock® Bone Preservation Stem (K073570)

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DEVICE DESCRIPTION:

The subject DePuy ASR™ XL Modular Acetabular Cup components are 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 with a porous coating and is available in outer diameter sizes 64mm through 70mm in two-millimeter increments. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. There are no separate liner components to this system, as the liners are integral to the one-piece acetabular cups.

Two cup configurations will be offered: a "spiked" cup with three fixation spikes on the outer surface of the cup for adjunct fixation, and an acetabular cup with no spikes. Both configurations are specific to the DePuy ASR™ Modular Cup System cleared in K040627 and K073413. This submission is a line extension of the acetabular cup components. These acetabular cups will be compatible with DePuy ASR™ femoral components.

The uni femoral head is manufactured from cobalt-chrome-molybdenum (CoCrMo) alloy and is available in a range of diameters from 57mm to 63mm in two-millimeter increments. The uni femoral heads have an internal taper which mates with a taper sleeve adapter specific to DePuy 12/14 or 11/13 tapers. The femoral heads articulate with corresponding one-piece metal acetabular cups. The ASR Uni femoral heads (sizes 39mm through 55mm) were cleared in the DePuy ASR™ Modular Acetabular Cup System, K040627.

The subject heads use taper sleeve adapters to mate the DePuy femoral heads to DePuy femoral stems and are manufactured from cobalt-chrome-molybdenum (CoCrMo) alloy.

INDICATIONS AND INTENDED USE:

Indications for Use:

The DePuy ASR™ XL Modular Acetabular Cup System is indicated for use in the following conditions, where there is evidence of sufficient sound bone to seat and support the components:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head and neck.
4. Failed previous hip surgery, including internal fixation, arthrodesis and hemi-arthroplasty.
5. Certain cases of ankylosis.

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Porous-coated DePuy ASR™ XL Modular 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™ XL Modular Acetabular Cup System is compatible with DePuy ASR™ femoral components.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy ASR™ XL Modular Acetabular Cup components described in this submission are, in our opinion, substantially equivalent to those included in the previously cleared DePuy ASR™ Modular Acetabular Cup System (K040627); the DePuy ASR™ 300 Acetabular Cup System (K073413); the Wright Medical Metal TRANSCEND® Articulation System (K021349); the DePuy ASR™ Adapter Sleeve (K070359); the DePuy Ultima® Adapter Sleeves (K965156); the Corail AMT™ Hip Prosthesis (K042992); and the DePuy Tri-Lock® Bone Preservation Stem (K073570), based upon the similarities in design, material composition and intended use/indications for use. A modification is simply being made to add additional cup sizes. In addition, minor revisions are being made to the Indications for Use and the Instructions for Use (IFU) to minimize the necessity for multiple IFUs and to update the contents to reflect current practice. 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

DePuy Orthopaedics, Inc.
% Ms. Dawn Sinclair
Regulatory Affairs Associate
700 Orthopaedic Drive
Warsaw, Indiana 46582

JUL - 2 2008

Re: K080991
Trade/Device Name: DePuy ASR™ XL 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: March 17, 2008
Received: April 7, 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

Indications for Use Statement

510 (k) Number (if known): K080991

Device Name: DePuy ASR™ XL Modular Acetabular Cup System

Indications for Use:

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1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
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3. Acute traumatic fracture of the femoral head and neck.
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5. Certain cases of ankylosis.

Porous-coated DePuy ASR™ XL Modular 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)

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

510(k) Number K080991

(Posted November 13, 2003)