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AUG 5 - 2005

510(k) Summary

NAME OF FIRM:	DePuy Orthopaedics, Inc. PO Box 988 700 Orthopaedics Warsaw, IN 46581-0988
510(k) CONTACT:	Natalie Heck Manager, Regulatory Affairs
TRADE NAME:	DePuy ASR™ Modular Acetabular Cup System
COMMON NAME:	Femoral Hip Prosthesis
CLASSIFICATION:	**Class III per 21 CFR 888.3330 Hip Joint metal/metal semiconstrained, with an uncemented acetabular component prosthesis**
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Pinnacle® Metal-on-Metal Acetabular Cup Line (K002883 & K003523) Wright Medical Metal TRANSCEND® Articulation System (K021349) DePuy Ultima® Unipolar Head and Adapter Sleeves (K965156)

DEVICE DESCRIPTION:

The DePuy ASR™ Modular Acetabular Cup System is comprised of a one-piece metal acetabular cup, a unipolar femoral head, and a taper sleeve adapter.

The acetabular component is designed as a cobalt-chrome molybdenum (CoCrMo) alloy one-piece cup with Porocoat® porous coating and is available in outer diameter sizes 44mm through 62mm 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.

The uni femoral head is manufactured from cobalt-chrome molybdenum (CoCrMo) alloy and is available in a range of diameters from 39 to 55 mm 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 taper sleeve adapters are manufactured from cobalt-chrome molybdenum (CoCrMo) alloy. The 12/14 taper sleeve adapters are offered in neck length options of +1.5, +5, and +8.5. The 11/13 taper sleeve adapters were previously cleared in the Ultima® Unipolar Head and Adapter

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Sleeves 510(k), K965156 (Jan 24, 1997), and are offered in neck length options of +0, +6, and +12.

INDICATIONS FOR USE:

The DePuy ASR™ Modular Acetabular Cup System 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.

BASIS OF SUBSTANTIAL EQUIVALENCE:

DePuy believes the DePuy ASR™ Modular Acetabular Cup System to be substantially equivalent to the DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners; the Wright Medical Metal TRANSCEND Articulation System; and the DePuy Ultima Adapter Sleeves based upon the similarities in design, material composition, and intended use/indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005

Ms. Natalie Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988

Re: K040627
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: III
Product Code: KWA
Dated: May 23, 2005
Received: May 24, 2005

Dear Ms. Heck:

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 Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040627
Device Name: DePuy ASR™ Modular Acetabular Cup System

Indications for Use:

The DePuy ASR™ Modular Acetabular Cup System 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.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

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

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