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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™ Resurfacing Femoral Heads
COMMON NAME:	Resurfacing femoral head
CLASSIFICATION:	888.3400: Hip joint femoral (hemi-hip) metallic resurfacing prosthesis; **Class II**
DEVICE PRODUCT CODE:	87 KXA
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy T.A.R.A Total Hip, K810325 Cemented Femoral Head Resurfacing Device (Biomet Orthopaedics, Inc.), K021799

DEVICE DESCRIPTION:
The DePuy ASR™ Resurfacing Femoral Heads are designed for use in hemi-arthroplasty applications to replace the articular surface of the femoral head. The implants consist of a one-piece cobalt-chromium-molybdenum (Co-Cr-Mo) metal femoral head with a short stem used as a central guide pin. The implants range in sizes 39mm through 63mm to suit varying patient anatomy.

The femoral resurfacing heads have a polished exterior surface and an internal cavity designed for use with bone cement for fixation to the patient's prepared femoral head. The implant allows for the minimal removal of bone from the femoral head, replacing the bone with a metal shell (cap). Articulation occurs between the polished femoral resurfacing implant and the patient's natural acetabulum.

INDICATIONS FOR USE:
The DePuy ASR™ Resurfacing Femoral Heads are intended for cemented use in hemi-arthroplasty (partial hip replacement procedure). Indications are for patients suffering severe pain and disability due to osteoarthritis, rheumatoid arthritis, congenital hip dysplasia, post-traumatic arthritis, avascular necrosis, or slipped capital femoral epiphysis. Additional indications include other abnormalities where major pathology affects the femoral head; where the acetabular cavity is normal and not deformed or weakened; and where acetabular replacement is either not required or not desirable.

BASIS OF SUBSTANTIAL EQUIVALENCE:
DePuy considers the DePuy ASR™ Resurfacing Femoral Heads to be substantially equivalent to the femoral resurfacing heads submitted in the T.A.R.A. Total Hip Prosthesis, K810325 and the Biomet Cemented Femoral Resurfacing Head device, K021799, based on similarities in design, material composition, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2003

Ms. Natalie Heck
Manager, Regulatory Affairs
DePuy Orthopedics, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581

Re: K032659
Trade/Device Name: Depuy ASR™ Resurfacing Femoral Heads
Regulation Number: 21 CFR 888.3400
Regulation Name: Hip Joint Femoral (Hemi-hip) Metallic Resurfacing Prosthesis
Regulatory Class: Class II
Product Code: KXA
Dated: August 27, 2003
Received: September 5, 2003

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 (301) 594-4639. 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 may be obtained 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/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K03 2659

Device Name: **DePuy ASR™ Resurfacing Femoral Heads**

Indications for Use:

The DePuy ASR™ Resurfacing Femoral Heads are intended for cemented use in partial hip replacement procedures (hemi-arthroplasty). Indications are for patients suffering severe pain and disability due to osteoarthritis, rheumatoid arthritis, congenital hip dysplasia, post-traumatic arthritis, avascular necrosis, or slipped capital femoral epiphysis. Additional indications include other abnormalities where major pathology affects the femoral head; where the acetabular cavity is normal and not deformed or weakened; and where acetabular replacement is either not required or not desirable.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use Y L OR Over-The-Counter Use N
(Per 21 CFR 801.109)

for Mark N Milhous

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

510(k) Number K03 2659