USER:	**CURTSINGER, MARGARET A (mac)**
FOLDER:	**K073413 - 77 pages (FOI:10007828)**
COMPANY:	**DEPUY ORTHOPAEDICS, INC. (DEPUORTHA)**
PRODUCT:	**PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL UNCEMENTED ACETABULAR COMPONENT) (KWA)**
SUMMARY:	**Product: DEPUY ASR 300 ACETABULAR CUP SYSTEM**

DATE REQUESTED:	**Fri Dec 10 24:00:00 2010**
DATE PRINTED:	**Thu Dec 16 11:33:06 2010**
Note:	**PDN Version**

Table of Contents

K073413 (pg. 1 of 2)

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

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 Bachmann for MXM

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

510(k) Number K073413

AFFIDAVIT

CDR Lisa D. Lawrence, being first duly sworn, deposes and says:

I am the Records Management Officer, for the Center for Devices and Radiological Health, Food and Drug Administration.

In this capacity I have custody of official records of the United States Food and Drug Administration.

A comprehensive search of CDRH file systems has been conducted. The following pages for file K073413 cannot be located and therefore cannot be produced for this request.

- **Correspondence** **2 pages**

Lisa D. Lawrence

CDR Lisa D. Lawrence

County of Montgomery
State of Maryland

Subscribed and sworn before me this 8th day of December 2010.

Tomaschia Holwood

Notary Public

My Commission Expires 9/20/2012.

OR/ DGRND

K 073 413

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, IN 46581-0988
USA
Tel: +1 (574) 267 8143
Fax: +1 (574) 371 4950

Special 510(k): Device Modification

December 3, 2007

Food and Drug Administration
CDRH/ODE
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Reference: **Special 510(k): Device Modification**
K040627, DePuy ASR™ Modular Acetabular Cup System, cleared August 5, 2005

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate on the DePuy ASR™ 300 Acetabular Cup System, as a **Special 510(k): Device Modification** to address minor design modifications to the previously FDA cleared DePuy ASR™ Modular Acetabular Cup System (K040627). This submission includes a paper and an electronic copy on CD that is an exact duplicate of the paper copy.

The following modification was implemented on the currently marketed DePuy ASR™ Modular Acetabular Cup System:

- Addition of three spikes on the outer surface of the cup for adjunct fixation.

The indications for the DePuy ASR™ 300 Acetabular Cup System have not changed from those cleared in K040627.

DePuy believes the modifications discussed in this 510(k) submission are eligible for the Special 510(k) process since they have the same fundamental scientific technology and intended use as the predicate devices.

Pursuant to 21 CFR 807.95(c) (3), DePuy considers this 510(k) submission to be confidential commercial information and requests that FDA treat it as such, as afforded by 18 USC 1905, 21 USC 331 (j), 5 USC 552, and other applicable laws. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone (574) 372-5023, fax (574) 371-4987, or email Dsincla3@dpyus.jnj.com.

Sincerely,

Dawn R. Sinclair

Dawn R. Sinclair
Regulatory Associate, Regulatory Affairs
DePuy Orthopaedics, Inc.

SPECIAL
510(k)
Submission

ASR™ 300 Acetabular Cup System

700 ORTHOPAEDIC DRIVE WARSAW IN 46582

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MD6033031-956733** Write the Payment Identification number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submits the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfer.
6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
DEPUY ORTHOPAEDICS INC 700 Orthopaedic Drive Warsaw IN 46582 US	Rhonda Myer 2.1 E-MAIL ADDRESS rmyer7@dpyus.jnj.com 2.2 TELEPHONE NUMBER (include Area code) 574-371-4927
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 352109957	2.3 FACSIMILE (FAX) NUMBER (Include Area code) 574-371-4987

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma

Select an application type:

[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select one of the types below

[X] Original Application

Supplement Types:

[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION	
$3,404.00	15-Oct-2007

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
12/3/2007	MD6033031-956733	

SECTION A — TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☒ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA &HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☐ Yes ☒ No *(If Yes, please complete Section I, Page 5)*

SECTION B — SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name DePuy Orthopaedics, Inc.	Establishment Registration Number *(if known)* 1818910		
Division Name *(if applicable)* N/A	Phone Number *(including area code)* (574) 371-4906		
Street Address 700 Orthopaedic Drive	FAX Number *(including area code)* (574) 371-4987		
City Warsaw	State / Province IN	ZIP/Postal Code 46582	Country USA
Contact Name Dawn Sinclair			
Contact Title Regulatory Affairs Associate	Contact E-mail Address Dsincla3@dpyus.jnj.com		

SECTION C — APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)* ( )		
Street Address	FAX Number *(including area code)* ( )		
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

SECTION D1 — REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

☐ Other Reason *(specify):*

SECTION D2 — REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Repose to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

☐ Other Reason *(specify):*

SECTION D3 — REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KWA	2	LPH	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K040627	1	DePuy ASR Modular Acetabular Cup System	1	DePuy
2	K000306	2	Pinnacle Acetabular Cup System	2	DePuy
3	K823145	3	Porocoat Lunceford Acetabulum	3	DePuy
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Acetabular Cup Prosthesis

	Trade or Proprietary or Model Name for This Device		Model Number
1	DePuy ASR 300 Acetabular Cup System	1	999830744; 999830746; 999830748; 999830750; 999830752; 999830754; 999830756; 999830758; 999830760; 999830762
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
87 KWA

C.F.R. Section *(if applicable)*
888.3330

Device Class

☐ Class I ☐ Class II
☒ Class III ☐ Unclassified

Classification Panel

Orthopedic Devices Branch, Division of General and Restorative Devices (DGRD)

Indications *(from labeling)*

Unchanged from K040627, see attached

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STER ILIZATION SITES RELATING TO A SUBMISSION

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 8010379	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name DePuy International Limited		Establishment Registration Number 8010379		
Division Name *(if applicable)*		Phone Number *(including area code)* (574) 371-4906		
Street Address St. Anthony Road		FAX Number *(including area code)* (574) 371-4987		
City Leeds		State / Province N/A	ZIP/Postal Code LS11 8DT	Country United Kingdom
Contact Name Ms. Randa Franklin	Contact Title Sr. Regulatory Specialist		Contact E-mail Address rfrankl2@dpyus.jnj.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number (b)(4)	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
ame (b)(4)		ent Registration Number (b)(4)		
Division Name *(if applicable)*		g area code) (b)(4)		
(b)(4)		FAX Number *(including area code)* (b)(4)		
(b)(4)		State / Province N/A	ZIP/Postal Code N/A	(b)(4)
(b)(4)	Contact Title Principal Consultant		(b)(4)	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)* ( )		
Street Address		FAX Number *(including area code)* ( )		
City		State / Province	ZIP/Postal Code	Country
Contact Name	Contact Title		Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
1	Standards No.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Special 510(k): Device Modification

December 3, 2007

Food and Drug Administration
CDRH/ODE
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Reference: **Special 510(k): Device Modification**
K040627, DePuy ASR™ Modular Acetabular Cup System, cleared August 5, 2005

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate on the DePuy ASR™ 300 Acetabular Cup System, as a **Special 510(k): Device Modification** to address minor design modifications to the previously FDA cleared DePuy ASR™ Modular Acetabular Cup System (K040627). This submission includes a paper and an electronic copy on CD that is an exact duplicate of the paper copy.

The following modification was implemented on the currently marketed DePuy ASR™ Modular Acetabular Cup System**:**

- Addition of three spikes on the outer surface of the cup for adjunct fixation.

The indications for the DePuy ASR™ 300 Acetabular Cup System have not changed from those cleared in K040627.

DePuy believes the modifications discussed in this 510(k) submission are eligible for the Special 510(k) process since they have the same fundamental scientific technology and intended use as the predicate devices.

Pursuant to 21 CFR 807.95(c) (3), DePuy considers this 510(k) submission to be confidential commercial information and requests that FDA treat it as such, as afforded by 18 USC 1905, 21 USC 331 (j), 5 USC 552, and other applicable laws. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone (574) 372-5023, fax (574) 371-4987, or email Dsincla3@dpyus.jnj.com.

Sincerely,

Dawn R. Sinclair
Regulatory Associate, Regulatory Affairs
DePuy Orthopaedics, Inc.

Design and Use of the Device

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?[A]	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?[A]		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		X
Does the device contain a drug?		X

[A] A device may be intended for both prescription and over-the-counter use. If so, the answer to both of these questions is yes

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Section 4 – Indications for Use Statement

510 (k) Number (if known): _____

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.

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) Page 1 of 1

Section 5 – 510 (k) Summary

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

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.

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.

Section 6 – Truthful and Accurate Statement

[As required by 21 *CFR* 807.87 (k)]

I certify that, in my capacity as Senior Bioengineer of DePuy International Limited, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Chris Hunt
Senior Bioengineer

Date

Section 7 – Class III Summary and Certification

[As required by 21 *CFR* 807.94]

I certify that, in my capacity as Regulatory Affairs Associate at DePuy Orthopaedics, Inc., a Johnson & Johnson company, that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for metal-on-metal total hip systems. I further certify that I am aware of the types of problems to which metal-on-metal total hip systems are susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems is complete and accurate.

_____
Dawn R. Sinclair

_____
Date

_____
(Premarket Notification [510(k)] Number)

SUMMARY OF THE TYPES AND CAUSES OF SAFETY OR EFFECTIVENESS PROBLEMS

METAL-ON-METAL TOTAL HIP SYSTEMS

Based on the literature summary provided in G960262 for the DePuy Ultima Metal-On-Metal Acetabular Cup System, the most significant complications associated with historical metal-on-metal total hip replacement systems include:

- Loosening, possibly related to surgical technique, poor fixation, sub-optimal bearing design resulting in high frictional torque and/or bearing seizure, or sub-optimal range of motion in early designs;
- Pain, possibly related to loosening;
- Calcar resorption, possibly related to poor early stem designs and not the metal-on-metal articulation;

Other potential complications which could be associated with metal-on-metal hip replacement, but have not been conclusively documented clinically include:

- Local and systemic reactions to increased metal ion release and metal wear debris, especially a higher incidence of certain site specific cancers;
- Fretting and corrosion of the implant due to galvanic corrosion between dissimilar metals;

Other types of safety and effectiveness problems which are associated with metal-on-metal hip replacement are those which are associated with all total joint replacements. These include: infection, dislocation, cardiovascular disorders (including venous thrombosis, pulmonary embolism, and myocardial infarction), pneumonia, atelectasis, hematoma, nerve damage, delayed wound healing, reaction to bone cement, metal sensitivity, bone fracture, soft tissue imbalance, failure to relieve pain, failure to restore range of motion and deformity of the joint.

In order to reduce the chance of complications with a metal-on-metal hip replacement device, the following conditions, which tend to adversely affect safety and/or effectiveness of any total joint arthroplasty, should be reduced or eliminated: marked osteoporosis with poor bone stock and danger of impaired abutment of implants, systemic and metabolic disorders leading to progressive deterioration of solid bone support for the implant (e.g. cortisone therapies, immunosuppressive therapies), history of general infectious disease (e.g. erysipelas) or local infectious disease, severe deformities leading to impaired anchorage or improper positioning of the implant, tumors of the supporting bone structure, allergic reactions to the implant materials , and tissue reactions to corrosion or wear products.

Section 8 – Financial Certification or Disclosure Statement

This section is not applicable because clinical studies were not conducted for this submission.

Section 9 – Declarations of Conformity and Summary Reports

This section is not applicable since this submission is not an Abbreviated 510(k) submission.

Section 10 – Executive Summary

Pursuant to Section 510 (k) of the Federal Food, Drug and Cosmetic Act and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations and the Safe Medical Devices Act of 1990, DePuy Orthopaedics, Inc., 700 Orthopaedic Drive, Warsaw, Indiana, 46582, hereby submits the following information as a Special 510(k) for design modifications of the DePuy ASR™ Modular Acetabular Cup System, cleared in K040627.

A. 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 DePuy ASR 300 Acetabular Cup System is identical in design to the predicate acetabular cups cleared in the DePuy ASR™ Modular Acetabular Cup System (K040627 on August 5, 2005) with the addition of spikes on the outer surface of the cup.

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 outer diameter sizes 44mm through 62mm in two-millimeter increments. There are no separate liner components to this system, as the liners are integral to the one-piece acetabular cups. The spike design is identical to the design of the predicate Pinnacle 300 Acetabular Cups cleared in K000306 on March 23, 2000 while the material and manufacturing method is identical the predicate Porocoat Lunceford Acetabulum cleared in K823145 on February 9, 1983.

B. 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.

C. 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.

D. Device Comparison Table

The DePuy ASR 300 Acetabular Cup System is considered substantially equivalent to the DePuy ASR Modular Acetabular Cup System, the Pinnacle 300 Acetabular Cup System and the Porocoat Lunceford Acetabulum. **Table 1** is provided to summarize the similarities and differences between the devices. As the table illustrates, the indications for use and design of the subject acetabular cups are identical to the acetabular cups cleared in K040627 and K000306 while the material and manufacturing methods for the spikes are identical to that in K823145.

Table 1. DEVICE COMPARISON TABLE

Characteristics	Subject Device	Predicate Device	Predicate Device	Predicate Device
Device Name:	**DePuy ASR™ 300 Acetabular Cup System**	**DePuy ASR™ Modular Acetabular Cup System K040627**	**Pinnacle® Acetabular Cup System K000306**	**Porocoat® Lunceford Acetabulum K823145**
Acetabular Cup Design:				
Shell Profile	Low profile	Low profile	Full profile	Low profile
Construction	One piece shell	One piece Shell	Modular Metal Shell with UHMWPE liner	Modular Metal Shell with UHMWPE liner
Sizes – Outer Diameters (OD)	44mm – 62mm (2mm increments)	44mm – 62mm (2mm increments)	48mm – 66mm (2mm increments)	44mm – 58mm (2mm increments)
Spikes	3	N/A	3	3
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.	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.	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 revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.	General indications for the device are severe rheumatoid or osteoarthritis, avascular necrosis, post-traumatic arthritis, and other disorders where subchodral bone stock has not been compromised.
Material/ Manufacturing Methods:				

Acetabular Cup	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	Titanium alloy ASTM F-136	Cast High Carbon Co-Cr-Mo alloy ASTM F-75
OD Coating – Cup	Porocoat® porous coating with DuoFix™ HA Coating	Porocoat® porous coating with DuoFix™ HA Coating	Porocoat® porous coating	Porocoat® porous coating
Spikes	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	N/A	Titanium alloy ASTM F-136	Cast High Carbon Co-Cr-Mo alloy ASTM F-75
OD Coating – Spikes	Porocoat® porous coating with DuoFix™ HA	N/A	Porocoat® porous coating	Porocoat® porous coating
Packaging	(b)(4)			
Sterile Method	Gamma	Gamma	Gamma	Gamma

E. Summary of Performance Testing

Biomechanical testing was not performed for the subject device. The subject ASR 300 version of the ASR Acetabular Cups have the same fit and function as the previously cleared acetabular cups (K040627) therefore, the previous mechanical testing is valid for the subject ASR 300 design. Further, the external cup geometry, coating specification, spike design and surgical technique are identical to features on predicate devices, which have been shown to be safe and effective.

F. Compliance with Special Controls

Sections 513 and 514 of the ACT, as amended under the Safe Medical Devices Act of 1990, do apply to this type of device, but a performance standard has not yet been promulgated. Further, DePuy is not aware of any requirements for post market surveillance or other special controls for this device at this time.

Section 11 – Device Description

A. 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 DePuy ASR 300 Acetabular Cup System is identical in design to the predicate acetabular cups cleared in the DePuy ASR Modular Acetabular Cup System (K040627 on August 5, 2005) with the addition of three spikes on the outer surface of the cup. The identical features are:

- The subject acetabular cups will be manufactured from the same ASTM F-75 cobalt-chrome molybdenum (CoCrMo) alloy that is identical to that used for the predicate acetabular cups cleared in K040627.
- The sizing of the subject acetabular cups and the predicate device (K040627) will be identical. There will be ten sizes of acetabular cups, 44mm through 62mm in two-millimeter increments.
- The design of the subject acetabular cup, like the predicate device (K040627), will be low profile.
- The bearing surface has a high degree of sphericity and low surface roughness, like the predicate device (K040627), to provide favorable wear characteristics when combined with the appropriate femoral component.
- The bone-interfacing surface of the subject acetabular cup, like the predicate device (K040627), will feature Porocoat® porous coating with the addition of a hydroxyapatite (HA) coating. The Porocoat porous coating material and process is identical to that used for previously cleared devices (P820024 AML and K030979 Solution System). The HA powder used in the plasma spray process is identical to that previously characterized for the predicate acetabular cups cleared in K040627 and conforms to ASTM F1185-88 Hydroxyapatite (Ca5(PO4)3OH) ceramic.

The *only* design difference between the acetabular cup cleared in K040627 and the subject acetabular cup is the addition of three spikes on the outer surface of the cup, each of which has a cylindrical shaft and conical tip. The spikes are intended to pierce the bone of the acetabulum and provide immediate fixation in addition to the interference (frictional) fit achieved by underreaming the acetabulum. The diameter of the spikes and spike tip geometry is constant across the size range. The spike shafts are cast onto the implant and have a porous layer formed of beads, coated with hydroxyapatite (HA). The spike features are geometrically identical to the spike design of the predicate Pinnacle 300 Acetabular Cup implants cleared in K000306 on March 23, 2000 while the spike material and manufacturing method are identical to the predicate Porocoat Lunceford Acetabulum cleared in K823145 on February 9, 1983.

The subject DePuy ASR 300 Acetabular Cup System is compatible with ASR femoral components cleared in K040627 on August 5, 2005. In addition, previously cleared ASR 12/14 and Ultima 11/13 taper sleeve adapters and femoral stems manufactured of cobalt chrome or titanium alloy and having taper sizes of 12/14 or 11/13 are used as compatible components in total hip arthroplasty. A list of part numbers and descriptions for the subject acetabular cups and compatible components is provided in **Exhibit A**.

Engineering drawings for the subject device are provided in **Exhibit B**.
A device graphic is provided below in **Figure 1**.

Figure 1. DePuy ASR 300 Acetabular Cup

B. <u>Materials</u>

The subject DePuy ASR 300 Acetabular Cup System is manufactured from the same high carbon cast cobalt-chrome molybdenum (CoCrMo) alloy as the predicate ASR Acetabular Cups (K040627). The material meets the requirements of *ASTM F-75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants.*

The spikes featured on the subject DePuy ASR 300 Acetabular Cup System are manufactured from the same high carbon cast cobalt-chrome (CoCrMo) alloy as the predicate Porocoat Lunceford Acetabulum (K823145). The material meets

the requirements of *ASTM F-75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants.*

C. Summary of Design Control Activities

The proposed modifications to the DePuy ASR Acetabular Cups were evaluated using a (b)(4) The design verification activities that were performed to evaluate the modified device are listed in **Table 2**.

Table 2. DEVICE MODIFICATIONS, RISKS & VERIFICATION ACTIVITIES

DEVICE MODIFICATION	RISK	VERIFICATION ACTIVITY	ACCEPTANCE CRITERIA	RESULTS OF VERIFICATION
Addition of three spikes to the external surface of the ASR™ acetabular component	(b)(4)			

DEVICE MODIFICATION	RISK	VERIFICATION ACTIVITY	ACCEPTANCE CRITERIA	RESULTS OF VERIFICATION
			(b)(4)	

Section 12 – Substantial Equivalence Discussion

The DePuy ASR 300 Acetabular Cup System is substantially equivalent to the devices listed below in **Table 3**.

Table 3. PREDICATE DEVICE INFORMATION

Manufacturer	510(k) Clearance (date)	Device Name
DePuy	K040627 (August 5, 2005)	ASR™ Acetabular Cup System
DePuy	K000306 (March 23, 2000)	Pinnacle® Acetabular Cup System
DePuy	K823145 (February 9, 1983)	Porocoat® Lunceford Acetabulum

There are no new applications, indications or materials presented here. The DePuy ASR 300 Acetabular Cup System is substantially equivalent to the existing DePuy ASR Acetabular Cup System, Pinnacle Acetabular Cup System and the Porocoat Lunceford Acetabulum based on the similarities in intended use, indications for use, materials, design, packaging and sterility.

As a summary, a comparison matrix between the subject DePuy ASR 300 Acetabular Cup System and the predicate devices is provided in **Table 4**.

Table 4. DEVICE COMPARISON TABLE

Characteristics	Subject Device	Predicate Device	Predicate Device	Predicate Device
Device Name:	**DePuy ASR™ 300 Acetabular Cup**	**DePuy ASR™ Modular Acetabular Cup System K040627**	**Pinnacle® Acetabular Cup System K000306**	**Porocoat® Lunceford Acetabulum K823145**
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.	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.	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 revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.	General indications for the device are severe rheumatoid or osteoarthritis, avascular necrosis, post-traumatic arthritis, and other disorders where subchodral bone stock has not been compromised.
Acetabular Cup Design:				
Shell Profile	Low profile	Low profile	Full profile	Low profile
Construction	One piece shell	One piece Shell	Modular Metal Shell with UHMWPE liner	Modular Metal Shell with UHMWPE liner
Sizes – Outer Diameters (OD)	44mm – 62mm (2mm increments)	44mm – 62mm (2mm increments)	48mm – 66mm (2mm increments)	44mm – 58mm (2mm increments)
Articulation requirements	Superfinished surface	Superfinished surface	N/A	N/A
Spike Design:				
Number of spikes	3	N/A	3	3

Characteristics	Subject Device	Predicate Device	Predicate Device	Predicate Device
Device Name:	**DePuy ASR™ 300 Acetabular Cup**	**DePuy ASR™ Modular Acetabular Cup System K040627**	**Pinnacle® Acetabular Cup System K000306**	**Porocoat® Lunceford Acetabulum K823145**
Cylindrical diameter	3.70mm	N/A	3.70mm	3.9624mm
Height (spike height from cup OD center)	44mm OD: 20.2975mm 62mm OD: 29.2735mm	N/A	44mm OD*: 20.2975mm 62mm OD: 29.2735mm	44mm OD: 22.5mm 58mm OD: 24.23mm
Tip angle	60°	N/A	60°	60°
Tip diameter	4.70mm	N/A	4.72mm	3.9624mm
Orientation on cup OD	120°	N/A	120°	120°
Material/ Manufacturing Methods:				
Acetabular Cup	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	Titanium alloy ASTM F-136	Cast High Carbon Co-Cr-Mo alloy ASTM F-75
OD Coating – Cup	Porocoat® porous coating with DuoFix™ HA Coating	Porocoat® porous coating with DuoFix™ HA Coating	Porocoat® porous coating	Porocoat® porous coating
Spikes	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	N/A	Titanium alloy ASTM F-136	Cast High Carbon Co-Cr-Mo alloy ASTM F-75
OD Coating – Spikes	Porocoat® porous coating with DuoFix™ HA	N/A	Porocoat® porous coating	Porocoat® porous coating
Packaging	(b)(4)			
Sterile Method	Gamma	Gamma	Gamma	Gamma

*Pinnacle Acetabular Cup size 44mm is outside of the cleared size range (48mm-66mm), therefore the spike height was derived by linearly projecting spike lengths from existing sizes to illustrate that the spike design of the subject ASR 300 device is identical to the predicate Pinnacle device.

Section 13 – Proposed Labeling

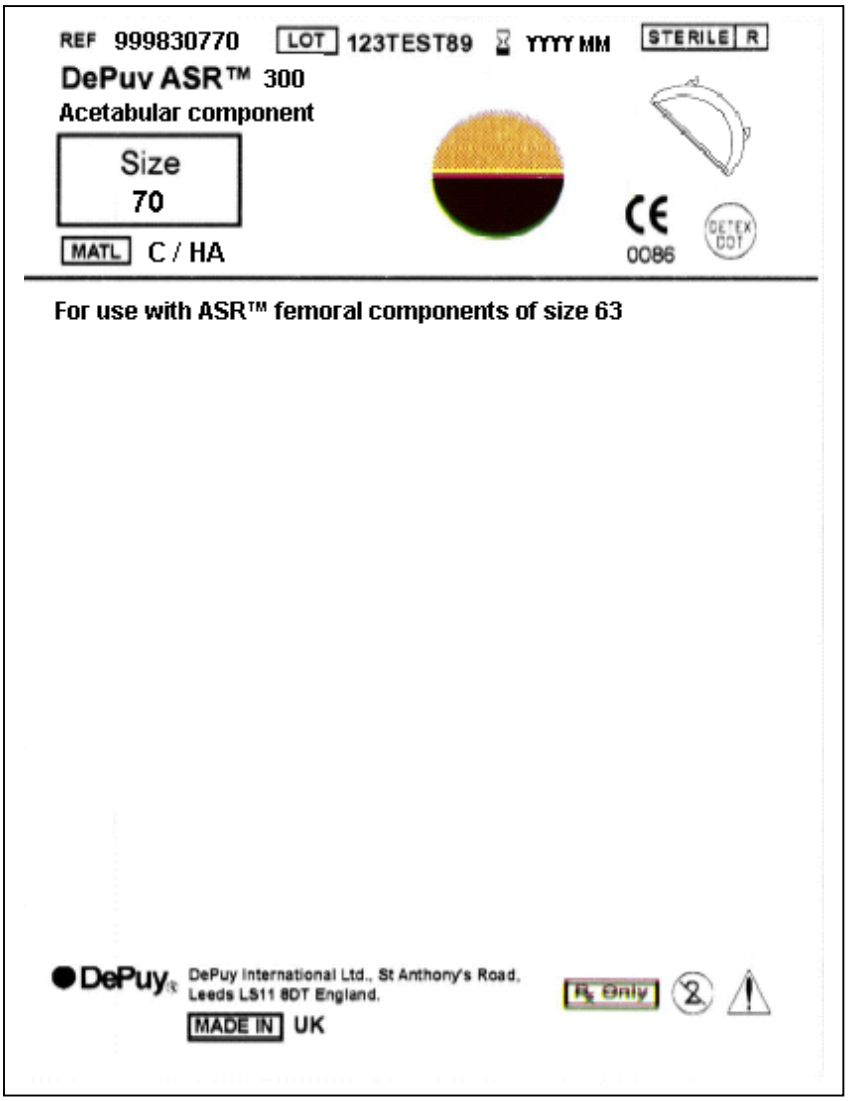
Draft labels and a draft package insert are provided below.

Promotional/advertising materials for the subject device have not yet been developed. They will, however, be similar in design and content to those for the ASR Acetabular Cup System currently distributed by DePuy.

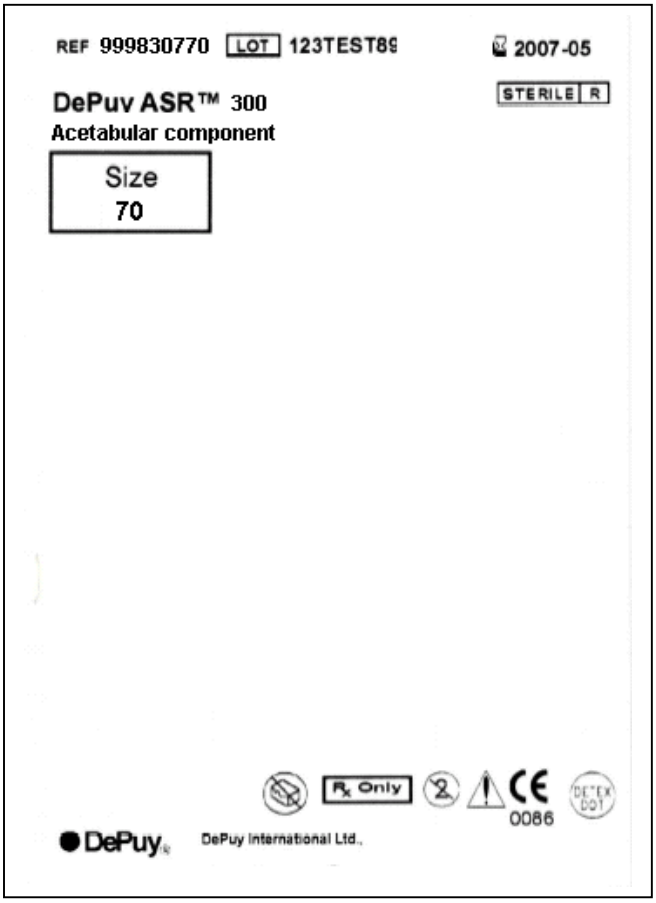
DEPUY ASR 300 ACETABULAR COMPONENT

Note: The following label sample is a **draft** as final label samples were not available at the time of submission. The sponsor recognizes that the size shown on the draft label is not included in the range for the current subject device and will modify the size accordingly for the proposed size range.

Main Label (applied to the product Carton)



Inner Pack Label (applied to the Inner pack)



Patient and Distribution Labels

Instructions For Use

ENGLISH

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Total Hip System-
DePuy ASR™ 300 Acetabular Cup System

For Single Use Only

Sterilized by gamma irradiation

Description
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.

Indications and Usage
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.

CAUTION: DO NOT USE BONE CEMENT FOR FIXATION OF A HYDROXYAPATITE COATED PROSTHESIS.

Information for Use
An instrumentation system, as well as a system of trial components, is available to assure proper fit an alignment of the prosthesis. Correct fit and alignment will reduce stresses at interface surfaces to enhance implant fixation. The surgeon should refer to the appropriate surgical technique manual details on the use of the instrument system and implantation of the prosthesis. This manual is available from your local DePuy sales representative or distributor.

Contraindications
Use is contraindicated in cases with active or recent joint sepsis, insufficient bone stock, marked atrophy or deformity in the upper femur, skeletal immaturity, chronic renal failure, or where loss of musculature or neuromuscular disease would render the procedure unjustifiable.

Warnings
Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental or occupational conditions will likely result in extreme stresses to the implant may result in premature failure due to loosening, fracture or wear.

CAUTION: The following conditions, singularly or concurrently, tend to impose severe loading on the affected extremity, thereby placing the patient at higher risk for failure of the hip replacement:

1. Obesity or excessive patient weight.
2. Manual labor.
3. Active sports participation.

4. High levels of patient activity.
5. Likelihood of falls.
6. Alcohol or drug addiction.
7. Other disabilities, as applicable.

CAUTION: The following conditions singularly or concurrently, tend to adversely affect the fixation of hip replacement implants:

1. Marked osteoporosis or poor bone stock.
2. Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g., diabetes mellitus, steroid therapies, immunosuppressive therapies, etc.).
3. History of general or local infections.
4. Severe deformities leading to impaired fixation or improper positioning of the implant.
5. Tumors of the supporting bone structures.
6. Allergic reactions to implant materials (e.g., bone cement, metal, polyethylene).
7. Congenital dysplasia of the hip which may reduce the bone stock available to support the acetabular cup prosthesis in total hip replacement.
8. Tissue reactions to implant corrosion or implant wear debris.
9. Disabilities of other joints (i.e., knees and ankles).

Postoperative care is extremely important. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion and activity levels permissible. Early motion and load bearing should be carefully monitored.

This implant should not be used with other manufacturers' components. Use of components other than those recommended could lead to loosening, wear fracture during assembly and premature failure.

Do not alter or modify implants in any way.

Precautions

Always use a trial prosthesis to check correct device positioning prior to inserting the final implant. Incorrect positioning of the device may lead to excessive wear and/or early loosening of the device.

To prevent contamination of this prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surface before the final decision to implant has been made.

An implant should never be re-used. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.
Likewise, a new implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

The highly polished bore of the device should not come into contact with abrasive surfaces, as this may damage the bore and affect performance.

Adverse Effects

Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements. Subclinical nerve damage has also been reported more frequently, often associated with surgical trauma. Dislocation and subluxation resulting from improper positioning and/or muscle and fibrous tissue laxity may also occur, as may loosening and subsequent failure of the total hip prosthesis. Histological reactions have been reported as an apparent response to exposure to a foreign material. The actual clinical significance of these reactions is unknown. Implanted metal alloys release metallic ions into the body. In situations where bone cement is not used, higher ion release due to increased surface area of a porous coated prosthesis is possible. There have been reports of failure of bone to grow into porous surfaces and fix components. Shedding or fragmentation of the porous surface has been reported, with potential for release of metallic debris into the joint space. Radiolucencies of bone adjacent to porous surfaces have been noted, although the clinical significance of this observation is uncertain in many cases. **Serious adverse effects may necessitate surgical intervention.**

Sterility and Handling

The components are supplied sterile by exposure to gamma irradiation.

DO NOT RESTERILIZE and DO NO USE if the package is damaged or broken and sterility may be compromised.

Components may **not** be resterilized by the hospital because of the possibility of damaging the articulating and interfacing surfaces of the implant and/or damaging or contaminating the porous and hydroxyapatite surface. The care and handling of porous coated and hydroxyapatite coated implants demands greater attention because of the increased potential for particulate and microbiological contamination. Body fluids, tissues and particulate matter adhere to the beaded surface. Therefore, it is critical to minimize handling of the prosthesis. The package should be opened only after the correct size has been determined, as opened packages may not be returned for credit.

Further information is available from your DePuy representative on request.

Section 14 – Sterilization/Shelf Life

Packaging and sterilization methods for the subject device will be equivalent to those used for the DePuy ASR Acetabular Cup System cleared in K040627. The following contract sterilizer will be used:

Contract Sterilizer: (b)(4)

Sterilization:

The subject DePuy ASR 300 Acetabular Cup implant is provided sterile, using the following parameters.

Method & Dose:

(b)(4)

Sterility Assurance Level (SAL):

(b)(4)

Validation Method:

(b)(4)

Pyrogenicity:

(b)(4)

Packaging:

(b)(4)

Section 15 – Biocompatibility

The subject ASR 300 Acetabular Cup does not require biocompatibility testing because the cobalt-chrome-molybdenum alloy used in their fabrication meet the requirements of the FDA consensus standard *ASTM F-75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants.*

Section 16 – Software

This section is not applicable because the device does not contain software.

Section 17 – Electromagnetic Compatibility/Electrical Safety

The device does not include electronic components; therefore electromagnetic compatibility is not applicable.

Section 18 – Performance Testing – Bench

Biomechanical testing was not performed for the subject device. The subject ASR 300 version of the ASR Acetabular Cups have the same fit and function as the previously cleared acetabular cups (K040627) therefore, the previous mechanical testing is valid for the subject ASR 300 design. Further, the external cup geometry, coating specification, spike design and surgical technique are identical to features on predicate devices, which have been shown to be safe and effective.

Section 19 – Performance Testing – Animal

Animal testing was not performed on this device therefore this section is not applicable.

Section 20 – Performance Testing – Clinical

A clinical study was not conducted for this device therefore this section is not applicable.

Exhibit A: List of Devices

Subject Product Codes

Catalog Number	Product Description
999830744	ASR 300 ACETABULAR COMPONENT – SIZE 44MM
999830746	ASR 300 ACETABULAR COMPONENT – SIZE 46MM
999830748	ASR 300 ACETABULAR COMPONENT – SIZE 48MM
999830750	ASR 300 ACETABULAR COMPONENT – SIZE 50MM
999830752	ASR 300 ACETABULAR COMPONENT – SIZE 52MM
999830754	ASR 300 ACETABULAR COMPONENT – SIZE 54MM
999830756	ASR 300 ACETABULAR COMPONENT – SIZE 56MM
999830758	ASR 300 ACETABULAR COMPONENT – SIZE 58MM
999830760	ASR 300 ACETABULAR COMPONENT – SIZE 60MM
999830762	ASR 300 ACETABULAR COMPONENT – SIZE 62MM

Compatible Product Codes

Catalog Number	Part Number	Description	510(k) Clearance
999800139	999890239	ASR UNI FEMORAL HEAD SIZE 39MM	K040627
999800141	999890241	ASR UNI FEMORAL HEAD SIZE 41MM	K040627
999800143	999890243	ASR UNI FEMORAL HEAD SIZE 43MM	K040627
999800145	999890245	ASR UNI FEMORAL HEAD SIZE 45MM	K040627
999800146	999890246	ASR UNI FEMORAL HEAD SIZE 46MM	K040627
999800147	999890247	ASR UNI FEMORAL HEAD SIZE 47MM	K040627
999800149	999890249	ASR UNI FEMORAL HEAD SIZE 49MM	K040627
999800151	999890251	ASR UNI FEMORAL HEAD SIZE 51MM	K040627
999800153	999890253	ASR UNI FEMORAL HEAD SIZE 53MM	K040627
999800155	999890255	ASR UNI FEMORAL HEAD SIZE 55MM	K040627

The following are a representative sample of taper adapter sleeve and femoral stem compatible components for the DePuy ASR™ Modular Acetabular System, and should not be taken as a complete listing.

Femoral stem compatible components are limited to stems manufactured of Cobalt Chrome Molybdenum alloy or Titanium alloy, and having taper sizes of 11/13 or 12/14. This limitation corresponds to the listed taper sleeve adapter styles manufactured from Cobalt Chrome alloy.

Description	Material	Taper	Catalog Number	Part Number	510(k) Clearance
Ultima Unipolar Head Adapter Sleeve +0mm	CoCrMo	11/13	852621	852621	K965156 1/24/97
Ultima Unipolar Head Adapter Sleeve +6mm	CoCrMo	11/13	852622	852622	K965156 1/24/97
Ultima Unipolar Head Adapter Sleeve +12mm	CoCrMo	11/13	852623	852623	K965156 1/24/97
Taper Sleeve Adapters 12/14 +1.5	CoCrMo	12/14	999800102	999800312	K040627 8/5/05
Taper Sleeve Adapters 12/14 +5	CoCrMo	12/14	999800105	999800315	K040627 8/5/05
Taper Sleeve Adapters 12/14 +8.5	CoCrMo	12/14	999800108	999800318	K040627 8/5/05
AML Hip Stem	CoCrMo	12/14	1554-01-105	1554-01-105	K012364 10/19/01
Prodigy Hip Stem	CoCrMo	12/14	1520-16-050 1520-17-050	1520-16-050 1520-17-050	K000207 2/04/00
Replica Hip Stem	CoCrMo	12/14	1530-32-000 1530-33-000	1530-32-000 1530-33-000	K934334 12/21/94

Description	Material	Taper	Catalog Number	Part Number	510(k) Clearance
Vision Solution Std	CoCrMo	12/14	1571-02-000	1571-02-000	K953703 2/01/96
Summit Porous Hip Stem	Ti	12/14	1570-01-070	1570-01-070	K001991 8/25/00
Trilock Std Hip Stem	CoCrMo	12/14	1012-01-063	1012-01-063	K001982 7/26/00
Endurance Total Hip Stem	CoCrMo	12/14	1521-01-000	1521-01-000	K942370 11/10/94
Luster Total Hip Stem	CoCrMo	12/14	1521-80-001	1521-80-001	K983136 11/25/98
Summit Cemented Hip Stem	CoCrMo	12/14	1570-06-080	1570-06-080	K023453 11/13/02
Uni-Rom Hip Stem	Ti	11/13	85-5871 85-5872 85-5873 85-5874	664733 664734 664735 664736	K974331 2/06/98
SROM Hip Stem	Ti	11/13	56-3514 56-3516 56-3518	612195 612196 612197	K851422 9/18/85

Exhibit B: Engineering Drawings

(b)(4)

Exhibit C: Declaration of Conformity with Design Controls

Special 510(k)
Declaration of Conformity with Design Controls

DePuy ASR™ 300 Acetabular Cup

Verification Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for this modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

_____ Date_____

Chris Hunt
Senior Bioengineer
DePuy International Limited

Manufacturing Facility

The manufacturing facility, DePuy International Limited, is in conformance with the design control requirements as specified in 21 *CFR* 820.30 and the records are available for review.

_____ Date_____

Nick Sheppard
Project Quality Engineer
DePuy International Limited

Exhibit D: Predicate Device Clearance Information

K040627 (pg 1 of 2)

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

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)

Page 1 of 1

(Posted November 13, 2003)

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

510(k) Number K040627

K000306

MAR 2 3

DePuy
a Johnson & Johnson company

SUMMARY OF SAFETY AND EFFECTIVENESS

DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA
Tel: +1 (219) 267 8143
Fax: +1 (219) 267 7196

NAME OF FIRM: DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT: Lynnette Whitaker
Group Leader, Regulatory Affairs

TRADE NAME: Pinnacle Acetabular System

COMMON NAME: Acetabular Cup Prosthesis

CLASSIFICATION: 888.3358 Hip joint metal/polymer semi-constrained cementless prosthesis

DEVICE PRODUCT CODE: 87 LPH

SUBSTANTIALLY EQUIVALENT DEVICES: SUMMIT™ Acetabular System

DEVICE DESCRIPTION AND INTENDED USE:
The Pinnacle Acetabular 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 revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

All Pinnacle porous-coated acetabular shells are indicated for cementless application.

The Pinnacle Acetabular System is part of a modular system for use in total hip replacement. The acetabular component is provided as two separate units, a porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner manufactured from ultra high molecular weight polyetheylene (UHMWPE), which locks into the outer shell. The liner component articulates with a femoral head of an appropriate diameter.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The Pinnacle Acetabular System has the following similarities to the acetabular cup liners that were cleared in K983014: same intended use; same material; same method of manufacture; same design; same sterilization and packaging methods. The Pinnacle Acetabular System demonstrated equivalent performance to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 23 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynnette Whitaker
Group Leader, Regulatory Affairs
Depuy Orthopedics, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K000306
Trade Name: Pinnacle Acetabular System
Regulatory Class: II
Product Code: LPH
Dated: Febrary 24, 2000
Received: Febrary 28, 2000

Dear Ms. Whitaker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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.

MAR 2 3 2000

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

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

Enclosure

K000306

510(k) Number (if known) K000306

Device Name Pinnacle Acetabular System

Indications for Use:

The Pinnacle Acetabular 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 revision of the previous hip arthroplasty and for patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

All Pinnacle porous-coated acetabular shells are indicated for cementless application.

Concurrence of CDRH, Office of Device Evaluation

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000306

Prescription Use Yes
(Per 21 CFR 801.109)

OR

Over-The Counter Use No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

RECEIVED
FEB 18 1983
DePUY Warsaw, Indiana FEB 9 1983

Mr. Steven J. Wentworth
Clinical Affairs Coordinator
DePuy
Division of Boehringer Mannheim Corp.
P.O. Box 988
Warsaw, Indiana 46580

Re: K823145
Porocoat[R] Lunceford Acetabulum
[Component of Total Hip System]
Dated: October 18, 1982
Received: October 25, 1982

Dear Mr. Wentworth:

We have reviewed your Section 510(k) notification of intent to market the above device. Because the description of the device specifies two significantly different applications - cemented and non-cemented, the scientific review and equivalency determination have been divided accordingly.

Based upon our review, we have concluded that the device for cemented application is equivalent to devices marketed in interstate commerce prior to May 28, 1976; and that the device for non-cemented use is not substantially equivalent to any device that was in commercial distribution before May 28, 1976, or to any device introduced since that date which has been classified in Class I (General Controls) or Class II (Performance Standards).

Cemented Use

The decision is based upon "Porocoated" components being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic 'bone cement.' Thus, marketing of the "Porocoated" device would be contingent upon the labeling explicitly stating that the porous-surfaced component is intended to be fixed within bone with acrylic bone cement. If the labeling is satisfactory, you may market your device for cemented use subject to the general controls provision of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either Class II (Standards) or Class III (Premarket Approval), it would be subject to additional controls.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practices, labeling, and the misbranding and adulteration provisions of the Act. In the near future, the scope of general controls will be broadened to include additional regulations relating to restricted devices, records and reports, and others.

All regulations and information on meetings of the device classification panels, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so that you can convey your views to FDA if you desire. Also, the Federal Register will notify you of any additional requirements subsequently imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Office of the Hearing Clerk, FDA, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter should not be construed as approval of your device or its labeling. If you desire advice on the status of labeling for your device or other information pertaining to your responsibilities under the Act, please contact the Office of Medical Devices, Division of Compliance Operations, 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Non-Cemented Use

Additionally, we have concluded that the device for non-cemented use is not substantially equivalent to any device that was in commercial distribution before May 28, 1976, or to any device introduced since that date which has been classified in Class I (General Controls) or Class II (Performance Standards). This decision is based on the fact that all other metallic-backed, polymeric bearing acetabular components are designed for cemented application only. The ability of this device to be securely affixed without cement for the longer term has not been clinically demonstrated. Therefore, your device for non-cemented application is classified by statute in Class III under Section 513(f) of the Act.

Section 515(a)(2) of the Act requires Class III devices to have an approved premarket approval application (PMA) before they can be legally marketed unless the device has an investigational device exemption under Section 520(g) of the Act or unless the device has been reclassified.

Premarket Approval. To prepare a premarket approval application, statutory provisions appearing in Section 515(c) of the Act must be followed. To assist you in preparing a PMA, we have enclosed a copy of the proposed PMA procedures regulation and a "Guideline for the Arrangement and Content of a PMA."

Investigational Use. In the absence of an approved premarket approval application, a Class III device may be distributed only for investigational use. Enclosed is a copy of the Investigational Device Exemption regulation, which must be followed if your device is used in a clinical investigation.

Petition for Reclassification. If you believe that your device should not have to undergo premarket approval before it is commercially distributed, you may petition FDA for reclassification of your device under Section 513(f)(2) of the Act.

Premarket approval applications, investigational device exemption requests, and petitions for reclassification should be submitted to:

Food and Drug Administration
Office of Medical Devices
Document Control Center (HFK-20)
8757 Georgia Avenue
Silver Spring, Maryland 20910

Any commercial distribution of this device, for use without bone cement, prior to approval of an application for premarket approval or the effective date of any order by the FDA reclassifying your device into Class I or II, would be a violation of the Federal Food, Drug, and Cosmetic Act.

If you need any information concerning our decision or the alternatives available to you under the law, please contact Carl A. Larson, Ph.D., at (301) 427-7156.

Sincerely yours,

Robert G. Britain

Robert G. Britain
Associate Director for
Device Evaluation
Office of Medical Devices
National Center for Devices
and Radiological Health

Enclosures