USER:	**CURTSINGER, MARGARET A (mac)**
FOLDER:	**K080991 - 216 pages (FOI:10008002)**
COMPANY:	**DEPUY ORTHOPAEDICS, INC. (DEPUORTHA)**
PRODUCT:	**PROSTHESIS, HIP, SEMI-CONSTRAINED (METAL UNCEMENTED ACETABULAR COMPONENT) (KWA)**
SUMMARY:	**Product: DEPUY ASR XL MODULAR ACETABULAR CUP SYSTEM**

DATE REQUESTED:	**Fri Dec 17 24:00:00 2010**
DATE PRINTED:	**Wed Feb 09 11:06:18 2011**
Note:	**Releasable Version**

Table of Contents

K080991 # 1/3

510(k) Summary

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

JUL - 2 2008

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
MANUFACTURER:	DePuy International Limited St. Anthony Road Leeds, United Kingdom LS11 8DT Establishment Registration Number: 8010379
510(K) CONTACT:	Dawn Sinclair Regulatory Affairs Associate Telephone: (574) 372-5023 Facsimile: (574) 371-4987 Electronic Mail: Dsincla3@dpyus.jnj.com
DATE PREPARED:	February 25, 2008
PROPRIETARY NAME:	DePuy ASR™ XL Modular Acetabular Cup System
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	Class III per 21 *CFR* 888.3330, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
DEVICE PRODUCT CODE(S):	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy ASR™ Modular Acetabular Cup System (K040627) DePuy ASR™ 300 Acetabular Cup System (K073413) Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes) (K021349) DePuy Ultima® Unipolar Head and Adapter Sleeves (K965156) DePuy ASR™ Taper Sleeve Adapter (K070359) Corail AMT™ Hip Prosthesis (K042992) DePuy Tri-Lock® Bone Preservation Stem (K073570)

K080991 #2/3

DEVICE DESCRIPTION:

The subject DePuy ASR™ XL Modular Acetabular Cup components are part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular cup is designed as a cobalt-chrome-molybdenum (CoCrMo) alloy one-piece cup with a porous coating and is available in outer diameter sizes 64mm through 70mm in two-millimeter increments. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. There are no separate liner components to this system, as the liners are integral to the one-piece acetabular cups.

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

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

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

INDICATIONS AND INTENDED USE:

Indications for Use:

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

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

K080991 #3/3

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Intended Use:

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

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

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy ASR™ XL Modular Acetabular Cup components described in this submission are, in our opinion, substantially equivalent to those included in the previously cleared DePuy ASR™ Modular Acetabular Cup System (K040627); the DePuy ASR™ 300 Acetabular Cup System (K073413); the Wright Medical Metal TRANSCEND® Articulation System (K021349); the DePuy ASR™ Adapter Sleeve (K070359); the DePuy Ultima® Adapter Sleeves (K965156); the Corail AMT™ Hip Prosthesis (K042992); and the DePuy Tri-Lock® Bone Preservation Stem (K073570), based upon the similarities in design, material composition and intended use/indications for use. A modification is simply being made to add additional cup sizes. In addition, minor revisions are being made to the Indications for Use and the Instructions for Use (IFU) to minimize the necessity for multiple IFUs and to update the contents to reflect current practice. The subject device does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2008

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

Re: K080991
Trade/Device Name: DePuy ASR™ XL Modular Acetabular Cup System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: March 17, 2008
Received: April 7, 2008

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Indications for Use Statement

510 (k) Number (if known): K080991

Device Name: DePuy ASR™ XL Modular Acetabular Cup System

Indications for Use:

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

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

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K080991

(Posted November 13, 2003)

Document Cover Sheet:

Date of Submission:	17-MAR-2008
Description:	DEPUY ASR XL MODULAR ACETABULAR CUP SYSTEM
Date of Scan:	04-MAR-2009
Document Prep:	DSFU 3/4/09
Scanner:	TTK4 3/5/09
Image Quality Reviewer:	

K080991-K7219

FSR0701-000

- - 6 3 8 5 0 6 M A R 0 4 1 4 0 3 4 0

Document Expected	Page # Start	Page # End	Page In Doc	Indexer
Correspondence 16-SEP-2008	1	14	15	
Total Scan pages: 16				
Total separator pages: 1				
Total documents: 1				
Total document pages: 14				

QC Signature _____

QC Bar Code Sticker

Document Cover Sheet:

Date of Submission:	17-MAR-2008
Description:	DEPUY ASR XL MODULAR ACETABULAR CUP SYSTEM
Date of Scan:	01-AUG-2008
Document Prep:	MH 8/1/08
Scanner:	MH 8/4/08
Image Quality Reviewer:	

K080991-K6852

FSR0801-000

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Document Expected	Page # Start	Page # End	Page In Doc	Indexer
Decision Letter 02-JUL-2008	1	2	3	
Indications for Use 02-JUL-2008	3	3	2	
Reviewer Memorandum 01-JUL-2008	4	5	3	
Reviewer Notes 01-JUL-2008	6	34	30	
Acknowledgement Letter 08-APR-2008	35	36	3	
Total documents: 5				
Total document pages: 36				
Total separator pages: 5				
Total Scan pages: 42				

QC Signature _____

QC Bar Code Sticker

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 K080991 cannot be located and therefore cannot be produced for this request.

- Correspondence — Pages 1 and 2

Lisa D. Lawrence
CDR Lisa D. Lawrence

County of Montgomery
State of Maryland

Subscribed and sworn before me this 13th day of January 2011.

Jeanne Marie Richwood
Notary Public

My Commission Expires 9/20/2011.

AFFIDAVIT

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

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- Correspondence — Pages 1 and 2

Lisa D. Lawrence
CDR Lisa D. Lawrence

County of Montgomery
State of Maryland

Subscribed and sworn before me this 13th day of January 2011.

Jeanne Marie Richwood
Notary Public

My Commission Expires 9/20/2011.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 16 2008

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics, Inc.
% Ms. Dawn Sinclair
Regulatory Affairs Associate
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K080991
Device Name: DePuy ASR™ XL Modular Acetabular Cup System
Dated: August 15, 2008
Received: August 18, 2008

Dear Ms. Sinclair:

We have reviewed the information dated August 15, 2008, regarding the 510(k) notification K080991 previously submitted for the device referenced above. Based solely on the change or modification that you have described, it does not appear that you have significantly changed or modified the design, components, method of manufacture, or intended use of the device referenced above (see 21 CFR 807.81(a)(3)). Additionally, we did not review any data submitted with this add to file. It is, however, your responsibility to determine if the change or modification to the device or its labeling could significantly affect the device's safety or effectiveness and thus require submission of a new 510(k). Please refer to our guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device" at www.fda.gov/cdrh/ode/510kmod.html. The information you have supplied will be added to the file.

Sincerely yours,

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date:

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K080991/A1

To: Division Director: OR/DGRNM

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

✓ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____ No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: Michael Owens JTy 8/28/08

Date: 08/26/08

DMC
AUG 29 2008

DMC 9/10 2

DePuy
a Johnson & Johnson company
DePuy Orthopaedics, Inc.

PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA

Tel: +1 (574) 267 8143

AUG 18 2008

August 15, 2008

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

Re: Add-to-File - K080991 DePuy ASR™ XL Modular Acetabular Cup System

Dear Madam/Sir:

DePuy Orthopaedics received clearance to market the DePuy ASR™ XL Modular Acetabular Cup System on July 2, 2008. Upon reviewing the clearance letter and Indications for Use Statement, we discovered that there is a minor typographical error. In the numbered list of indications, number three includes the word "and" when the correct word is "or". Correction of this discrepancy will not change the Indications for Use in any way. A corrected Indications for Use Statement is enclosed for your review and placement in the 510(k) file.

Thank you in advance for your consideration of this submission. If there are any questions, please feel free to contact me by phone at (574) 372-5023 or by e-mail at Dsincla3@its.jnj.com.

Sincerely,

K55

Dawn Sinclair

Dawn Sinclair
Regulatory Affairs Associate
DePuy Orthopaedics, Inc.

Enclosure

3

Indications for Use Statement

510 (k) Number (if known): K080991

Device Name: DePuy ASR™ XL Modular Acetabular Cup System

Indications for Use:

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

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

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

510(k) REVIEW MEMORANDUM

9/10/08

To: The File, **K080991/A1**
From: Michael C. Owens, Biomedical Engineer, DGRND/OJDB
Date: August 26, 2008
Re: Add-to-File – K080991 DePuy ASR™ XL Modular Acetabular Cup System
Received: August 17, 2008
Due Date: October 17, 2008

Recommendation: No change in 510(k) status – K25 Letter.

Summary:

The DePuy ASR XL Modular Acetabular Cup System was cleared on July 2, 2008. The sponsor noticed a typographical error in the Indications for Use Statement. In the number list of indications, number three includes the word "and" when it should say "or". The sponsor states that correction of this discrepancy will not change the Indications for Use in any way. The sponsor has provided the corrected Indications for Use Statement and it has been attached to this review. **This is adequate.**

Comment

The sponsor originally contacted me via email on 08/13/2008 to notify me about the typographical error. I then contacted the sponsor via telephone and requested that they send the new IFU Statement as an add-to-file. The sponsor's email is attached to this review.

I contacted the sponsor on 08/26/2008 and asked for a revised 510(k) Summary with the aforementioned correction. The sponsor provided the revised 510(k) Summary on 08/26/2008. The revised document and sponsor's email are attached to this review.

The package insert in the original submission has the word "or" for indication number three.

5

Owens, Michael C (CDRH)

From: Sinclair, Dawn [DPYUS] [DSincla3@its.jnj.com]
Sent: Wednesday, August 13, 2008 10:44 AM
To: Owens, Michael C (CDRH)
Subject: 510(k) K080991
Attachments: Indications for Use Statement.doc

Hello, Michael:

Thank you once again for your review of our 510(k) K080991 - DePuy ASR XL Modular Acetabular Cup System. One of our "eagle-eye" engineers was looking at our Indications for Use Statement and noticed that we have an "and" where there should be an "or". Here is our cleared statement:

Indications for Use:

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

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.

2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head and **(should be "or")** neck.
4. Failed previous hip surgery, including internal fixation, arthrodesis and hemi-arthroplasty.
5. Certain cases of ankylosis.

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Would it be possible to replace our Indications for Use Statement with a corrected one? I'm attaching the corrected version if this will be possible:

<<Indications for Use Statement.doc>>
Many thanks for your assistance!

Best regards,

Dawn Sinclair
Regulatory Affairs

DePuy Orthopaedics, a J&J Company
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

Tel.: (574) 267-8143
Direct: (574) 372-5023

Fax: (574) 371-4987
E-mail: Dsincla3@its.jnj.com

Please note new e-mail address: DSincla3@its.jnj.com

Indications for Use Statement

510 (k) Number (if known): K080991

Device Name: DePuy ASR™ XL Modular Acetabular Cup System

Indications for Use:

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

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3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery, including internal fixation, arthrodesis and hemi-arthroplasty.
5. Certain cases of ankylosis.

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Owens, Michael C (CDRH)

From: Sinclair, Dawn [DPYUS] [DSincla3@its.jnj.com]
Sent: Tuesday, August 26, 2008 5:58 PM
To: Owens, Michael C (CDRH)
Subject: 510(k) K080991 - Revised 510(k) Summary
Attachments: DePuy ASR Larger Heads_K080991_Revised Summary.pdf

Hello, Michael:

Thank you for your call today - I'm sorry I missed it!

Attached please find a revised 510(k) Summary for K080991 with the corrected Indications for Use. Should you need anything further, please don't hesitate to call!

Warm regards,

Dawn Sinclair
Regulatory Affairs

DePuy Orthopaedics, a J&J Company
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

Tel.: (574) 267-8143
Direct: (574) 372-5023
Fax: (574) 371-4987
E-mail: Dsincla3@its.jnj.com

Please note new e-mail address: DSincla3@its.jnj.com

<<DePuy ASR Larger Heads_K080991_Revised Summary.pdf>>

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
DATE PREPARED:	February 25, 2008
PROPRIETARY NAME:	DePuy ASR™ XL Modular Acetabular Cup System
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	Class III per 21 *CFR* 888.3330, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
DEVICE PRODUCT CODE(S):	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy ASR™ Modular Acetabular Cup System (K040627) DePuy ASR™ 300 Acetabular Cup System (K073413) Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes) (K021349) DePuy Ultima® Unipolar Head and Adapter Sleeves (K965156) DePuy ASR™ Taper Sleeve Adapter (K070359)

DEVICE DESCRIPTION:

The subject DePuy ASR™ XL Modular Acetabular Cup components are part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular cup is designed as a cobalt-chrome-molybdenum (CoCrMo) alloy one-piece cup with a porous coating and is available in outer diameter sizes 64mm through 70mm in two-millimeter increments. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. There are no separate liner components to this system, as the liners are integral to the one-piece acetabular cups.

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

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

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

INDICATIONS AND INTENDED USE:

Indications for Use:

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

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

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Intended Use:

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

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

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy ASR™ XL Modular Acetabular Cup components described in this submission are, in our opinion, substantially equivalent to those included in the previously cleared DePuy ASR™ Modular Acetabular Cup System (K040627); the DePuy ASR™ 300 Acetabular Cup System (K073413); the Wright Medical Metal TRANSCEND® Articulation System (K021349); the DePuy ASR™ Adapter Sleeve (K070359), and the DePuy Ultima® Adapter Sleeves (K965156), based upon the similarities in design, material composition and intended use/indications for use. A modification is simply being made to add additional cup sizes. In addition, minor revisions are being made to the Indications for Use and the Instructions for Use (IFU) to minimize the necessity for multiple IFUs and to update the contents to reflect current practice. The subject device does not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2008

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

Re: K080991
Trade/Device Name: DePuy ASR™ XL Modular Acetabular Cup System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: March 17, 2008
Received: April 7, 2008

Dear Ms. Sinclair:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

Indications for Use Statement

510 (k) Number (if known): K080991

Device Name: DePuy ASR™ XL Modular Acetabular Cup System

Indications for Use:

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

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

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K080991

(Posted November 13, 2003)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

April 08, 2008

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
WARSAW, IN 46581
ATTN: DAWN SINCLAIR

510(k) Number: K080991
Received: 07-APR-2008
Product: DEPUY ASR XL MODULAR ACETABULAR CUP SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/cdrh/mdufma/index.html for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf.

A new provision of the Food and Drug Administration Amendments Act of 2007, 42 U.S.C. 282(j)(5)(B), requires that a certification form (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf) accompany all 510(k)/HDE/PMA submissions on or after December 26, 2007. You are responsible for registering certain device clinical trials in the Clinical Trials Data Bank (http://prsinfo.clinicaltrials.gov). If your submission does not include FDA Form 3674, please send 2 hardcopies of the completed certification form referencing the submission number identified above. Additional information about the new certification

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form may be found at the following link to the Federal Register Notice (http://www.fda.gov/OHRMS/DOCKETS/98fr/07-6023.htm).

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1655.pdf. Please refer to this guidance for information on a formalized interactive review process. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsub.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

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OR/DERND

K080991

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA
Tel: +1 (574) 267-8143

510(k) Premarket Notification

April 3, 2008

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

Reference: 510(k) Premarket Notification
DePuy ASR™ XL Modular Acetabular Cup System

Dear Madam/Sir:

Pursuant to Section 510(k) of the Food, Drug and Cosmetic Act and Title 21 Part 807 of the Code of Federal Regulations (21 *CFR* § 807.81), DePuy Orthopaedics, Inc submits the enclosed documentation in duplicate for the DePuy ASR™ XL Modular Acetabular Cup System as a **510(k) Premarket Notification.** The DePuy ASR™ XL Modular Acetabular Cup components are a line extension of the DePuy ASR™ Modular Acetabular Cup System, originally cleared under K040627, and the DePuy ASR™ 300 Acetabular Cup System, originally cleared under K073413. In addition, minor revisions are being made to the Indications for Use and the Instructions for Use (IFU) to minimize the necessity for multiple IFUs and to update the contents to reflect current practice. This submission includes a paper and an electronic copy on CD that is an exact duplicate of the paper copy.

Pursuant to 21 *CFR* 807.95(b), DePuy Orthopaedics considers this 510(k) submission to be confidential commercial information and requests that it be treated as such by FDA. DePuy Orthopaedics 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.

Enclosure

TRADITIONAL
510(k)
SUBMISSION

DePuy ASR™ XL Modular Acetabular Cup System

700 Orthopaedic Drive Warsaw, IN 46582

Medical Device User Fee Cover Sheet

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: **MD6034039-956733** 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

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

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

[ ] 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 12-Dec-2007

Medical Device User Fee Cover Sheet

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)
4/3/2008	MD6034039-956733	

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) 372-5023		
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)*

- ☐ 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

- ☐ Response to FDA correspondence:

- ☐ 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		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 Orthopaedics, Inc.
2	K073413	2	DePuy ASR 300 Acetabular Cup System	2	DePuy Orthopaedics, Inc.
3	K021349	3	Wright Medical Metal TRANSCEND Articulation System (Larger Sizes)	3	Wright Medical Technology, Inc.
4	K965156	4	DePuy Ultima Unipolar Head and Adapter Sleeves	4	DePuy Orthopaedics, Inc.
5	K070359	5	DePuy ASR Adapter Sleeve	5	DePuy Orthopaedics, Inc.
6	K042992	6	Corail AMT Hip Prosthesis	6	DePuy Orthopaedics, Inc.

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 XL Modular Acetabular Cup System	1	999805764/5966/6168/6370; 999830764/66/68/70; 999890157/59/61/63
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
KWA

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

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

Device Class

☐ Class I ☐ Class II
☒ Class III ☐ Unclassified

Indications *(from labeling)*

The DePuy ASR XL Modular Acetabular Cup System is indicated for use in the following conditions, where there is evidence of sufficient sound bone to seat and support the components: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head and neck. 4. Failed previous hip surgery, including internal fixation, arthrodesis and hemi-arthroplasty. 4. Certain cases of ankylosis. Porous-coated DePuy ASR XL Modular Acetabular Cups are indicated for cementless application.

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 Senior Regulatory Affairs Specialist		Contact E-mail Address rfrankl2@dpyus.jnj.com	

☒ Original ☐ Add ☐ Delete	blishment Identifier (FEI) Number (b)(4)	☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler

(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.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	11137	ISO	Sterilization of Health Care Products - Radiation - Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	1995	9/12/2007
2	F75	ASTM	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)		5/21/2007
3	F799	ASTM	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants		5/21/2006
4	F1185	ASTM	Standard Specification for Composition of Hydroxylapatite for Surgical Implants		5/21/2003
5	F1537	ASTM	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants	2000	9/12/2000
6	F620	ASTM	Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants		9/21/2007
7					

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

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
DePuy Orthopaedics, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
03/17/2008

3. ADDRESS *(Number, Street, State, and ZIP Code)*
700 Orthopaedic Drive
Warsaw, IN 46581-0988

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) (574) 372-5023
(Fax) (574) 371-4987

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

DePuy ASR XL Modular Acetabular Cup System

87KWA, 888.3330

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☒ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
Dawn Sinclair

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Dawn Sinclair
(Title) Regulatory Affairs Associate

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
700 Orthopaedic Drive
Warsaw, IN 46581-0988

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) (574) 372-5023
(Fax) (574) 371-4987

15. DATE OF CERTIFICATION
3/17/08

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. **Date -** This is the date of the application/submission which the certification accompanies.

3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. **Certification -** This section contains three different check-off boxes.
   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/ submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.

12. **Name and Title of Person Who Signed in number 11. -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. **& 14. -** Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.

15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
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 number.

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA
Tel: +1 (574) 267-8143

510(k) Premarket Notification

March 17, 2008

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

Reference: 510(k) Premarket Notification
DePuy ASR™ XL Modular Acetabular Cup System

Dear Madam/Sir:

Pursuant to Section 510(k) of the Food, Drug and Cosmetic Act and Title 21 Part 807 of the Code of Federal Regulations (21 *CFR* § 807.81), DePuy Orthopaedics, Inc submits the enclosed documentation in duplicate for the DePuy ASR™ XL Modular Acetabular Cup System as a **510(k) Premarket Notification.** The DePuy ASR™ XL Modular Acetabular Cup components are a line extension of the DePuy ASR™ Modular Acetabular Cup System, originally cleared under K040627, and the DePuy ASR™ 300 Acetabular Cup System, originally cleared under K073413. In addition, minor revisions are being made to the Indications for Use and the Instructions for Use (IFU) to minimize the necessity for multiple IFUs and to update the contents to reflect current practice. This submission includes a paper and an electronic copy on CD that is an exact duplicate of the paper copy.

Pursuant to 21 *CFR* 807.95(b), DePuy Orthopaedics considers this 510(k) submission to be confidential commercial information and requests that it be treated as such by FDA. DePuy Orthopaedics 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.

Enclosure

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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Description **Page**

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Indications for Use Statement

510 (k) Number (if known): _____

Device Name: DePuy ASR™-XL Modular Acetabular Cup System

Indications for Use:

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

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

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003) Page 1 of 1

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
DATE PREPARED:	February 25, 2008
PROPRIETARY NAME:	DePuy ASR™ XL Modular Acetabular Cup System
COMMON NAME:	Acetabular Cup Prosthesis
CLASSIFICATION:	Class III per 21 *CFR* 888.3330, Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
DEVICE PRODUCT CODE(S):	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy ASR™ Modular Acetabular Cup System (K040627) DePuy ASR™ 300 Acetabular Cup System (K073413) Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes) (K021349) DePuy Ultima® Unipolar Head and Adapter Sleeves (K965156) DePuy ASR™ Taper Sleeve Adapter (K070359) Corail AMT™ Hip Prosthesis (K042992) DePuy Tri-Lock® Bone Preservation Stem (K073570)

DEVICE DESCRIPTION:

The subject DePuy ASR™ XL Modular Acetabular Cup components are part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular cup is designed as a cobalt-chrome-molybdenum (CoCrMo) alloy one-piece cup with a porous coating and is available in outer diameter sizes 64mm through 70mm in two-millimeter increments. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. There are no separate liner components to this system, as the liners are integral to the one-piece acetabular cups.

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

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

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

INDICATIONS AND INTENDED USE:

Indications for Use:

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

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

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Intended Use:

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

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

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy ASR™ XL Modular Acetabular Cup components described in this submission are, in our opinion, substantially equivalent to those included in the previously cleared DePuy ASR™ Modular Acetabular Cup System (K040627); the DePuy ASR™ 300 Acetabular Cup System (K073413); the Wright Medical Metal TRANSCEND® Articulation System (K021349); the DePuy ASR™ Adapter Sleeve (K070359); the DePuy Ultima® Adapter Sleeves (K965156); the Corail AMT™ Hip Prosthesis (K042992); and the DePuy Tri-Lock® Bone Preservation Stem (K073570), based upon the similarities in design, material composition and intended use/indications for use. A modification is simply being made to add additional cup sizes. In addition, minor revisions are being made to the Indications for Use and the Instructions for Use (IFU) to minimize the necessity for multiple IFUs and to update the contents to reflect current practice. The subject device does not raise any new issues of safety or effectiveness.

Premarket Notification

Truthful and Accurate Statement

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

In accordance with 21 *CFR* 807.87 (k), I certify that, in my capacity as Programme Manager for 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.

Mary J. Stewart
Programme Manager

13 March 08
Date

Premarket Notification

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

Dawn R. Sinclair

April 3, 2008

Date

(Premarket Notification [510(k)] Number)

DePuy ASR™ XL Modular Acetabular Cup System

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.

Financial Certification or Disclosure Statement

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

Declarations of Conformity and Summary Reports

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

Traditional 510(k)
DePuy ASR™ XL Modular Acetabular Cup System

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 510(k) Premarket Notification.

I. Administrative Information:

A. Manufacturer:

DePuy International Limited
St. Anthony Road
Leeds
West Yorkshire
UK LS11 8DT

Establishment Registration Number: 8010379

Contract Sterilizer: (b)(4)

B. Contact Person:

Dawn Sinclair
Regulatory Affairs Associate
Tel: (574) 372-5023
Fax: (574) 371-4987
Email: dsincla3@dpyus.jnj.com

C. Subject Device Information:

Proprietary Name: DePuy ASR™ XL Modular Acetabular Cup System

Common Name: Acetabular Cup Prosthesis

Regulatory Class & Reference: Class III per 21 *CFR* 888.3330 Hip Joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Product Code & Name: 87 KWA Prosthesis, Hip Femoral Metal/Metal

C. Predicate Device Information:

DePuy ASR™ Modular Acetabular Cup System	K040627	Cleared Aug. 5, 2005
DePuy ASR™ 300 Acetabular Cup System	K073413	Cleared Jan. 30, 2008
Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes)	K021349	Cleared Jul. 1, 2002
DePuy ASR™ Adapter Sleeve	K070359	Cleared Mar. 6, 2007
DePuy Ultima® Unipolar Adapter Sleeves	K965156	Cleared Jan. 24, 1997
Corail AMT™ Hip Prosthesis	K042992	Cleared Feb. 11, 2005
DePuy Tri-Lock® Bone Preservation Stem	K073570	Cleared Feb. 21, 2008

Copies of the 510(k) clearance letters are provided in **Exhibit 5**.

D. Indications for Use:

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

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

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

D. Materials:

Acetabular Cup:	ASTM F-75	Cast High Carbon Cobalt Chromium Molybdenum Alloy
Femoral Head:	ASTM F-75	Cast High Carbon Cobalt Chromium Molybdenum Alloy
Taper Sleeve Adapter:	ASTM F-799	Forged Cobalt Chromium Molybdenum Alloy

E. Engineering Drawings:

Engineering drawings are provided in **Exhibit 2**.

F. Proposed Labeling:

Draft labels and package insert can be found in **Exhibit 3**.

II. Device Description:

A. Device Description:

The subject DePuy ASR™ XL Modular Acetabular Cup components are part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular component is designed as a cobalt-chrome-molybdenum (CoCrMo) alloy one-piece cup with Porocoat® porous coating and the addition of a hydroxyapatite (HA) coating on the outer surface. The acetabular shell possesses a highly polished, superfinished internal bearing surface, and is available with outer diameter sizes 64mm through 70mm in two-millimeter increments. The outer surface of the cup features a porous coating of sintered metal beads, which serves to increase biologic fixation via tissue ingrowth into the porous coating, and an additional coating of hydroxyapatite (HA) on the outer surface that works to augment the fixation.

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

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

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

The exterior of the DePuy ASR™ XL Modular Acetabular Cups are coated with a Porocoat® porous coating. Porocoat® porous coating has been fully characterized in previous PMA and 510(k) submissions (e.g., P820024 AML®, and K030979 Solution System®). See **Table 1** below for a summary of the properties of the Porocoat® porous coating.

Table 1: Characterization of Porocoat® Porous Coating

(b)(4)

B. Device Photographs

Fig 1: DePuy ASR™ One-piece Cup and DePuy ASR™ Uni Femoral Head

Fig 2: Assembled Components Shown with Summit Stem

Fig3: DePuy ASR ™ 300 Acetabular Cup

III. Testing Summary:

(b)(4)

(b)(4)

A. Friction and Wear Tests for Larger Size Heads:

Wear Testing:

(b)(4)

Frictional Testing:

(b)(4)

IV. 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 Orthopaedics is not aware of any requirements for post-market surveillance or other special controls for this device at this time.

V. Substantial Equivalence:

A. Substantially Equivalent Devices:

Acetabular Shell Component

The DePuy ASR™ XL Modular Acetabular Cup System 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 64mm through 70mm in two-millimeter increments. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. There is no separate liner component to this system, as it is a one-piece acetabular shell used with a unipolar femoral head and taper adapter sleeves.

The subject device shell component uses Porocoat® material and process that is used for previously cleared devices (P820024 AML® and K030979 Solution System®). The coating consists of multiple layers of CoCrMo alloy beads, which are sintered to the exterior portion of the shell. The interior of the shell is designed to articulate with the subject uni femoral heads. Articulating surfaces of both the uni femoral head and one-piece acetabular cup are superfinished to ensure form tolerance and a fine surface finish. The HA powder used in the plasma spray process, conforms to ASTM F-1185 Hydroxyapatite ($Ca_5(PO_4)_3OH$) ceramic.

The Wright Medical's Metal TRANSCEND® (Larger Sizes) one-piece acetabular cup is a cast, high carbon CoCrMo alloy. The cup sizes range from 46mm through 64mm and accept femoral heads from 36mm through 54mm in diameter. The TRANSCEND® acetabular cup has a superfinished inner diameter, with a porous coated outer diameter.

Femoral He ads

The subject uni femoral heads are substantially equivalent to Wright Medical's TRANSCEND® Articulation System (Larger Sizes). Both are supplied in larger diameter sizes (DePuy Orthopaedics: available in 39mm through 63mm; Wright Medical: available in 38mm through 54mm). Both are manufactured from cast high carbon CoCrMo alloys conforming to ASTM specifications and articulate with a one-piece CoCrMo alloy acetabular shell. Articulating surfaces of both the uni femoral head and one-piece acetabular cup are super finished to ensure proper tolerances. (b)(4)

(b)(4)

Taper Sleeve Adapters

The subject heads use taper sleeve adapters to mate the femoral head to the femoral stem, whereas the TRANSCEND® Articulation System (Larger Sizes) uses a range of femoral heads designed with specific internal taper specifications to fit with femoral stem tapers. The modularity of using taper sleeve adapters in two taper options allow for a reduced number of femoral head components while offering various femoral head offsets and compatibility with multiple femoral stems. The subject device taper connections are manufactured from forged CoCrMo alloy and are based upon the design used for the adapter sleeves described in the DePuy Ultima® Unipolar Adapter Sleeves 510(k), K965156, cleared on January 24, 1997; the DePuy ASR™ Modular Acetabular Cup System 510(k), K040627, cleared on August 5, 2005, and; the DePuy ASR™ Adapter Sleeve 510(k), K070359, cleared on March 6, 2007.

Table 2: Similarities and Differences Matrix

Characteristics	Subject Device	Predicate Device	Predicate Device	Predicate Device
Device Name:	**Proposed DePuy ASR™ XL Modular Acetabular Cup System**	**DePuy ASR™ Modular Acetabular Cup System K040627**	**DePuy ASR™ 300 Acetabular Cup System K073413**	**Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes) K021349**
Acetabular Cup Design:				
Shell Profile	Low profile	Low profile	Low profile	Low profile
Construction	One piece shell	One piece shell	One piece shell	One piece shell
Outer Diameters	64mm – 70mm (2mm increments)	44mm – 62mm (2mm increments)	44mm – 62mm (2mm increments)	46mm – 64mm (2mm increments)
Inner Diameter	57mm–63mm (2mm increments)	39mm-55mm (2mm increments)	39mm-55mm (2mm increments)	36mm-54mm (2mm increments)
Spikes	N/A	N/A	3	N/A
Indications for Use:				
	The device is indicated for use in the following conditions, where there is evidence of sufficient sound bone to seat and support the components: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head and neck. 4. Failed previous hip surgery, including internal fixation, arthrodesis and hemi-arthroplasty. 5. Certain cases of ankylosis.	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 non-union 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 non-union 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.	Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia; 2) inflammatory degenerative joint disease such as rheumatoid arthritis; 3) correction of functional deformity; and, 4) revision procedures where other treatments or devices have failed.

Characteristics	Subject Device	Predicate Device	Predicate Device	Predicate Device
Device Name:	**Proposed DePuy ASR™ XL Modular Acetabular Cup System**	**DePuy ASR™ Modular Acetabular Cup System K040627**	**DePuy ASR™ 300 Acetabular Cup System K073413**	**Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes) K021349**
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	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	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 with DuoFix™ HA Coating	Porous coating
Spikes	N/A	N/A	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	N/A
OD Coating – Spikes	N/A	N/A	Porocoat® porous coating	N/A
Articulation Requirements	Superfinished surface	Superfinished surface	Superfinished surface	Superfinished surface
Sterile Method	Cobalt-60 Gamma Radiation (25kG min)	Cobalt-60 Gamma Radiation (25kG min)	Cobalt-60 Gamma Radiation (25kG min)	Gamma Radiation

Table 3: Predicate Devices

Name	Material	510(k)	Clearance Date
DePuy ASR Modular Acetabular Cup System	Cast High Carbon CoCrMo alloy ASTM F-75	K040627	August 5, 2005
DePuy ASR 300 Acetabular Cup System	Cast High Carbon CoCrMo alloy ASTM F-75	K073413	January 30, 2008
Wright Medical TRANSCEND Articulation System	Cast High Carbon CoCrMo alloy ASTM F-75	K021349	July 1, 2002
DePuy ASR Taper Sleeve Adapter	Wrought CoCrMo alloy ASTM F-1537	K070359	March 6, 2007
DePuy Ultima Unipolar Head and Adapter Sleeves	Wrought CoCrMo alloy ASTM F-1537	K965156	January 24, 1997
Corail AMT Hip Prosthesis	Forged Titanium alloy (Ti-6Al-4V) ASTM F-620	K042992	February 11, 2005
DePuy Tri-Lock Bone Preservation System	Forged Titanium alloy (Ti-6Al-4V) ASTM F-620	K073570	February 21, 2008

Copies of the above clearance letters are provided in **Exhibit 5**.

B. Basis of Substantial Equivalency:

The DePuy ASR™ XL Modular Acetabular Cup components described in this submission are, in our opinion, substantially equivalent to those included in the previously cleared DePuy ASR™ Modular Acetabular Cup System (K040627); the DePuy ASR™ 300 Acetabular Cup System (K073413); the Wright Medical Metal TRANSCEND® Articulation System (K021349); the DePuy ASR™ Adapter Sleeve (K070359); the DePuy Ultima® Adapter Sleeves (K965156); the Corail AMT™ Hip Prosthesis (K042992); and the DePuy Tri-Lock® Bone Preservation System (K073570), based upon the similarities in design, material composition and intended use/indications for use. A modification is simply being made to add additional cup sizes. In addition, minor revisions are being made to the Indications for Use and the Instructions for Use (IFU) to minimize the necessity for multiple IFUs and to update the contents to reflect current practice. The subject device does not raise any new issues of safety or effectiveness.

VI. Proposed Labeling

Draft labels and a draft package insert are provided in **Exhibit 3**.

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 Orthopaedics.

VII. Sterilization

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)

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

Method & Dose:

The subject devices are supplied packaged and sterilized by exposure to Cobalt-60 Gamma Radiation at a minimum dose of 25 kilogray.

Sterility As surance Level (SAL):

Minimum (SAL) is set at of 10^{-6}.

Validation Method:

(b)(4)

Pyrogenicity:

No pyrogenicity claims are made for these devices.

VIII. Packaging:

The subject DePuy ASR™ XL Modular Acetabular Cup product will be packaged in a double sterile packaging system. This system offers containment, protection, and preservation of the product. This primary packaging is then placed inside a carton for distribution.

IX. Biocompatibility

The subject DePuy ASR™ XL Modular Acetabular Cups do 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.*

X. Software

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

XI. Electromagnetic Compatibility/Electrical Safety

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

XII. Performance Testing - Animal

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

XIII. Performance Testing - Clinical

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

EXHIBIT 1

List of Devices/Part Numbers

Subject Product Codes

Part Number	Catalogue Number	Product Description
999800764	999805764	ASR XL ACETABULAR CUPS – SIZE 64MM
999800766	999805966	ASR XL ACETABULAR CUPS – SIZE 66MM
999800768	999806168	ASR XL ACETABULAR CUPS – SIZE 68MM
999800770	999806370	ASR XL ACETABULAR CUPS – SIZE 70MM
999830764	999830764	ASR XL SPIKED CUP – SIZE 64MM
999830766	999830766	ASR XL SPIKED CUP – SIZE 66MM
999830768	999830768	ASR XL SPIKED CUP – SIZE 68MM
999830770	999830770	ASR XL SPIKED CUP – SIZE 70MM

Part Number	Catalogue Number	Product Description
999890257	999890157	ASR UNI FEMORAL IMPLANT SIZE 57MM
999890259	999890159	ASR UNI FEMORAL IMPLANT SIZE 59MM
999890261	999890161	ASR UNI FEMORAL IMPLANT SIZE 61MM
999890263	999890163	ASR UNI FEMORAL IMPLANT SIZE 63MM

Compatible Product Codes

Part Number	Catalogue Number	Product Description	510(k) Clearance
999800744	999803944	ASR ACETABULAR CUPS – SIZE 44MM	K040627
999800746	999804146	ASR ACETABULAR CUPS – SIZE 46MM	K040627
999800748	999804348	ASR ACETABULAR CUPS – SIZE 48MM	K040627
999800750	999804550	ASR ACETABULAR CUPS – SIZE 50MM	K040627
999800752	999804652	ASR ACETABULAR CUPS – SIZE 52MM	K040627
999800754	999804754	ASR ACETABULAR CUPS – SIZE 54MM	K040627
999800756	999804956	ASR ACETABULAR CUPS – SIZE 56MM	K040627
999800758	999805158	ASR ACETABULAR CUPS – SIZE 58MM	K040627
999800760	999805360	ASR ACETABULAR CUPS – SIZE 60MM	K040627
999800762	999805562	ASR ACETABULAR CUPS – SIZE 62MM	K040627
999830744	999830744	ASR 300 SPIKED CUP – SIZE 44MM	K073413
999830746	999830746	ASR 300 SPIKED CUP – SIZE 46MM	K073413
999830748	999830748	ASR 300 SPIKED CUP – SIZE 48MM	K073413
999830750	999830750	ASR 300 SPIKED CUP – SIZE 50MM	K073413
999830752	999830752	ASR 300 SPIKED CUP – SIZE 52MM	K073413
999830754	999830754	ASR 300 SPIKED CUP – SIZE 54MM	K073413
999830756	999830756	ASR 300 SPIKED CUP – SIZE 56MM	K073413
999830758	999830758	ASR 300 SPIKED CUP – SIZE 58MM	K073413
999830760	999830760	ASR 300 SPIKED CUP – SIZE 60MM	K073413
999830762	999830762	ASR 300 SPIKED CUP – SIZE 62MM	K073413

Part Number	Catalogue Number	Description	510(k) Clearance
999890239	999890139	ASR UNI FEMORAL IMPLANT SIZE 39MM	K040627
999890241	999890141	ASR UNI FEMORAL IMPLANT SIZE 41MM	K040627
999890243	999890143	ASR UNI FEMORAL IMPLANT SIZE 43MM	K040627
999890245	999890145	ASR UNI FEMORAL IMPLANT SIZE 45MM	K040627
999890246	999890146	ASR UNI FEMORAL IMPLANT SIZE 46MM	K040627
999890247	999890147	ASR UNI FEMORAL IMPLANT SIZE 47MM	K040627
999890249	999890149	ASR UNI FEMORAL IMPLANT SIZE 49MM	K040627
999890251	999890151	ASR UNI FEMORAL IMPLANT SIZE 51MM	K040627
999890253	999890153	ASR UNI FEMORAL IMPLANT SIZE 53MM	K040627
999890255	999890155	ASR UNI FEMORAL IMPLANT SIZE 55MM	K040627

The following is a representative sample of taper adapter sleeve and femoral stem compatible components for the DePuy ASR™ XL Modular Acetabular Cup 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 Molybdenum (CoCrMo) alloy.

Description	Material	Taper	Representative Part Number	510(k) Clearance
DePuy ASR Taper Sleeve Adapter –3mm	CoCrMo	11/13	999890333	K070359 3/6/07
Ultima Unipolar Head Adapter Sleeve +0mm	CoCrMo	11/13	852621	K965156 1/24/97
Ultima Unipolar Head Adapter Sleeve +6mm	CoCrMo	11/13	852622	K965156 1/24/97
Taper Sleeve Adapters 11/13 +0mm	CoCrMo	11/13	999890340*	K040627 8/5/05
Taper Sleeve Adapters 11/13 +3mm	CoCrMo	11/13	999890343*	K040627 8/5/05
Taper Sleeve Adapters 11/13 +6mm	CoCrMo	11/13	999890346*	K040627 8/5/05
Taper Sleeve Adapters 11/13 +9mm	CoCrMo	11/13	999890349*	K040627 8/5/05
DePuy ASR Taper Sleeve Adapter –1mm	CoCrMo	12/14	999890353	K070359 3/6/07
Taper Sleeve Adapters 12/14 +2mm	CoCrMo	12/14	999800312	K040627 8/5/05
Taper Sleeve Adapters 12/14 +5mm	CoCrMo	12/14	999800315	K040627 8/5/05
Taper Sleeve Adapters 12/14 +8mm	CoCrMo	12/14	999800318	K040627 8/5/05
AML Hip Stem	CoCrMo	12/14	1554-01-105	K012364 10/19/01
Prodigy Hip Stem	CoCrMo	12/14	1520-16-050 1520-17-050	K000207 2/04/00
Replica Hip Stem	CoCrMo	12/14	1530-32-000 1530-33-000	K934334 12/21/94
Vision Solution Std	CoCrMo	12/14	1571-02-000	K953703 2/01/96
Summit Porous Hip Stem	Ti	12/14	1570-01-070	K001991 8/25/00
Tri-Lock Std Hip Stem	CoCrMo	12/14	1012-01-063	K001982 7/26/00

Description	Material	Taper	Representative Part Number	510(k) Clearance
Endurance Total Hip Stem	CoCrMo	12/14	1521-01-000	K942370 11/10/94
Luster Total Hip Stem	CoCrMo	12/14	1521-80-001	K983136 11/25/98
Summit Cemented Hip Stem	CoCrMo	12/14	1570-06-080	K023453 11/13/02
Tri-Lock BPS	CoCrMo	12/14	1012-14-120 1012-04-120	K073570 2/21/08
G2 Total Hip System	Ti and CoCrMo	11/13	858437 858436	K982812 12/4/98
Uni-Rom Hip Stem	Ti	11/13	85-5871 85-5872 85-5873 85-5874	K974331 2/06/98
S-ROM Hip Stem	Ti	11/13	56-3514 56-3516 56-3518	K851422 9/18/85
Corail AMT	Ti	12/14	L20309 L20310 L20311 L20312	K042992 2/11/05
Corail AMT Hip Prosthesis	Ti	12/14	L20106	K070554 9/11/07

*Cleared through internal documentation to the 510(k) in accordance with Bluebook Memorandum #K97-1. Appropriate documentation on file at DePuy Orthopaedics, Inc.

EXHIBIT 2

Engineering Drawings

(b)(4)

(b)(4)

(b)(4)

EXHIBIT 3

Draft Labels and Package Insert

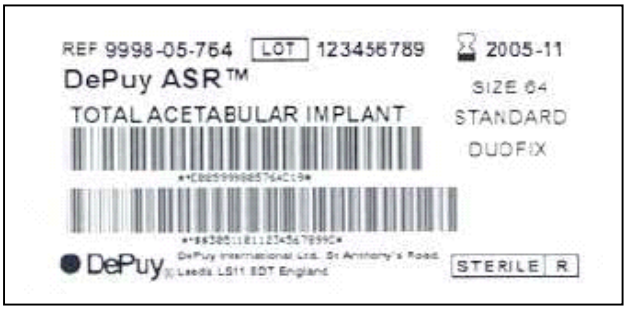
Labeling Details

The DePuy ASR™ Acetabular Implant products are labeled with multi-lingual labels. Samples of the labels are shown below:

<u>Main Label (applied to the product Carton)</u>

Inner Pack Label (applied to the Inner pack)

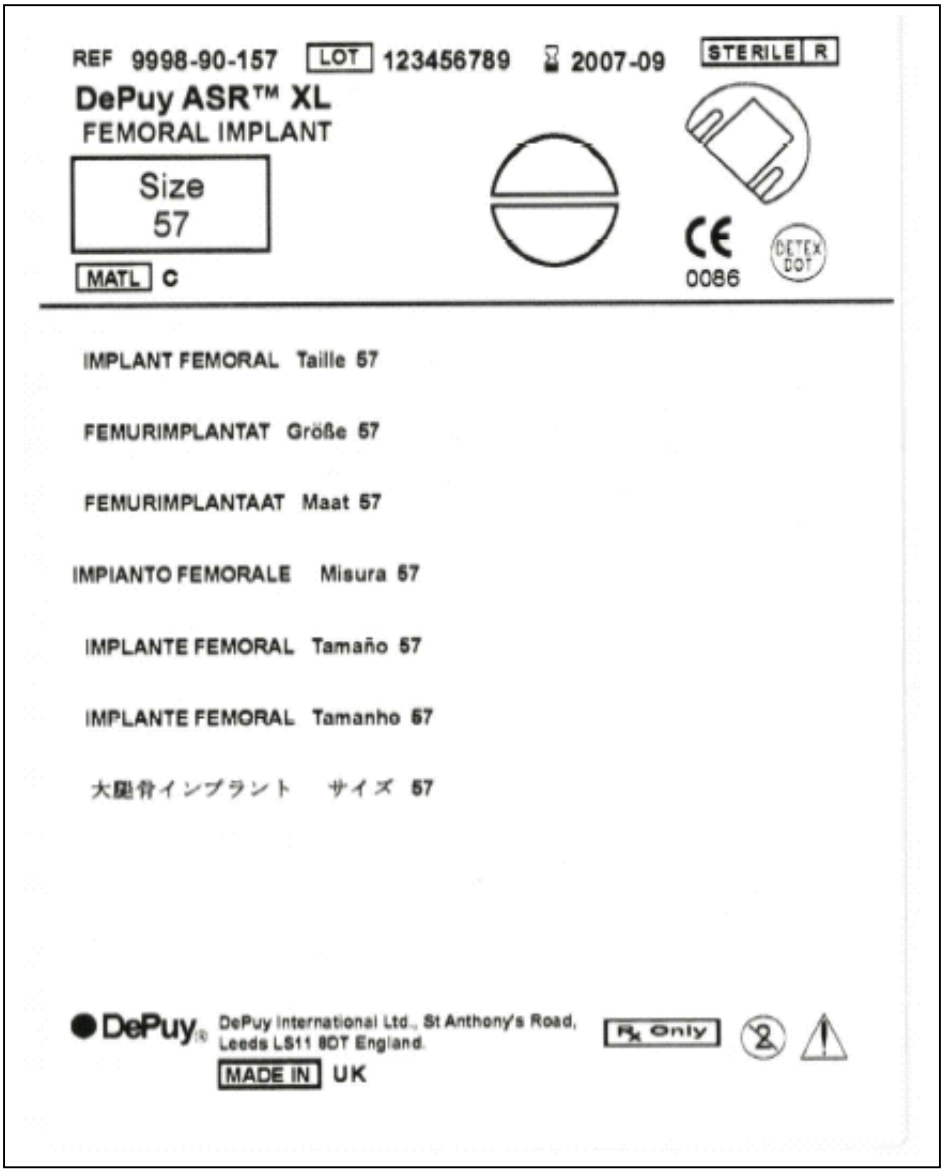
Patient and Distribution Labels



Labeling Details

The DePuy ASR™ XL Femoral Implant products are labeled with multi-lingual labels. Samples of the labels are shown below:

Main Label (applied to the product Carton)



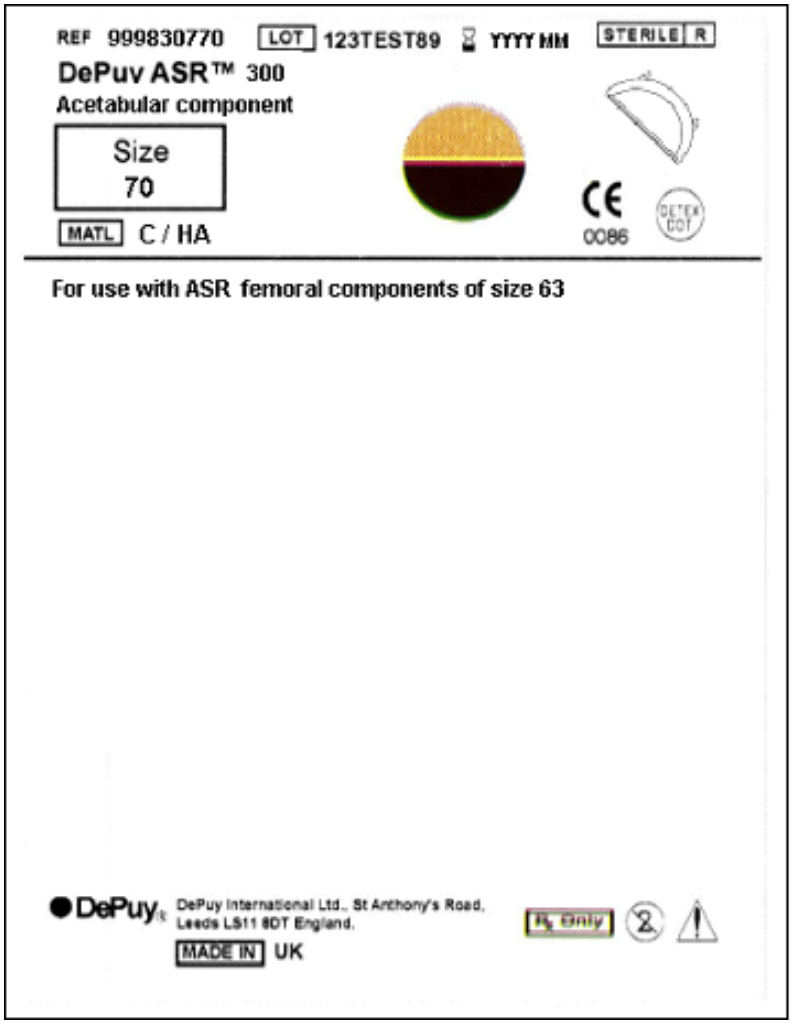
Inner Pack Label (applied to the Inner pack)

Patient and Distribution Labels

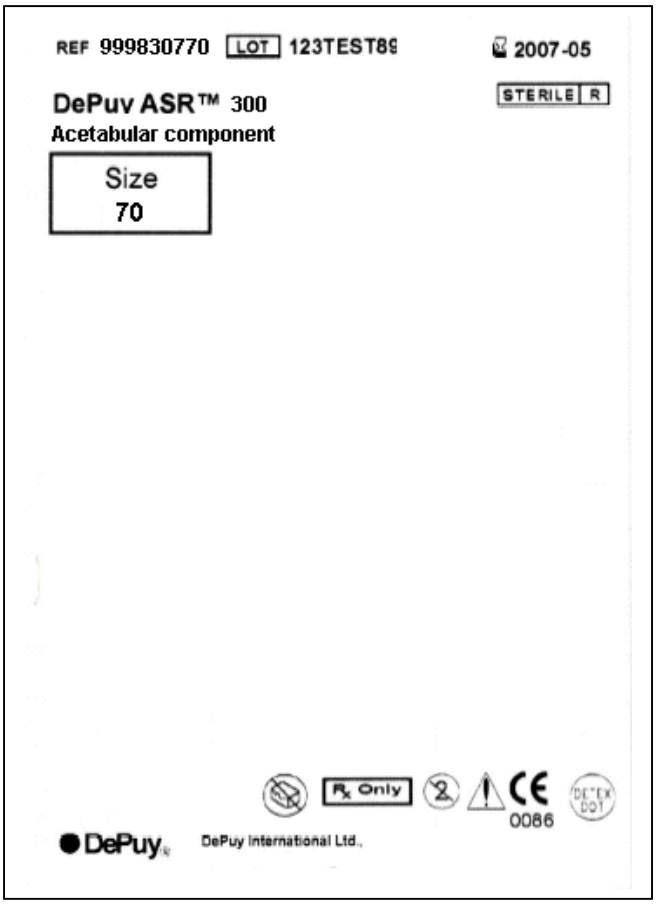
Proposed Labeling Details

The DePuy ASR™ 300 product is to be labeled with multi-lingual labels.
Draft samples of the proposed labels are shown below (not including translations);

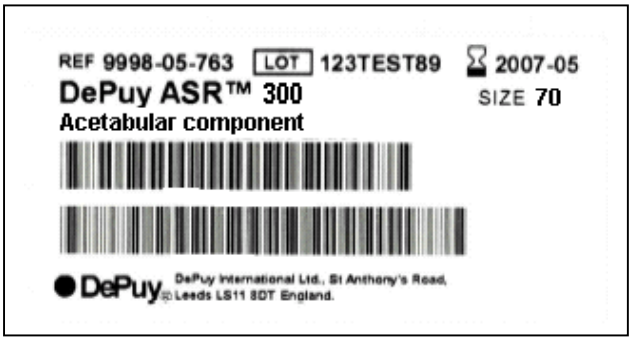
Main Label (applied to the product Carton)



Inner Pack Label (applied to the Inner pack)



Patient and Distribution Labels



Draft Instructions For Use

DRAFT PACKAGE INSERT FOR DEPUY ASR™ XL MODULAR ACETABULAR CUP SYSTEM, IFU-7814-0272

ENGLISH ONLY

Note: This IFU is used with other products, hence the reference to products not included in this submission.

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

For Single Use Only

Sterilized by gamma irradiation

DEVICE DESCRIPTION – Hip prosthesis and hemi-hip prosthesis

HIP PROSTHESIS
A Hip Prosthesis is composed of individually packaged metal monoblock or modular femoral component/s and modular or monoblock acetabular component/s designed to replace the natural articular surface of the hip joint.

HEMI-HIP PROSTHESIS
A Hemi-Hip Prosthesis is comprised of an individually packaged metal modular femoral component designed to replace the natural femoral head and neck in hemi-arthroplasty.

When using this DePuy hip or hemi-hip prosthesis component in conjunction with other DePuy components it is essential to review the intended use information packaged with the other components, as there may be information on indications, contraindications, warnings, precautions and information for use that are specific to the other components.

INTENDED USE

Hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

INDICATIONS

Hip replacement arthroplasty is indicated in the following conditions where there is evidence of sufficient sound bone to seat and support the components:

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

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

HEMI-HIP PROSTHESIS

Hemi-Hip Prostheses are intended to be used for hemi-hip arthroplasty where there is evidence of a satisfactory natural acetabulum and sufficient femoral bone to seat and support the femoral component.

Hemi-hip arthroplasty is indicated in the following conditions:

- Acute fracture of the femoral head or neck that cannot be appropriately reduced and treated with internal fixation.
- Fracture dislocation of the hip that cannot be appropriately reduced and treated with internal fixation.
- Avascular necrosis of the femoral head.
- Non-union of femoral neck fractures.
- Certain high subcapital and femoral neck fractures in the elderly.
- Degenerative arthritis involving only the femoral head in which the acetabulum does not require replacement.
- Pathology involving only the femoral head/neck and/or proximal femur that can be adequately treated by hemi-hip arthroplasty.

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

Hip arthroplasty or hemi-hip arthroplasty may be considered for younger patients if, in the opinion of the surgeon, an unequivocal indication for hip replacement outweighs the risks associated with the age of the patient and if limited demands regarding activity and hip joint loading can be assured. (see **WARNINGS AND PRECAUTIONS** section) This includes severely crippled patients with multiple joint involvement for whom a gain in hip mobility may lead to an expectation of significant improvement in the quality of their lives.

CONTRAINDICATIONS

The following conditions are contraindications for hip prostheses or hemi-hip prostheses used in hip arthroplasty

- Active local or systemic infection.
- Loss of musculature, neuromuscular compromise or vascular deficiency in the affected limb rendering the procedure unjustified.
- Poor bone quality, such as osteoporosis, where, in the surgeon's opinion, there could be considerable migration of the prosthesis or a significant chance of fracture of the femoral shaft and/or the lack of adequate bone to support the implant(s).
- Charcot's or Paget's disease.
- Chronic renal failure.
- Females of childbearing age are contraindicated due to the unknown effects of elevated levels of metal ions on the fetus.
- For hemi-hip arthroplasty, any pathological condition of the acetabulum, such as distorted acetabuli with irregularities, *protrusion acetabuli* (arthrokatadysis), or migrating acetabuli, that would preclude the use of the natural acetabulum as an appropriate articular surface for the hemi-hip prosthesis.

NOTE: Diabetes, at present, has not been established as a contraindication. However, because of the increased risk for complications such as infection, slow wound healing, etc., the physician should carefully consider the advisability of hip or hemi-hip arthroplasty in the severely diabetic patient.

WARNINGS AND PRECAUTIONS

Modular Femoral Heads and Acetabular Components

Use only DePuy modular femoral heads (and DePuy taper adapters if applicable) with DePuy femoral stems. The taper size of the femoral head (and matching taper adapter if applicable) MUST be matched to the taper size of the femoral stem. If the acetabulum is to be replaced use only a DePuy monoblock or DePuy modular acetabular system.

The size of the outer diameter of metal on metal bearings must be matched to the inner diameter of the monoblock acetabular cup or modular liner from the modular acetabular cup system.

The use of a DePuy ASR™ XL -3mm offset taper sleeve is NOT recommended for use with any of the following combinations:

- S-ROM 11x16x150 stem, 30 STD neck with either a 16F_XXL or 18F_XXL OVSZ with 16ID sleeve.
- S-ROM 13x18x160 stem, 30 STD neck with either a 18F_XXL or 20F_XXL OVSZ with 18ID sleeve.

DePuy ASR™ XL femoral components must only be used with DePuy ASR™ XL tapered sleeve adapters. The DePuy ASR™ XL tapered sleeve adapters must only be used with DePuy stems.

DePuy ASR™ acetabular components must only be used with DePuy ASR™ femoral components.

The Pinnacle metal insert mechanically locks with the metal shell via a taper junction. Do not mix inserts and shells from different systems. The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

CAUTION:

- Implants and trials components from different manufacturers or implant systems should never be used together.
- Hip prosthesis components should never be re-implanted. Even though the implant appears undamaged, the implant may have developed microscopic imperfections, which could lead to failure.
- Always use a trial prosthesis for trial purposes. Trials must have the same configuration, size, etc., ad the corresponding components to be permanently implanted.
- Do not alter or modify implants in any way.

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 implant:

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., metal).
7. Congenital dysplasia of the hip, which may reduce the bone stock available to support the acetabular cup prosthesis in hip replacement.
8. Tissue reactions to implant corrosion or implant wear debris.
9. Disabilities of other joints (i.e., knees and ankles).

WHEN THE SURGEON DETERMINES THAT HIP ARTHROPLASTY IS THE BEST MEDICAL OPTION AVAILABLE AND DECIDES TO USE THIS PROSTHESIS IN A PATIENT WHO HAS ANY OF THE ABOVE CONDITIONS OR WHO IS SIMPLY YOUNG AND ACTIVE, IT IS IMPERATIVE THAT THE PATIENT BE INSTRUCTED ABOUT THE STRENGTH LIMITATIONS OF THE MATERIALS USED IN THE DEVICE AND FOR IMPLANT FIXATION, AND THE RESULTANT NEED TO SUBSTANTIALLY REDUCE OR ELIMINATE ANY OF THE ABOVE CONDITIONS.

The surgical and postoperative management of the patient must be carried out with due consideration for all existing conditions. Mental attitudes or disorders resulting in a patient's failure to adhere to the surgeon's orders may delay postoperative recovery and/or increase the risk of adverse effects including implant or implant fixation failure.

Excessive physical activity or trauma to the replaced joint may contribute to premature failure of the hip replacement by causing a change in position, fracture, and/or wear of the implants. The functional life expectancy of prosthetic hip implants is, at present, not clearly established. The patient should be informed that factors such as weight and activity levels may significantly affect wear.

INFORMATION FOR USE

Preoperative

THE SURGEON SHOULD DISCUSS ALL PHYSICAL AND MENTAL LIMITATIONS PARTICULAR TO THE PATIENT AND ALL ASPECTS OF THE SURGERY AND THE PROSTHESES WITH THE PATIENT BEFORE SURGERY.

The discussion should include the limitations and possible consequences of joint replacement, and the necessity to follow the surgeon's instructions postoperatively, particularly in regard to patient activity and weight.

The preoperative planning and surgical techniques for implantation of these hip replacement components evolved from the surgical experience gained during the development of many hip prostheses. Surgeons should not begin the clinical use of any hip prosthesis before they have thoroughly familiarized themselves with its specific implantation technique. Certain methods may change with time as further clinical experience is gained. Critical appraisals of such changes are presented at regularly scheduled surgical instruction courses for which periodic attendance is advised. Surgical technique brochures and videos are available from DePuy.

lntraoperative

It is recommended that components at least one size larger and one size smaller than were preoperatively determined be available at surgery to accommodate intraoperative selection of the appropriate size(s).

Protective covers should be left on until the components are ready to be implanted. Do not use femoral heads or any other components if they have been dropped or have impacted a hard surface. Damage to the component may not be visible, but could cause early failure of the prosthesis. Before implanting a modular femoral head, the male taper on the femoral stem should be wiped clean of any blood, bone chips or other foreign materials. Foreign material between the modular head and the femoral stem taper and taper adapter (if applicable) may impede proper seating of the head on the stem. This could affect the performance of the modular femoral head or the locking mechanism between the modular femoral head and the femoral stem. Do not allow the coated portion of a porous coated or ceramic-coated prosthesis to come in contact with cloth or other fiber releasing materials.

Improper selection, placement, or positioning of implants may result in unusual stress conditions and a subsequent reduction in the functional life of the implant. Note that a femoral stem placed in varus increases the stress on the proximal medial femoral cortex and may lead to loosening of the implant. Potential pitfalls on the acetabular side include incomplete seating of the acetabular component or component malposition. Soft tissue or bone impingement, excessive socket medialization, and socket malposition should be avoided. A concentric, spherically reamed acetabulum will facilitate prostheses seating. Avoidance of an overly aggressive press-fit will also facilitate seating of the acetabular component within the acetabulum. Most implant systems recommend an ideal under reaming of the acetabular component to be no more than 1 millimeter. Seat

the acetabular shell at a 40-45º abduction angle with 15-20º of anteversion for proper positioning to decrease the chance for dislocation and wear. Incorrect alignment may result in suboptimal contact between the femoral head and the acetabular prosthesis articulating surfaces, resulting in the potential for increased wear and/or damage.

Prior to closure, the surgical site should be thoroughly cleansed of bone chips, extraneous bone cement (if used), ectopic bone, etc. The highly polished surface of the device should not come into contact with abrasive surfaces, as this may damage the surface and affect performance. Foreign particles at the metal/metal interface may cause excessive wear. Range of motion should be thoroughly checked for improper mating, instability, or impingement and corrected as appropriate.

Postoperative

Strict adherence by the patient to the surgeon's instructions and warnings is extremely important. Accepted practices should be followed in postoperative care.

The patient should be released from the hospital with complete written instructions and warnings regarding exercises and therapies and any limitations on their activities. Partial weight bearing with two crutches and later with one crutch should be continued until muscle function is sufficiently restored so that the operated extremity is no longer overloaded if crutches are discarded; this may take 10 to 12 weeks.

A continuing periodic patient follow-up is recommended. Because of the unknown functional lifetime of the implant, particularly with respect to the maintenance of implant fixation and bearing surfaces, A-P radiographs of the pelvis should be taken at each follow-up and compared with previous radiographs and correlated with the clinical assessment of the patient. If any radiographic changes are observed, such as the occurrence of radiolucencies, bone resorption, or any changes in the position of an implant, these changes should be closely monitored to determine whether they are static or progressive and the patient treated appropriately.

ADVERSE EVENTS AND COMPLICATIONS

The following are generally the most frequently encountered adverse events and complications in hip arthroplasty:

General

1. Change in position of the prosthetic components, often related to the factors listed in WARNINGS AND PRECAUTIONS.
2. Early or late loosening of the prosthetic components, often related to factors listed in WARNINGS AND PRECAUTIONS.
3. Fatigue fracture of the femoral prosthesis often related to factors listed in WARNINGS AND PRECAUTIONS.
4. Early or late infection.
5. 5.Peripheral neuropathies. Subclinical nerve damage may also occur as a result of surgical trauma.
6. Tissue reactions, osteolysis, and/or implant loosening caused by metallic corrosion, allergic reactions, or the accumulation of metal wear debris.

7. The potential long-term biological effects of metal wear debris and metal ion production is not known.

lntraoperative

1. Acetabular perforation.
2. Femoral shaft perforation, fissure, or fracture, which may require the use of internal fixation.
3. Trochanteric fracture.
4. Damage to blood vessels (e.g. iliac, obturator and femoral artery).
5. Temporary or permanent nerve damage (e.g. femoral, obturator or isolated peroneal nerve).
6. Subluxation or dislocation of the hip joint due to implant size or configuration selection, positioning of components and/or muscle and fibrous tissue laxity.
7. Lengthening or shortening of the affected extremity.

Early Postoperative

1. Cardiovascular disorders including venous thrombosis, pulmonary embolism and myocardial infarction.
2. Hematoma and/or delayed wound healing.
3. Pneumonia and/or atelectasis.
4. Subluxation or dislocation

Late Postoperative

1. Trochanteric avulsion from excessive muscular tension, weight-bearing, or inadvertent intraoperative weakening of the trochanter.
2. Aggravation of problems in the ipsalateral or contralateral knee and ankle joints due to leg length discrepancy, femoral medialization and/or muscular deficiencies.
3. Femoral or acetabular fracture due to trauma or excessive loading, particularly in the presence of poor bone stock caused by severe osteoporosis, bone defects from previous surgery, intraoperative reaming procedures, or bone resorption.
4. Bone resorption, which may contribute to the deterioration of fixation and eventual loosening of the implant.
5. Periarticular calcification or ossification, which may lead to a decrease in joint mobility and range of motion.
6. Traumatic arthrosis of the ipsilateral knee, secondary to intraoperative positioning, of the extremity during surgery.
7. Subluxation or dislocation.

HOW SUPPLIED

The taper adapter, modular femoral head, liner from the 2 piece acetabular system and monoblock acetabular cup components are individually packaged and supplied STERILE. All metal components are sterilized using radiation. Remove from the package using accepted aseptic technique only after the correct size has been determined.

DO NOT RE-STERILIZE and DO NOT USE if the package is damaged or broken and sterility may be compromised.

Components may not be re-sterilized by the hospital because of the possibility of damaging the articulating and interfacing surfaces of the implants and/or damaging or contaminating the ceramic (hydroxyapatite) coated surfaces. The care and handling of ceramic-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 the 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.

EXHIBIT 4

Test Reports

Pages 106 through 145 redacted for the following reasons:
- -
Exemption 4: These pages contain proprietary test data.

EXHIBIT 5

Predicate Device 510(k) Clearance Letters

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

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)

Page 1 of 1

Barbara Bachmann for MXM

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

510(k) Number K073413

JUL 1 2002 K021349

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the Metal TRANSCEND® Articulation System.

Submitted By:	Wright Medical Technology, Inc.
Date:	April 26, 2002
Contact Person:	Ehab M. Esmail Manager Regulatory Affairs
Proprietary Name:	**Metal TRANSCEND®** **Articulation System (LARGER SIZES)**
Common Name:	TOTAL HIP SYSTEM
Classification Name and Reference:	21 CFR 888.3320 Hip joint metal/ metal semi-constrained, with a cemented acetabular component prosthesis – Class III 21 CFR 888.3330 Hip joint metal/ metal semi-constrained, with an uncemented acetabular component prosthesis – Class III
Device Product Code and Panel Code:	Orthopedics/87/KWA

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The Metal TRANSCEND® Articulation System is indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1. non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2. inflammatory degenerative joint disease such as rheumatoid arthritis;

3. correction of functional deformity; and,
4. revision procedures where other treatments or devices have failed

The Metal TRANSCEND® Articulation System components are for single use only.

B. DEVICE DESCRIPTION

The previously submitted and cleared Metal TRANSCEND® Articulation System (Exhibit 1: 510(k) K004043) is composed of two pieces, a metal shell and a metal liner that mates to the shell by the use of a taper locking mechanism. This two piece design limits the size of the femoral heads. The use of a monoblock superfinished shell allows larger head sizes to be used. The new Metal TRANSCEND® Articulation System (larger sizes) should increase the range of motion and decrease the risk of dislocation as compared to the current TRANSCEND® (510(k) K004043) Metal on Metal bearing couple.

The Metal TRANSCEND® Articulation System (larger sizes) consists of the following components that are substantially equivalent to the previously cleared components submitted under the Metal TRANSCEND® Articulation System (510(k): K004043): metal monoblock acetabular shells, and metal femoral heads.

Design features of the Metal TRANSCEND® Articulation Monoblock Shell (larger sizes) are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Porous coated with CoCrMo (ASTM F75) Sintered beads
- Available sizes: ranging from 46mm to 64mm (outer diameter) in 2mm increments (The inner diameter of each shell is 10mm smaller than the outer diameter)
- The articulating surface of the implants will be superfinished (1 microinch Ra maximum) to insure form tolerance and a fine surface finish
- A one-piece acetabular shell allows the surgeon to reconstruct the acetabulum while removing very little bone to accommodate a larger Femoral Head.

Design features of the Metal TRANSCEND® Femoral Head (larger sizes) are summarized below:

- Manufactured from cast cobalt-chromium-molybdenum conforming to ASTM F75
- Available sizes: 38mm, 40mm, 42mm, 44mm, 46mm, 48mm, 50mm, 52mm, 54mm
- Available neck lengths: -3.5, 0, +3.5
- The articulating surface of the implants will be superfinished (1 microinch Ra maximum) to insure form tolerance and a fine surface finish
- The taper connection for the Metal TRANSCEND® Femoral Heads (larger sizes) will be identical to the Metal TRANSCEND® Femoral Heads (510(k):K004043) and is intended to be used with our existing femoral stems manufactured with WMT12/14 taper.

C. MATERIALS

The materials used for the Metal TRANSCEND® Articulation System (larger sizes) are substantially equivalent to competitive devices previously cleared for market.

Monoblock Acetabular Shells

- Cast Cobalt-Chromium-Molybdenum CoCrMo (ASTM F75)
- Porous coated with CoCrMo (ASTM F75) Sintered beads

Femoral Head

- Cast Cobalt-Chromium-Molybdenum CoCrMo (ASTM F75)

D. CLINICAL DATA

The intended use, material, design features, type of interface, and reported ware rates of the Metal TRANSCEND® Articulation System (larger heads) are substantially equivalent to the previously submitted and cleared Metal TRANSCEND® Articulation System (510(k): K004043).

Therefore, Clinical success similar to that of the previously cleared components submitted under the Metal TRANSCEND® Articulation System (510(k) K004043) is expected. The clinical data (TRANSCEND® Metal Articulation System Controlled Clinical Trial in support of 510(k) Statistical Analysis Report Version 8.0 December 23, 2000– Volume 1 & 2) was previously submitted under the Metal TRANSCEND® Articulation System (510(k) K004043). The data was collected prospectively from multi-sites. After excluding a single site with significantly poorer survival than all other sites that was identified as having problems with surgical technique, 2-year cumulative survival was found to be clinically equivalent to (no worse than) the Dobbs metal on metal cohort. Nearly 90% of procedures resulted in "at least good results" at 1 and 2 years as determined by the Harris Hip Score, results that compared favorably with literature-based cohorts of THR. There was more than a 50% increase in the SF-12 physical function component score. Complications and adverse events were rare. Radiolucencies >2mm were rare. There were no findings of subsidence of the stem or migration of the cup >2mm.

In conclusion, this controlled clinical trial provides substantial evidence that the Metal TRANSCEND™ Articulation System (larger sizes) is as safe and effective as approved predicate devices with clinically equivalent patient outcomes relative to such devices, thus supporting a 510(k) claim.

E. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material, type of interface, and design features of the Metal TRANSCEND® Articulation System are substantially equivalent to the competitive devices. The safety and effectiveness of the Metal TRANSCEND® Articulation System are adequately supported by the substantial equivalence information, materials data, testing results, and clinical data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Mr. Ehab M. Esmail
Manager Regulatory Affairs
Wright Medical Technology
5677 Airline Road
Arlington, Tennessee 38002

Re: K021349
Trade Name: Metal TRANSCEND® Articular System (Larger Sizes)
Regulation Number: 21 CRF 888.3320 and 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and
Hip joint metal/ metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: April 26, 2002
Received: April 29, 2002

Dear Mr. Esmail:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 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" (21CFR Part 807.97). 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

K021349

WRIGHT
MEDICAL TECHNOLOGY, INC.
5677 AIRLINE ROAD
ARLINGTON, TN 38002
901-867-9971

Metal TRANSCEND® Articulation System

INDICATIONS STATEMENT

Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions:

1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia;
2) inflammatory degenerative joint disease such as rheumatoid arthritis;
3) correction of functional deformity; and,
4) revision procedures where other treatments or devices have failed.

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

510(k) Number K021349

Summary of Safety & Effectiveness Data for the ULTIMA* Unipolar Head and Adapter Sleeves

Johnson & Johnson Professional, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

K965156

JAN 24 1997

1. **Contact Person**

Johanna Newman, Assoc. Regulatory Affairs Specialist, (508) 828-3268.

2. **Device Name**

Proprietary Name:	ULTIMA* Unipolar Head and Adapter Sleeves
Common Name:	Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Classification Name:	Prosthesis, Hip
Regulatory Class:	Class II by 21 CFR § 888.3360
Product Code:	87 JDG
Owner/ Operator #	9001269

3. **Device Classification**

Classification for ULTIMA* Unipolar Head and Adapter Sleeves has been placed in Class II by 21 CFR § 888.3360

4. **Statement of Substantial Equivalence**

The safety and effectiveness of the ULTIMA* Unipolar Head and Adapter Sleeves is substantially equivalent in terms of function to the Johnson & Johnson ULTIMA* Unipolar Modular Head and the Howmedica Unitrax Unipolar System. Furthermore, analysis results demonstrate that the ULTIMA* Unipolar Head and Adapter Sleeves meets the set criteria for the establishment of "substantial equivalence".

5. **Indications for Use**

The ULTIMA* Unipolar Head is indicated for use in conjunction with a modular femoral stem in partial hip replacement procedures for patients suffering severe pain and disability due to:

1. femoral neck fracture,
2. avascular necrosis of the femoral head,
3. osteoarthritis,
4. abnormalities where:
   - the major pathology affects the femoral head,
   - the acetabular cavity is normal and not deformed or weakened,
   - acetabular replacement is not required or desirable.

6. Physical Description

The ULTIMA* Unipolar Head is provided in a size range of 38mm to 63mm (outer diameter), in 1mm increments. Sizes from 44mm through 63mm are manufactured as a two-piece assembly. The two pieces are made of cast cobalt-chromium-molybdenum alloy conforming to ASTM F75. Both pieces are treated with hot isostatic pressing and solution annealing. The two cast pieces are machined and then joined permanently by electron beam welding to form a hollow unipolar head. Sizes from 38mm through 43mm are cast from cobalt-chromium-molybdenum alloy as a solid head, and are isostatic pressed and solution annealed before machining. Both of these size ranges are finish machined to the outer diameter size. The outer diameter is highly polished for articulation with the implant recipient's natural acetabulum.

The ULTIMA* Unipolar Head has a tapered bore which can receive a variety of Adapter Sleeves. The adapter sleeves can be tapered on the outside to the mate with the unipolar head, and tapered on the inside to mate with the appropriate femoral stem trunnion. The adapter sleeves are available in a 10/12 taper, in size increments for -3mm, +0mm, +5mm. and +10mm neck lengths; in a 11/13 taper, in size increments for +0mm, +6mm, and +12mm neck lengths; and in a 12/14 taper, in size increments for +0mm, +3.5mm, and +7mm neck lengths. The adapter sleeves are machined from cobalt-chromium-molybdenum alloy in wrought bar form conforming ASTM F799.

Table 1. *Similarities and Differences Matrix*

	ULTIMA* Unipolar Head and Adapter Sleeves	**ULTIMA* Unipolar Modular Head**	**Howmedica Unitrax Unipolar System**
	[redacted]	[redacted]	[redacted]
DESIGN			
Range of sizes	38mm-63mm (1mm increments)	38mm-65mm (1mm increments)	38mm-63mm (1mm increments)
Adapter sleeve for increased neck length	Yes	No	Yes
Number neck length sizes	*10/12 taper*: -3mm, +0mm, +5mm, +10mm *11/13 taper*: +0mm, +6mm, +12mm *12/14 taper*: +0mm, +3.5mm, +7mm	+0mm, +5mm	-4mm, +0mm, +5mm, +10mm
Morse-taper locking mechanism to modular femoral stem	Yes	Yes	Yes
INTENDED USE			
Partial hip replacement	Yes	Yes	Yes
MATERIALS			
Manufactured from Co-Cr-Mo	Yes	Yes	Yes

K070359

510 (k) Summary

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

MAR 06 2007

NAME OF SPONSOR:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, Indiana 46582 Establishment Registration Number: 1818910
510(K) CONTACT:	Rhonda Myer Regulatory Affairs Telephone: (574) 371-4927 Facsimile: (574) 371-4987 Electronic Mail: Rmyer7@dpyus.jnj.com
DATE PREPARED:	January 31, 2007
PROPRIETARY NAME:	ASR™ Hip Taper Sleeve Adapter
COMMON NAME:	Femoral Hip Prosthesis
CLASSIFICATION:	Class III device 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 ASR™ Modular Acetabular Cup System, K040627 DePuy Ultima Unipolar Head and Sleeve Adapters, K965156

DEVICE DESCRIPTION:
The DePuy ASR Taper Sleeve Adapter mates with the ASR Femoral Heads (K040627) and any 11/13 or 12/14 DePuy femoral stem to provide differing offsets to best match the patient's anatomy.

INTENDED USE AND INDICATIONS:

Intended Use:
The subject taper sleeve adapters mate the femoral head to the femoral stem. This allows for a reduced number of femoral head components and offers various femoral head offsets and compatibility with multiple femoral stems. The subject device mates with all existing DePuy 11/13 and 12/14 stems.

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:

The substantial equivalence of the ASR Taper Sleeve Adapter is shown by its similarity in intended use, indications for use, materials and design to the existing DePuy ASR™ Modular Acetabular Cup System Sleeve Adapters, K040627 and the DePuy Ultima Unipolar Head and Sleeve Adapters, K965156.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAR 06 2007

Re: K070359
Trade/Device Name: ASR™ Hip Taper Sleeve Adapter
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: February 6, 2007
Received: February 7, 2007

Dear Ms. Myer:

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) 276-0120. 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/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

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

Indications for Use Statement

510 (k) Number (if known): K070359

Device Name: **DePuy ASR™ Taper Sleeve Adapter**

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 if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of General, Restorative,
an[illegible]ogical Devices

51[illegible] Number K070359

5

FEB 1 1 2005 K042992

510(k) Summary

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact:	**Nancy S. Friddle** Senior Regulatory Associate Phone: (574) 371-4923 FAX: (574) 371-4987
Trade Name:	**Corail AMT™ Hip Prosthesis**
Common Name:	Total Hip Prosthesis
Device Classification And Product Code:	**Class II** **LZO**; 21 CFR 888.3353; Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis **Class III** **KWA**; 21 CFR 888.3330; Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Substantially Equivalent Device:	**HA Coating** DePuy Corail® K953111 **Hip stem** DePuy Titan™ K001991 (Marketed by name Summit™)
Device Descriptions:	The Corail AMT Hip is a tapered stem available both collarless and collared. This hip stem is manufactured from F-136 titanium (Ti-6Al-4V) and has a layer of hydroxyapatite (HA) coating applied. The Corail AMT Hip is available in standard offset, lateralized high offset and a Coxa vara lateralized offset. The standard offset

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stems, collared and collarless, are available in 11 sizes (Size 8 to Size 20). The lateralized high offset and the lateralized Coxa vara high offset are available in 8 sizes (Size 9 to Size 16).

Intended use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components.

Indications for use:

Total hip replacement is indicated in the following conditions:

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

The non-porous Corail AMT Hip Stem is indicated for cementless use only.

Substantial equivalence:

The Corail AMT Hip Prosthesis has the same intended use, is made from the same material and has a similar design as the predicate devices and is therefore substantially equivalent.

No performance standards have been established under Section 514 of the Federal Food, Drug, and Cosmetic Act for femoral hip stems.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Ms. Nancy S. Friddle
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K042992
Trade/Device Name: Corail AMT™ Hip Prosthesis
Regulation Number: 21 CFR 888.3330 and 21 CFR 888.3353
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis and Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: III
Product Code: KWA, LZO, LWJ, and MEH
Dated: December 30, 2004
Received: January 3, 2005

Dear Ms. Friddle:

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.

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 240-276-0120. 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,

for Celia Witten, Ph.D., M.D.
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): K042992

Device Name: **Corail AMT™ Hip Prosthesis**

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

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

The non-porous Corail AMT Hip Stem is indicated for cementless use only.

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)

for Mark N Melkerson

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

510(k) Number K042992

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

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

Re: K073570
Trade/Device Name: DePuy Tri-Lock Bone Preservation Stem
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, LZO, LPH
Dated: January 18, 2008
Received: January 22, 2008

Dear Ms. Myer:

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

K073570

p. 1/1

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

Indications for Use Statement

510 (k) Number (if known): _____

Device Name: DePuy Tri-Lock® Bone Preservation Stem

Indications for Use:

The DePuy Tri-Lock Bone Preservation Stem is indicated for cementless use in the treatment of:

1. A severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis;
2. Avascular necrosis of the femoral head;
3. Acute traumatic failure of the femoral head or neck;
4. Failed previous surgery, including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthoplasty, or other total hip replacement; and
5. Certain cases of ankylosis.

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)

EXHIBIT 6

Authorization Letters to Access MAF & Raw Material Specification

(b)(4)

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Michael Owens

Subject: 510(k) Number K080991

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☐ Hold (Additional Information or Telephone Hold).

☑ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?		✓	
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days -< 2 years old)			✓
Child (2 years -< 12 years old)			✓
Adolescent (12 years -< 18 years old)			✓
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓

Rev. 7/2/07

4

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	*Contact OSB.*		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*		✓

Regulation Number	Class*	Product Code
21 CFR 888.3330	III	KWA

(*If unclassified, see 510(k) Staff)

Additional Product Codes: –

Review: for JRF — (Branch Chief) — OSDB (Branch Code) — 07/01/2008 (Date)

Final Review: _____ (Division Director) — (Date)

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K080991

Date: 07/01/2008
To: The Record
From: Michael C. Owens

Office: ODE
Division: DGRND

510(k) Holder: DePuy Orthopaedics, Inc.
Device Name: DePuy ASR XL Modular Acetabular Cup System
Contact: Dawn Sinclair
Phone: (574) 371-5023
Fax: (574) 371-4987
Email: Dsincla3@dpyus.jnj.com

OK PDL 7/10/08

I. Purpose and Submission Summary:

The 510(k) holder would like to introduce the DePuy ASR XL Modular Acetabular Cup System into interstate commerce. This submission is a line extension of the acetabular cup components cleared under K040627 and K073413 as well as the femoral heads cleared under K040627. The subject system consist of an acetabular cup that is designed as a cobalt-chrome-molybdenum (CoCrMo) alloy one-piece cup with a porous coating and is available in outer diameter sizes 64mm through 70mm in two-millimeter increments (44mm-62mm cleared in K040627 and K073413). The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. The cups are offered with and without spikes. Both configurations are specific to the DePuy ASR™ Modular Cup System cleared in K040627 and K073413. These acetabular cups will be compatible with DePuy ASR™ femoral components. The uni femoral head is manufactured from cobalt-chrome-molybdenum (CoCrMo) alloy and is available in a range of diameters from 57mm to 63mm in two-millimeter increments. The uni femoral heads have an internal taper which mates with a taper sleeve adapter specific to DePuy 12/14 or 11/13 tapers. The femoral heads articulate with corresponding one-piece metal acetabular cups. The ASR Uni femoral heads (sizes 39mm through 55mm) were cleared in the DePuy ASR™ Modular Acetabular Cup System, K040627. The subject heads use taper sleeve adapters to mate the DePuy femoral heads to DePuy femoral stems and are manufactured from cobalt-chrome-molybdenum (CoCrMo) alloy.

The major concerns identified in the original submission were changes in material, diametrical clearance, and diameters. In the original deficiency letter for K040627, clinical data was requested to address these concerns. However, the sponsor chose to respond with additional preclinical testing (i.e., wear and frictional torque) in S001 and S002. After discussing the submission in engineering rounds, it was decided that, considering the changes that have already been allowed with mechanical testing, the amount and content of the preclinical testing supplied was adequate for these changes. However, testing in the original submission was only done on 55mm components and when asked to provide testing for sizes above 55mm, the sponsor chose to withdraw the acetabular cups with diameters greater than 55mm and the corresponding heads. Please refer to the review memo for K040627 for a complete review of the original ASR Modular Hip System submission.

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In the current submission, the sponsor has provided additional wear and frictional torque testing on the 63mm heads to address concerns raised in the original submission regarding wear performance and frictional torque for large diameter components (b)(4)

(b)(4)

Furthermore, the Biomet M2a Magnum System (K042037) was cleared with a diameter range of 40mm-60mm without clinical data. In conclusion, the results show that that the increased diameters do not raise any new concerns and the proposed subject components are within a reasonable range of what has already been cleared in the Biomet submission.

Therefore, I am recommending that the subject devices be found **substantially equivalent (SE)** to the other legally marketed predicate device.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	x		
Truthful and Accuracy Statement	x		
510(k) Summary or 510(k) Statement	x		
Standards Form	x		
Clinical Trial Form	x		
Class III Summary and Certification	x		

Comment

The sponsor was contacted via email on June 23, 2008 and asked to provide the standards form as it pertains to the current submission.

The sponsor provided the following standards forms via email on 06/27/2008:

ASTM F1185 - Standard Spec. for Composition of Hydroxylapatite for Surgical Implants (2003)
ASTM F1537 - Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants (2007)
ASTM F75 - Standard Spec for Cobalt-28 Chromium-6 Molybdenum Alloy Castings & Casting Alloy for Surgical Implants (2006)
ASTM F799 - Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (2007)

(b)(4)

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		x	
Is the device an implant (implanted longer than 30 days)?	x		
Does the device design use software?		x	
Is the device sterile?	x		

	Yes	No	N/A
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?	x		

The subject DePuy ASR™ XL Modular Acetabular Cup components are part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular cup is designed as a cobalt-chrome-molybdenum (CoCrMo) alloy one-piece cup with a porous coating and is available in outer diameter sizes 64mm through 70mm in two-millimeter increments. The outer surface of the cup has a porous coating with the addition of a hydroxyapatite (HA) coating. There are no separate liner components to this system, as the liners are integral to the one-piece acetabular cups.

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

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

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

Engineering Drawings are included in Exhibit 2.

A list of compatible components is included in Exhibit 1.

Comment

The sponsor has added several compatible sleeve adapters and femoral stems compared to K040627. In K040627, the sponsor was asked to address femoral fatigue for larger diameter heads. The sponsor stated that it is not the size of the femoral head that affects the fatigue strength of the femoral stem, but rather the femoral head offset. The sponsor's typical stem fatigue testing is performed with the (b)(4) (b)(4) Fatigue testing was been carried out on the ASR Unifemoral heads and taper sleeve adaptor taper sleeve adaptor assembly. No fatigue failure was observed (see RDRO63/04 and RDR151/03). Testing used (b)(4) (b)(4) The current submission has identified taper sleeve adapters that are also well below a +15 offset.

Note: *The sponsor states that the list of compatible components is a representative sample and should not be taken as a complete listing. The sponsor states that 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. A similar statement is also provided in the original submission (K040627).*

IV. Indications for Use

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

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

Porous-coated DePuy ASR™ XL Modular Acetabular Cups are indicated for cementless application.

Comment

The current indications are identical to the Corail AMT Prosthesis which was cleared in K042992. The Corail system was also cleared for M/M articulation (KWA) (CoCrMo 12/14 taper; 22.25, 26, 32, and 36mm and CoCrMo Metal Insert-DePuy Pinnacle K002881, K003523). The original submission was cleared for the following indications:

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 non-union 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 sponsor was sent an email on June 23, 2008, and asked to clarify why the indications have been modified from the previous submissions K040627 and K073413 since the current submission is a line extension.

The sponsor responded via email on June 27, 2008. In the email, the sponsor states the following:

Although the wording may have changed slightly, we haven't made a modification to the indications, in comparison with the cleared indications for the DePuy ASR Modular Acetabular Cup System (K040627). We simply put the various indications into a numbered list so that they can be more easily and quickly read. The exact Indications for Use Statement can also be found in one of our identified predicate devices, the DePuy Tri-Lock BPS (K073570).

The sponsor has made a modification to the IFU Statement. The sponsor has added "failed previous hip surgery, including internal fixation, arthrodesis and hemiarthroplasty" and "Certain cases of ankylosis". However, these modifications have been cleared for metal-on-metal (KWA). After speaking with a few members of the branch, it was decided that these modifications were allowable for the current submission.

V. Predicate Device Comparison

Characteristics	Subject Device	Predicate Device	Predicate Device	Predicate Device
Device Name:	**Proposed DePuy ASR™ XL Modular Acetabular Cup System**	**DePuy ASR™ Modular Acetabular Cup System K040627**	**DePuy ASR™ 300 Acetabular Cup System K073413**	**Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes) K021349**
Acetabular Cup Design:				
Shell Profile	Low profile	Low profile	Low profile	Low profile
Construction	One piece shell	One piece shell	One piece shell	One piece shell
Outer Diameters	64mm – 70mm (2mm increments)	44mm – 62mm (2mm increments)	44mm 62mm (2mm increments)	46mm – 64mm (2mm increments)
Inner Diameter	57mm–63mm (2mm increments)	39mm-55mm (2mm increments)	39mm-55mm (2mm increments)	36mm-54mm (2mm increments)
Spikes	3	N/A	3	N/A
Indications for Use:				
	The device is indicated for use in the following conditions, where there is evidence of sufficient sound bone to seat and support the components: 1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia. 2. Avascular necrosis of the femoral head. 3. Acute traumatic fracture of the femoral head and neck. 4. Failed previous hip surgery, including internal fixation, arthrodesis and hemi-arthroplasty. 5. Certain cases of ankylosis.	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 non-union 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 non-union 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.	Indicated for use in total hip arthroplasty for reduction or relief of pain and/or improved hip function in skeletally mature patients with the following conditions: 1) non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia; 2) inflammatory degenerative joint disease such as rheumatoid arthritis; 3) correction of functional deformity; and, 4) revision procedures where other treatments or devices have failed.

Characteristics	Subject Device	Predicate Device	Predicate Device	Predicate Device
Device Name:	**Proposed DePuy ASR™ XL Modular Acetabular Cup System**	**DePuy ASR™ Modular Acetabular Cup System K040627**	**DePuy ASR™ 300 Acetabular Cup System K073413**	**Wright Medical Metal TRANSCEND® Articulation System (Larger Sizes) K021349**
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	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	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 with DuoFix™ HA Coating	Porous coating
Spikes	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	N/A	Cast High Carbon Co-Cr-Mo alloy ASTM F-75	N/A
OD Coating – Spikes	N/A	N/A	Porocoat® porous coating	N/A
Articulation Requirements	Superfinished surface	Superfinished surface	Superfinished surface	Superfinished surface
Sterile Method	Cobalt-60 Gamma Radiation (25kG min)	Cobalt-60 Gamma Radiation (25kG min)	Cobalt-60 Gamma Radiation (25kG min)	Gamma Radiation

Comment

The Biomet M2a was cleared with Cast CoCrMo heads ranging from 38-60mm. It was also cleared with an acetabular outer diameter range of 44-66mm and an inner diameter range of 38-60mm.

The sponsor was contacted via email on June 23, 2008 and asked to provide a justification for removing the coating from the outer diameter of the pegs compared to the ASR predicate they were originally cleared under.

The sponsor responded via email on June 27, 2008. The sponsor stated that the spikes on the acetabular cups in both 510(k) submissions are coated identically with Porocoat® porous coating along with Duofix™ HA Cotating.

VI. Labeling

The sponsor provided draft package labels in Exhibit 3. The draft package labels include the device name, manufacturer, size, expiration date, the word "STERILE", method of sterilization, and symbols for prescription-use and single-use only.

The sponsor has also provided a draft package insert in Exhibit 3. The draft package insert includes a device description, indications, contraindications, warnings and precautions, information for use (preoperative, intraoperative, and postoperative), adverse events and complications.

The sponsor notes that the package insert is used with other products.

VII. Sterilization/Shelf Life/Reuse

The sponsor states that the packaging and sterilization methods for the subject device will be equivalent to those used for the DePuy ASR Acetabular Cup System cleared in K040627.

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam, EtO, Radiation):	gamma radiation Cobalt-60	
b. **Dose**, for radiation (e.g., 25 – 40 kGy):	≥25 kGy	
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorohydrin that remain on the device (note: not to include ethylene glycol residual level because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);	N/A	
2. A description of the Validation Method for the sterilization cycle (not data): (e.g., Overkill/Half-cycle method, bioburden method, combination method)	(b)(4)	
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))	(b)(4)	
4. Is it labeled "Pyrogen Free"?		x
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))	N/A	
5. A description of the packaging (not including package integrity test data):	The subject DePuy ASR XL Modualr Acetabular Cup products will be packaged in a double sterile packaging system. The primary packaging is then placed inside a carton for distribution.	

The subject device is labeled for single use only.

VIII. Biocompatibility

The subject components are made from cobalt-chrome-molybdenum alloy according to ASTM F75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants.

VIII. Software: N/A

IX. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety: N/A

X. Performance Testing – Bench

The sponsor states that additional testing was been conducted to address concerns expressed by FDA following review of the DePuy ASR™ Modular Acetabular Cup System, K040627, and to establish large head friction and wear properties. The provided test reports were performed using

(b)(4)

Wear Testing

(b)(4)

(b)(4)

Frictional Testing

(b)(4)

(b)(4)

Comment

The previous submission was taken to engineering rounds to discuss concerns regarding a material change and larger head sizes which result in changes in clearance. It was noted that changes that we could potentially clear through preclinical data alone include the following:

1. A change in material if the new material has been used for a metal/metal hip in the past. (Wear testing)
2. A change in clearance as long as appropriate wear and frictional torque testing has been completed and the clearances are not outside of the range of what is thought to be effective.
3. A change in head diameter with wear and frictional torque testing as long as the head size is not well outside the range of what we have clinical data on.
4. Changes to the non-articulating components of a metal/metal system are probably already cleared without new clinical data, depending on the change.

In conclusion, it was noted that clinical data would not be necessary for the original submission, but there was some concern about frictional torque of the largest components

The sponsor was asked in the previous submission to provide a rationale for only completing frictional torque on 55mm components, (b)(4)

(b)(4)

In the current submission, the sponsor provided additional wear and frictional torque testing

(b)(4)

Note: *In the previous submission it was noted that testing was not done on the larger components because they would not fit in the simulator. The current test protocols looked similar to the original. Therefore, it was not clear how the sponsor was able to fit the larger components. The sponsor was contacted via telephone on June 23, 2008 and asked to address the issue. The sponsor*

(b)(4)

(b)(4) *The sponsor provided images of the test setup via email on June 27, 2008. The images have been attached to this review for reference.*

In the original submission, there was concern regarding the use of surface replacement components instead of the subject head/stem. In response to this concern, the sponsor offered a same reasoning as the current submission. The sponsor states that by nature of their design, hip joint replacement devices transmit load through the bearing surface, specifically the joint contact area. The sponsor then states that there is no difference whether the femoral components take the form of a modular head and femoral stem or a surface replacement device.

The sponsor states that in testing the surface replacement devices, (b)(4)

(b)(4)

Note: *The sponsor's rationale is sufficient. However, it was not clear how this was achieved in their testing. Therefore, the sponsor was asked to provide a rationale for how they applied the load in order to mimic the load encountered by the actual ASR XL larger size cups. The sponsor provided the following response:*

(b)(4)

I think that the test specimens are adequate for addressing the specific concerns regarding the bearing surface interaction. As noted above, the surface replacement components are identical in material, outer diameter, surface finish and bearing clearance. The application of the load can be adjusted where appropriate. With a femoral stem the load is transferred to the head through the neck which can be simulated by applying the load from the simulator in the correct direction through the modified head component.

XI. <u>Performance Testing – Animal:</u> N/A

XII. <u>Performance Testing – Clinical:</u> N/A

XIII. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	x		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	x		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?	x		If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?			If **NO** = Request Data
9. Data Demonstrate Equivalence?			Final Decision:

XIV. Deficiencies

The sponsor was contacted via email on June 23, 2008 and asked to address the following:

- The current submission is a line extension of the DePuy ASR Modular Acetabular Cup System cleared in K040627. Therefore, it is unclear why the indications have been modified from the previous submission. Please provide a justification for the modified indications. Please identify a legally marketed predicate metal-on-metal hip system that was cleared for the proposed indications. Please also provide a comparison (e.g., material, dimensions) to the legally marketed predicate. Alternatively, you may change your proposed indications to match your previous submission (K040627).

  Response

  In an email received on June 27, 2008, the sponsor states that although the wording may have changed slightly, we haven't made a modification to the indications, in comparison with the cleared indications for the DePuy ASR Modular Acetabular Cup System (K040627). We simply put the various indications into a numbered list so that they can be more easily and quickly read. The exact Indications for Use Statement can also be found in one of our identified predicate devices, the DePuy Tri-Lock BPS (K073570).

  Comment:

  The sponsor has made a modification to the IFU Statement. The sponsor has added "failed previous hip surgery, including internal fixation, arthrodesis and hemiarthroplasty" and "Certain cases of ankylosis". However, these modifications have been cleared for metal-on-metal (KWA). After speaking with a few members of the branch, ***it was decided that these modifications were allowable for the current submission.***

- According to the predicate comparison, the current spiked acetabular cup does not include coating on the outer diameter of the spikes compared to the predicate (K073413) cup which includes Porocoat® porous coating with DuoFix™ HA Coating. However, no justification was provided for the

modification. Please provide a justification for this modification and provide a rationale for why the modification does not raise any concerns regarding the performance of the subject device.

Response

In an email received on June 27, 2008, the sponsor states that the spikes on the acetabular cups in both 510(k) submissons are coated identically with Porocoat® porous coating along with DuoFix™ HA Coating. ***This is adequate.***

- Effective January 2, 2008, all firms that choose to use a standard in the review of any new 510k (Traditional, Abbreviated or Special), need to fill out the new standards form (Form 3654) and submit it with their 510(k). The form can be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf. Please provide a copy of this form as it pertains to the current submission.

Response

The sponsor provided the following standards forms via email on 06/27/2008:

ASTM F1185 - Standard Spec. for Composition of Hydroxylapatite for Surgical Implants (2003)
ASTM F1537 - Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants (2007)
ASTM F75 - Standard Spec for Cobalt-28 Chromium-6 Molybdenum Alloy Castings & Casting Alloy for Surgical Implants (2006)
ASTM F799 - Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (2007)

(b)(4)

This is adequate.

XV. Contact History

The complete CTS interactive review log has been attached for reference.

XVI. Recommendation

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

I recommend that the subject device be found **substantially equivalent (SE)** to the other legally marketed predicate device.

Reviewer — Date: 07/01/08

for JRF
Branch Chief — Date: 07/01/2008

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 11137 Sterilization of Health Care Products-Radiation-Parts 1 & 2 (2006)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☑	☐
FDA Recognition number [3] # 14-224		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 11137 - Sterilization of Health Care Products-Radiation-Parts 1 & 2 (2006)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9	Method VDmax - Substantiation of 25kGy or 15kGy as steriliz. dose	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

DePuy chose to use the Method VDmax approach in Section 9 to satisfy this requirement.

JUSTIFICATION

Acceptable results were obtained as required in Section 9.2.6 "Stage 5: Interpretation of results".

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1185 Standard Spec. for Composition of Hydroxylapatite for Surgical Implants (2003)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☐	☑
FDA Recognition number [3] #		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1185 Standard Spec. for Composition of Hydroxylapatite for Surgical Implants

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☑ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION	This is a material spec. Compliance assured by material supplier via certificate of conformity and test data (each lot).	
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1537 Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants (2007)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 8-152		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1537 Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy for Surgical Implants (2007)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

Material specification - compliance assured by material supplier via certificate of conformity and testing (each lot).

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F75 Standard Spec for Cobalt-28 Chromium-6 Molybdenum Alloy Castings & Casting Alloy for Surg. Implants (2006)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3] # 8-137		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☑
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F75 Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy Castings & Casting Alloy for Surg. Implants (2006)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
Material spec - compliance assured by material supplier via certificate of conformity and testing (each lot).		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F799 Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surg. Implants (2007)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2] ?	☑	☐
FDA Recognition number [3]	# 017	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☑
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☑
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F799 Standard Spec. for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surg. Implants (2007)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

Material specification - compliance assured by material supplier via certificate of conformity and testing (each lot).

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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(b)(4)

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Date: 06/30/2008	**Topic:** The sponsor thanked me.
Type: Email	**User:** Michael Owens

Summary:

Hello, Michael:

Thank you! I look forward to hearing from you.

Kind regards,

Dawn

Date: 06/30/2008	**Topic:** I responded to the sponsor.
Type: Fax	**User:** Michael Owens

Summary:

Ms. Sinclair,

Thank you for your response. I will review what you have provided and contact you if I have an questions.

Best Regards,

Michael Owens

Date: 06/27/2008	**Topic:** The sponsor provided photos of their test set up.
Type: Email	**User:** Michael Owens

Summary:

Hello, Michael:

Attached please find the photos you requested of set-up and fixturing.

Please let me know if you have any questions or require additional information. Thank you once again for your kind consideration of our 510(k) submission.

Best regards,

Dawn Sinclair
Regulatory Affairs

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Date: 06/27/2008	**Topic:** The sponsor provided their response.
Type: Email	**User:** Michael Owens

Summary:

Hello, Michael:

Thank you again for agreeing to review this response prior to placing the 510(k) on a 30-day hold. Please find below our response to the issues you have raised.

* I am forwarding photos of the set-up/fixturing used to mimic the load experienced by the ASR XL Cups. Due to the size, I will send the photos in a separate e-mail.

* Indications for Use modification: Although the wording may have changed slightly, we haven't made a modification to the indications, in comparison with the cleared indications for the DePuy ASR Modular Acetabular Cup System (K040627). We simply put the various indications into a numbered list so that they can be more easily and quickly read. The exact Indications for Use Statement can also be found in one of our identified predicate devices, the DePuy Tri-Lock BPS (K073570).

* Coating on the spikes compared to the predicate 510(k) K073413 acetabular spiked cup - I apologize for any confusion created by the current submission. The spikes on the acetabular cups in both 510(k) submissons are coated identically with Porocoat® porous coating along with DuoFix(tm) HA Coating.

* Form 3654 - Please find attached a Form 3654 for each standard referenced in the 510(k).

I trust all of your concerns have been addressed. Should you wish us to change the Indications for Use statement, please let me know. And, of course, should you have any additional questions, please feel free to contact me at tel. (574) 372-5023. Thank you so much for your kind consideration.

Best regards,

Dawn Sinclair

Date: 06/24/2008	**Topic:** The sponsor's response to an email sent on June 23, 2008.
Type: Email	**User:** Michael Owens

Summary:

Helo, Michael:

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Thank you for your e-mail; I appreciate your not putting the 510(k) on hold until next week. I believe we can prepare an adequate response to all of your concerns and send the requested pictures prior to June 30th.

Best regards,

Dawn Sinclair
Regulatory Affairs

Date: 06/23/2008	**Topic:** Question from sponsor
Type: Email	**User:** Michael Owens

Summary:

Hello, Michael:

If you don't have the pictures before the end of today, does that mean you will be placing the submission on a 30-day hold?

Thanks!

Dawn

Date: 06/23/2008	**Topic:** Additional Information Request
Type: Email	**User:** Michael Owens

Summary:

The submission will not be put on hold at the moment. Please provide the pictures as requested. In addition please address the following:
The current submission is a line extension of the DePuy ASR Modular Acetabular Cup System cleared in K040627. Therefore, it is unclear why the indications have been modified from the previous submission. Please provide a justification for the modified indications. Please identify a legally marketed predicate metal-on-metal hip system that was cleared for the proposed indications. Please also provide a comparison (e.g., material, dimensions) to the legally marketed predicate. Alternatively, you may change your proposed indications to match your previous submission (K040627).
According to the predicate comparison, the current spiked acetabular cup does not include coating on the outer diameter of the spikes compared to the predicate (K073413) cup which includes Porocoat? porous coating with DuoFix? HA Coating. However, no justification was provided for the modification. Please provide a justification for this modification and provide a rationale for why the modification does not raise any concerns regarding the performance of the subject device.
Effective January 2, 2008, all firms that choose to use a standard in the review of any new 510k

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(Traditional, Abbreviated or Special), need to fill out the new standards form (Form 3654) and submit it with their 510(k). The form can be found at http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf. Please provide a copy of this form as it pertains to the current submission.
If you can provide a response by Monday, June 30th, I can avoid putting the submission on hold. Unfortunately, I will be out of the office starting tomorrow June 24, 2008. I will return Monday June 30, 2008. If you have any questions please contact Jonette Foy, Ph.D. (Branch Chief Orthopedic Joint Devices Branch).

Date: 06/23/2008	**Topic:** Clarification
Type: Telephone Call	**User:** Michael Owens

Summary:

The sponosr was asked to provide clarification regarding their testing protocol. In the original submission (K040627) the proposed sizes were removed because the sponosr could not load them in the simulator. IT appears that they are using a simular protocol in the current submission. Therefore, it is not clear what modification were made to the test set up to accomodate the larger components.

The sponsor was also asked to provide an technical explanation of how they were able to simulate the force application of the subject modular head/neck assembly with the surface replacement device.

Date: 06/23/2008	**Topic:** Sponsor's response
Type: Email	**User:** Michael Owens

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(b)(4)

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