



**USER:** CURTSINGER, MARGARET A (mac)

**FOLDER:** K003523 - 79 pages (FOI:10008002)

**COMPANY:** DEPUY ORTHOPAEDICS, INC.  
(DEPUORTHA)

**PRODUCT:** PROSTHESIS, HIP, SEMI-CONSTRAINED  
(METAL UNCEMENTED ACETABULAR  
COMPONENT) (KWA)

**SUMMARY:** Product: DEPUY PINNACLE  
METAL-ON-METAL ACETABULAR CUP  
LINERS

**DATE REQUESTED:** Fri Dec 03 24:00:00 2010

**DATE PRINTED:** Fri Jan 07 13:19:06 2011

**Note:** Releasable Version

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DEC 13 2000

K003523



**SUMMARY OF SAFETY AND EFFECTIVENESS**

**DePuy Orthopaedics, Inc.**

**NAME OF FIRM:**

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

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

**510(k) CONTACT:**

Lynnette Whitaker  
Manager, Regulatory Affairs

**TRADE NAME:**

DePuy Pinnacle Metal-On-Metal Acetabular Cup  
Liners

**COMMON NAME:**

Acetabular Cup Prosthesis

**CLASSIFICATION:**

888.3330 Hip joint metal/metal semi-constrained, with  
an uncemented acetabular component, prosthesis

**DEVICE PRODUCT CODE:**

87 ~~DK~~ KWA

**SUBSTANTIALLY EQUIVALENT  
DEVICES:**

DePuy Pinnacle Metal-On-Metal Acetabular Cup  
Inter-Op™ Durasul™ Acetabular Inserts, Sulzer  
Orthopaedics, Inc.

**DEVICE DESCRIPTION AND INTENDED USE:**

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 36mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

It is indicated for use as the acetabular component 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, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 36mm diameter Co-Cr-Mo femoral heads only.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are nearly identical to the Pinnacle Metal-On-Metal Acetabular Cup Liners that were cleared previously. The intended use, articular surface characteristics, material and locking mechanism with the outer shell are the same. The only minor change to the cup is to inner diameter of the cup, which is now 36mm.

0000003



DEC 13 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Lynetter Whitaker, RAC  
Manager, Regulatory Affairs  
DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
P.O. Box 988  
Warsaw, Indiana 46581-0988

Re: K003523

Trade Name: Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners  
Regulatory Class: III  
Product Code: KWA  
Dated: November 13, 2000  
Received: November 15, 2000

Dear Ms. Whitaker:

We have reviewed your Section 510(k) notification of intent to market the ~~device referenced~~ above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general 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.

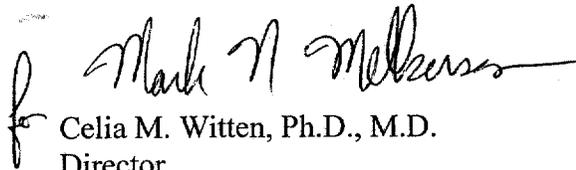
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Ms. Lynetter Whitaker, RAC

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

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

Enclosure

510(k) Number (if known) K003523

Device Name DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component 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, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 36mm diameter Co-Cr-Mo femoral heads only.

-----  
Concurrence of CDRH, Office of Device Evaluation

*for Mark N. Melkerson*

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number \_\_\_\_\_

K003523

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The Counter Use

0000004



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 05 2005

Ms. Rhonda A. Myer  
Regulatory Affairs Associate  
DePuy Orthopaedics, Inc.  
P.O. Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988

Re: K003523/A1  
Device Name: DePuy Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners  
Dated: July 26, 2005  
Received: July 27, 2005

Dear Ms. Myer:

We have reviewed the information dated July 26, 2005, regarding the 510(k) notification K003523 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](http://www.fda.gov/cdrh/ode/510kmod.html). The information you have supplied will be added to the file.

Sincerely yours,

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

AUG 05 2005

Ms. Rhonda A. Myer  
 Regulatory Affairs Associate  
 DePuy Orthopaedics, Inc.  
 P.O. Box 988  
 700 Orthopaedic Drive  
 Warsaw, Indiana 46581-0988

Re: K003523/A1

Device Name: DePuy Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners  
 Dated: July 26, 2005  
 Received: July 27, 2005

Dear Ms. Myer:

We have reviewed the information dated July 26, 2005, regarding the 510(k) notification K003523 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](http://www.fda.gov/cdrh/ode/510kmod.html). The information you have supplied will be added to the file.

Sincerely yours,

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

FILE  
 COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HF2-410	G. J. [Signature]	8/1/05						
410	[Signature]	8/1/05						
2-410	[Signature]	7/5						

cc: HFZ-401 DMC  
HFZ-404 510(k) Staff  
HFZ-410 Division  
D.O.  
f/t:Efrank:tmj:7-21-05

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Memorandum

Date: 7/27/05

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K003523/A1

To: Division Director: OR/DORND

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: Elizabeth L. FH

Date: 7/28/05

Draft #2: 9/8/99

Draft #3: 1/3/00

Draft #4: 3/7/03

DMC  
8/5

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**510(k) REVIEW MEMORANDUM**

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**To:** K003523/A1 *Elizabeth L. P...*  
**From:** Elizabeth Frank, Biomedical Engineer, M.S.  
FDA/CDRH/ODE/DGRND/Orthopedic Devices Branch (HFZ-410)  
**Date:** July 29, 2005  
**Device:** DePuy Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners  
**Company:** DePuy Orthopaedics, Inc.  
PO Box 988  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988  
**Contact:** Ms. Rhonda A. Myer, Regulatory Affairs Associate  
Phone: 574-371-4927, Email: [rmyer7@dpyus.inj.com](mailto:rmyer7@dpyus.inj.com)

*S. Rhonda 8/15*

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**Recommendation:** Information does not change the status of the 510(k), no other action required by the DMC; please add to image file. The sponsor will be sent a K-25 letter indicating a new 510(k) is not needed.

**Review:**

The sponsor has submitted an addendum to K003523. This information replaces the chart originally included as Exhibit 4 (pg. 31) of the submission, which contained a miscalculation. The corrected information on the chart was obtained from the calculations contained in the enclosed Table A.

In Supplement 2 of K040627 (under review) the sponsor submitted a table comparing the diametrical clearances of the subject and predicate devices. The first DePuy Metal-on-Metal Hip System was the Ultima® Metal-On-Metal Acetabular Cup (28mm) cleared in K001523. In K002883, the sponsor modified the backside, non-locking section of the Ultima liner to match the dome on the Pinnacle shells. No changes were made to the articulating surface of the system. In Exhibit 4 of K002883, the sponsor provides a comparison chart identifying that the diametrical clearance for the predicate Ultima and the 28mm Pinnacle system are identical, ranging from 40-80µm.

In K003523, the Pinnacle system was expanded to include 36mm liners. The comparison chart of the 28mm and 36mm Pinnacle liners (K003523, Exhibit 4) indicates the 28mm and 36mm liners have identical diametrical clearances (40-80µm). However, the sponsor has indicated in the comparison table of K040627 that the 36mm liners have a clearance of 80-120µm. On 7/12/05 the sponsor was contacted by telephone to clarify the diametrical clearance of the 36mm system. The sponsor discovered the chart in Exhibit 4 of the predicate device is incorrect. According to the engineering drawings of K003523 the Pinnacle 36mm system has a diametrical clearance of 80-120µm. The sponsor has submitted this add to file to correct this mistake.

According to current practices in ORDB the diametrical clearance of a system cannot be changed without clinical data. Therefore, given this new information the Pinnacle 36mm system would not have been cleared in 2000. However, after searching the Medical Device Reporting Program (MDRs) for adverse events associated with the Pinnacle 36mm liners, only 5 adverse events were reported. Three of these adverse events were failure for the liner and shell to line up appropriately, one adverse event was a patient revised due to pain and one adverse event gave no details. Over the same period of time, the comparable Sulzer metal-on-metal system had approximately 25 adverse events reported, while Zimmer had 3 reports regarding the 28mm acetabular insert and 3 reports regarding their Cobalt Chrome femoral head. Therefore, during the same time period the 36mm Pinnacle system had a reasonable number of adverse events reported. Therefore, the sponsor will not need to submit a new 510(k) based on the new information presented for the device already cleared (K003523).

K003523/A1



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

**Addendum to K003523**

July 26, 2005

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

**Reference:** DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners; K003523; Cleared  
December 13, 2000

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate on the DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners, as an addendum to K003523. This information replaces the chart originally included as **Exhibit 4** (page 31) of the submission, which contained a miscalculation. The corrected information on the chart was obtained from the calculations contained in the enclosed **Table A**.

We regret this error and appreciate the opportunity to correct the information.

Thank you for your time and consideration. If you should have any questions, please contact me at (574) 371-4927 or [rmyer7@dpyus.jnj.com](mailto:rmyer7@dpyus.jnj.com).

Sincerely,

Rhonda A. Myer  
Regulatory Affairs Associate

Enclosures

574-371-4927

6 5/6-7

**Exhibit 4**

**Comparison of Pinnacle 28mm and 36mm metal inserts**  
(Highlighted information below denotes corrected fields)

	Pinnacle 28mm	Pinnacle 36mm	Risk analysis method used to assess differences
Indications for use	The acetabular component 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. Also, patients with congenital hip dysplasia, protrusion acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.	SAME	
Device description	Metal liner that assembles into a metal shell.	SAME	
Shell	Titanium alloy porous coated shell with apical hole and 3 dome screw holes	SAME	
Shell material	Ti-6Al-4V with commercially pure titanium porous coating	SAME	
Locking of liner into shell	10 degree included angle taper junction	SAME	
Liner material	Wrought Co-Cr-Mo alloy	SAME	
Articulation requirements	40-80 microns clearance on diameter, roundness 5 microns or less	80-120 microns	(b)(4)
Inner diameter	28mm nominal	36mm nominal	
Sterilization	Gamma	SAME	
Use with femoral heads	DePuy S-ROM, PFC, and Articul/eze 28mm diameter Co-Cr-Mo femoral heads	DePuy S-ROM and Articul/eze 36mm diameter Co-Cr-Mo femoral heads	
Liner styles	Neutral only	SAME	
Liner sizes	Each shell OD has a corresponding insert	SAME	

**Table A**

**36mm Pinnacle MOM**

	Nominal Diameter	Tolerance (+/-)	MMC Diameter	LMC Diameter	Nominal Radius	Tolerance (+/-)	MMC Radius	LMC Radius
Head (in)	(b)(4)							
Insert (in)								
Clearance (in)								

	Nominal Diameter	Tolerance (+/-)	MMC Diameter	LMC Diameter	Nominal Radius	Tolerance (+/-)	MMC Radius	LMC Radius
Head (mm)	(b)(4)							
Insert (mm)								
Clearance (mm)								
Clearance (µm)								



April 28, 2009

Food and Drug Administration  
Rockville MD 20857

DEPUY ORTHOPAEDICS, INC.  
P.O. BOX 988  
WARSAW INDIANA 46581

Re: Premarket Notification Number: K003523

Dear Manufacturer:

The Food and Drug Administration (FDA) is currently in the process of evaluating the classification of class III devices that are currently marketed through clearance of a premarket notification (510(k)) submission. These devices were found to be substantially equivalent to a preamendments class III device type for which no date has yet been established for requiring the submission of a premarket approval application (PMA). (A class III preamendments device type is a device type that was legally on the market before May 28, 1976, and that was subsequently classified into class III.) FDA premarket notification (510(k)) records indicate that you received clearance to market a device belonging to one of the class III device types being evaluated. Accordingly, FDA is requesting that you submit specific information, discussed below, to support these classification efforts. These classification efforts will culminate in a decision either to call for a PMA for these class III devices, or to reclassify these devices into Class II (special controls) or Class I (general controls). FDA will reach this decision based on all available and reviewed information pertaining to each device type. For certain device types, classification panel hearings may be held to assist in these efforts. Any future proposed decisions will apply to the device type as a whole, not solely to your individual device.

As stated, FDA, in accordance with Section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. § 360e(i)), is requiring manufacturers who were marketing, or have clearance to market through a 510(k) substantial equivalence decision, the class III device types referenced above as of April 9, 2009, to submit certain information. The enclosed Federal Register notice details the specific device types, the requested information, and the submission instructions. You are required to submit this information by August 7, 2009, to:

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD, 20852.

Please note that items posted to this docket will be redacted in accordance with the Freedom of Information Act (FOIA) (5 U.S.C. § 552), and posted to the docket. To ensure your posted documents are redacted, prior to posting, please denote submissions uploaded to the docket as such by typing the following words in the top of the "General Comments" box:  
***"CONFIDENTIAL MATERIAL DO NOT POST TO THE WEB AS REQUESTED BY SUBMITTER. STATUS SHOULD BE CONFIDENTIAL."***

If you have information showing that you have received this letter in error, or that our records supporting this letter are inaccurate, such that you are relieved of the obligation to submit the requested information, please send an explanation of the error, noting your 510(k) number, to:

Attn.: 510(k) Staff, 515(i) Submission  
Document Mail Center, HFZ-401  
Center for Devices and Radiological Health  
9200 Corporate Boulevard  
Rockville, MD, 20850

Please note that in lieu of submitting the above requested information, you may also petition FDA to reclassify the device type in accordance with Section 513(e) of the act (21 U.S.C. 360c(e)) and our regulations found in 21 CFR Part 860. In general, FDA's review of reclassification petitions can be completed more efficiently when manufacturers collaborate and submit a single reclassification petition that includes all relevant and accurate information for the given device type. This collaboration can be organized by contacting other manufacturers of the pertinent device through either a professional association or other affiliation.

Additional information or inquiries relevant to this classification mandate can be obtained by referencing the FDA Class III website at: <http://www.fda.gov/cdrh/classiii.html>, or by contacting Sarah K. Morabito at (240) 276-3975.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Donna-Bea Tillman', written over a horizontal line.

Donna-Bea Tillman, Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 13 2000

Ms. Lynetter Whitaker, RAC  
Manager, Regulatory Affairs  
DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
P.O. Box 988  
Warsaw, Indiana 46581-0988

Re: K003523  
Trade Name: Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners  
Regulatory Class: III  
Product Code: KWA  
Dated: November 13, 2000  
Received: November 15, 2000

Dear Ms. Whitaker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general 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.

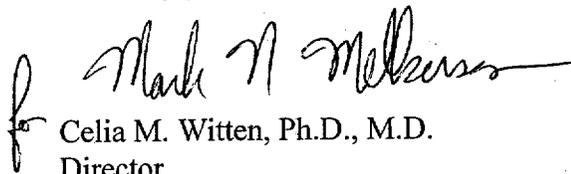
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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Page 2 - Ms. Lynetter Whitaker, RAC

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Sincerely yours,



Celia M. Witten, Ph.D., M.D.  
Director

Division of General, Restorative and  
Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known) K003523

Device Name DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component 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, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 36mm diameter Co-Cr-Mo femoral heads only.

-----  
Concurrence of CDRH, Office of Device Evaluation

*for Mark N. Melkerson*

(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number K003523

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The Counter Use

0000004

Memorandum

From: Reviewer(s) - Name(s)

*Peter Allen*

Subject: 510(k) Number

*K003523*

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

De Novo Classification Candidate?

YES

NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?

YES

NO

Is this device subject to the Tracking Regulation?

YES

NO

Was clinical data necessary to support the review of this 510(k)?

YES

NO

Is this a prescription device?

YES

NO

Was this 510(k) reviewed by a Third Party?

YES

NO

Special 510(k)?

YES

NO

Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers

YES

NO

This 510(k) contains:

Truthful and Accurate Statement  Requested  Enclosed  
(required for originals received 3-14-95 and after)

A 510(k) summary OR  A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin

YES

NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality

Confidentiality for 90 days

Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

Additional Product Code(s) with panel (optional):

*KWA ~~XXXX~~, III*

Review:

(Branch Chief)

*[Signature]*

*OR03*

(Branch Code)

*12-12-00*

(Date)

Final Review:

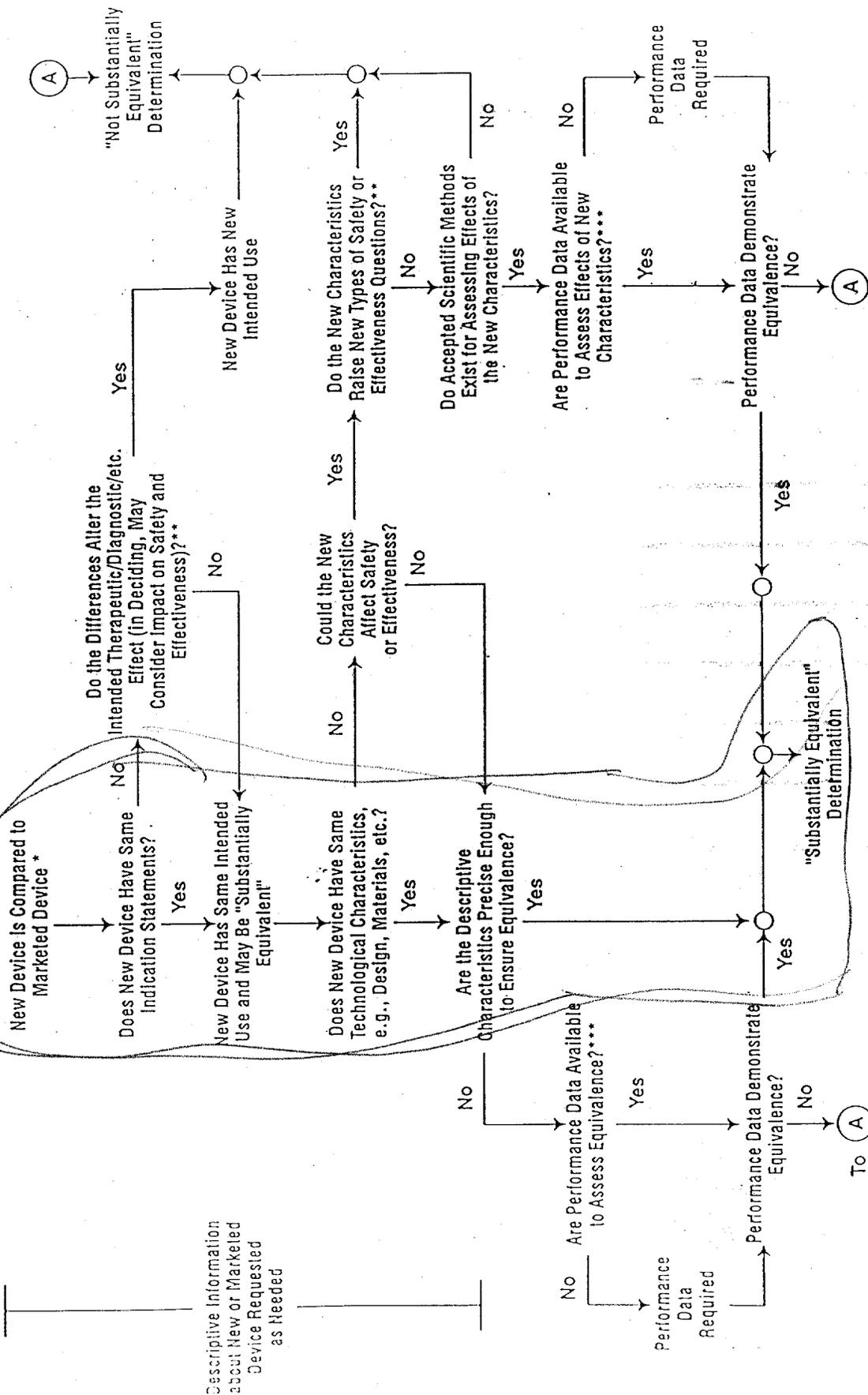
(Division Director)

*Mark N. Melanson*

*12/12/00*

(Date)

# 510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



\* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments Classified Post-Amendments) Devices is Unclear.

\*\* This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

\*\*\* Data May Be 10(k), Other 510(k)s, The Center's Classification Files, or the Literature.

**SPECIAL 510(k): Device Modification  
ODE Review Memorandum**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K003523

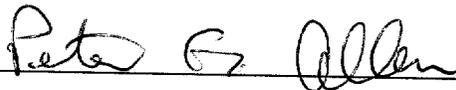
Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners - DePuy Orthopaedics, Inc. HWO

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This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.  
This change was for the addition of 36mm metal-on-metal acetabular liners to the Pinnacle (28mm) Metal-on-Metal Acetabular Cup Liners cleared in K002883.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics (geometry, sizes, materials, etc.) method of fixation, sterilization, and verification test results.
5. A **Design Control Activities Summary** which includes:
  - a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
  - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
  - c) A declaration of conformity with design controls. The declaration of conformity should include:
    - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
    - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.



(Reviewer's Signature)

11/17/00

(Date)

Comments

The predicate system for which these components may be considered a line extension is the DePuy Pinnacle (28mm) Metal-on-Metal Acetabular Cup Liners, cleared under K002883. The modification effected is an increase in the inner diameter of the metal liner to 36mm, this is the only change. Other acetabular cup liners of polyethylene having inner diameters up to 46mm have been cleared (K993259). Verification test acceptance criteria required the wear be equivalent to or less than the 28mm liner/head combination. The sponsor certifies that the acceptance criteria were met.

700 Orthopedic Drive • P.O. Box 988  
Warsaw, IN 46581-0988



# Fax

**To:** Peter Allen **From:** Lynnette Whitaker

**Fax:** 301-827-4349 **Pages:** 6

**Phone:** \_\_\_\_\_ **Date:** 12-12-00

**Re:** K003523 **CC:** \_\_\_\_\_

Urgent     For Review     Please Comment     Please Reply     Please Recycle

---

• **Comments:**

**DePuy Orthopaedics, Inc.**

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

Tel: +1 (219) 267 8143  
Fax: +1 (219) 267 7196

December 12, 2000

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

Reference: K003526, Pinnacle Metal on Metal 36mm Acetabular Cup Liners

Dear Mr. Allen:

Please find enclosed a revised package insert for the 36mm Pinnacle Metal on Metal Acetabular Cup Liners, as you requested in our phone conversation on December 12, 2000. The verbiage has been changed to indicate that the 28 mm liners should be used with femoral heads labeled for use with metal liners (please note that these 28mm femoral heads are also compatible for use with 28mm polyethylene liners), and that the 36mm metal liners should be used with the 36mm femoral heads (these heads are also compatible polyethylene 36mm liners).

This should make the proper use of the femoral heads and inserts more clear to the user. I trust this information is sufficient to complete your review of this Special 510(k) submission. Please contact me at 219-371-4903 if you have any other questions. Please note that we have a new fax number, which is 219-371-4987.

Sincerely,

A handwritten signature in cursive script that reads "Lynnette Whitaker".

Lynnette Whitaker  
Manager, Regulatory Affairs

## Metal-On-Metal Acetabular Cups

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

### Description

The DePuy Ultima and Pinnacle Metal-On-Metal (MOM) Acetabular Cup Systems are both comprised of a metal acetabular shell and a metal acetabular cup insert. In both MOM acetabular cup systems, the metal insert mechanically locks with the metal shell via a taper junction. (Delete last line)

**Do not mix Metal-on-Metal inserts and shells from different systems. Ultima MOM Acetabular Cup Inserts can be used only with Ultima MOM Acetabular Shells. Pinnacle MOM Acetabular Cup Inserts can be used only with Pinnacle Acetabular Shells.**

### Indications

The Ultima and Pinnacle Metal-On-Metal Acetabular Cups are indicated for use as the acetabular component 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, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

**The Ultima and Pinnacle Metal-On-Metal Acetabular Cups are intended for use only with DePuy 28mm Co-Cr-Mo femoral heads labeled for metal-on-metal use and 36mm diameter Co-Cr-Mo femoral heads. Inserts with a 28mm inner diameter should be used with 28mm femoral heads only. Inserts with a 36mm inner diameter should be used with 36mm femoral heads only.**

### Information for Use

An instrumentation system, as well as a system of trial components, is available to assure proper fit and alignment of the prosthesis. Correct fit and alignment will reduce stresses at interface surfaces to enhance implant fixation. The surgeon should refer to the appropriate surgical technique manual on use of the instrument system and implantation of the prosthesis. A special instrument is provided to enable the surgeon to remove the insert once it has been fitted in place. For the Ultima system only, it is recommended that a reamer of the same size designation as the shell is used since this will provide a 1.5mm diametral press fit.

### Contraindications

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

### Warnings

Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental or occupational conditions will likely result in extreme stresses to the implant may result in premature failure due to loosening, fracture or wear. Postoperative care is extremely important. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion and activity levels permissible. Early motion and load bearing should be carefully monitored.

This implant should not be used with other manufacturers' components. Use of components other than those recommended could lead to loosening, wear, fracture during assembly and premature failure. Use the Ultima Metal-On-Metal Shell only with the Ultima Metal-On-Metal insert. Use the Pinnacle Metal-On-Metal insert only with the Pinnacle Acetabular Shell.

The inner diameter of the Metal-On-Metal insert must correspond to the hip head size. Use of an insert with a non-matching hip head size (e.g. 28mm inner diameter insert with a 22mm head) will result in accelerated wear and early failure. *Inserts with a 28mm inner diameter should only be used with 28mm femoral heads labeled for metal-on-metal use. Inserts with a 36mm inner diameter should be used with 36mm femoral heads.*

### Precautions

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

An implant should never be re-used. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.

Likewise, a new implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces.

When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

The highly polished bore of the insert should not come into contact with abrasive surfaces, as this may damage the bore and affect performance. In addition, all mating surfaces should be clean before assembly to ensure proper seating. If the insert is not properly seated into the metal on metal shell it may become loose.

#### **Adverse Effects**

Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements. Subclinical nerve damage has also been reported more frequently, often associated with surgical trauma. Dislocation and subluxation resulting from improper positioning and/or muscle and fibrous tissue laxity may also occur, as may loosening and subsequent failure of the total hip prosthesis.

Histological reactions have been reported as an apparent response to exposure to a foreign material. The actual clinical significance of these reactions is unknown.

Implanted metal alloys release metallic ions into the body. In situations where bone cement is not used, higher ion release due to increased surface area of a porous coated prosthesis is possible.

There have been reports of failure of bone to grow into porous surfaces and fix components. Shedding or fragmentation of the porous surface has been reported, with potential for release of metallic debris into the joint space. Radiolucencies of bone adjacent to porous surfaces have been noted, although the clinical significance of this observation is uncertain in many cases.

**Serious adverse effects may necessitate surgical intervention.**

#### **Sterility and Handling**

The components of the Ultima and Pinnacle Metal-On-Metal Acetabular Cups are supplied sterile by exposure to gamma irradiation.

**DO NOT RESTERILIZE and DO NOT USE if the package is damaged or broken and sterility may be compromised.**

Components may not be resterilized by the hospital because of the possibility of damaging the articulating and interfacing surfaces of the implant and/or damaging or contaminating the porous surface.

The care and handling of porous coated implants demands greater attention because of the increased potential for particulate and microbiological contamination. Body fluids, tissues and particulate matter adhere to the beaded surface. Therefore, it is critical to minimize handling of the prosthesis.

The package should be opened only after the correct size has been determined, as opened packages may not be returned for credit.

Further information is available from your DePuy representative on request.

## Screening Checklist

### For all Premarket Notification 510(k) Submissions

<b>Device Name:</b> Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners							K003523					
<b>Submitter (Company):</b> DePuy Orthopaedics, Inc.												
<b>Items which should be included</b> <i>(circle missing &amp; needed information)</i>						<b>SPECIAL</b>		<b>ABBREVIATED</b>		<b>TRADITIONAL</b>		<input checked="" type="checkbox"/> <b>IF ITEM IS NEEDED AND IS MISSING</b>
						YES	NO	YES	NO	YES	NO	
<b>1. Cover Letter clearly identifies Submission as:</b> a) "Special 510(k): Device Modification" b) "Abbreviated 510(k)" c) Traditional 510(k)						<input checked="" type="checkbox"/>	GO TO # 2,3	<input type="checkbox"/>	GO TO # 2,4,5	<input type="checkbox"/>	GO TO #2, 5	
<b>2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS</b>								<input checked="" type="checkbox"/> <b>IF ITEM IS NEEDED</b>				
<b>Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)</b>						<b>NA</b>		<b>YES</b>		<b>NO</b>		<b>AND IS MISSING</b>
						<b>SPECIALS</b>		<b>ABBREVIATED</b>		<b>TRADITIONAL</b>		
						YES	NO	YES	NO	YES	NO	
a) trade name, classification name, establishment registration number, device class						<input checked="" type="checkbox"/>	NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
b) OR a statement that the device is not yet classified						FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device						NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
d) compliance with Section 514 - performance standards						NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
e) address of manufacturer						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
f) Truthful and Accurate Statement						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
g) Indications for Use enclosure						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
k) Proposed Labeling:						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i) package labeling (user info)						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ii) statement of intended use						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
iii) advertisements or promotional materials						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i) MRI compatibility (if claimed)						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
i) Labeling						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
ii) intended use						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
iii) physical characteristics						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
iv) anatomical sites of use						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
v) performance (bench, animal, clinical) testing						NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
vi) safety characteristics						NA	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
m) If kit, kit certification						<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
<b>3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE</b>												
a) Name & 510(k) number of legally marketed (unmodified) predicate device						<input type="checkbox"/>	<input type="checkbox"/>					<input type="checkbox"/>
b) STATEMENT - INTENDED USE AND INDICATIONS FOR						<input checked="" type="checkbox"/>	<input type="checkbox"/>	* If no - STOP not a special				<input type="checkbox"/>

<b>USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED*</b>				
<b>c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED*</b>				* If no - STOP not a special
<b>d) Design Control Activities Summary</b>				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
	<b>4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE</b>						
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below		
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed		
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device		
v) A specification of any deviations from each applicable standard that were applied		
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference		
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations		
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards		

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening  Yes  No  
 Date: 11/17/00

Reviewer: Peter G. Walker  
 Concurrence by Review Branch: [Signature]

15

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

Reviewer: K 003523  
Peter Allen  
Division/Branch: DGRND/ORDB  
Device Name: Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners  
Product To Which Compared (510(K) Number If Known): K002883

	YES	NO	
1. Is Product A Device	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
2. Is Device Subject To 510(k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Stop
3. Same Indication Statement?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
5. Same Technological Characteristics?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?	<input type="checkbox"/>	<input type="checkbox"/>	If YES = Stop NE
9. Accepted Scientific Methods Exist?	<input type="checkbox"/>	<input type="checkbox"/>	If NO = Stop NE
10. Performance Data Available?	<input type="checkbox"/>	<input type="checkbox"/>	If NO = Request Data
11. Data Demonstrate Equivalence?	<input type="checkbox"/>	<input type="checkbox"/>	Final Decision: <u>SE</u>

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation. Questions 4, 6, 8 and 11 are not applicable, see above. There were no "No" responses.

1. Intended Use:
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

## Internal Administrative Form

	YES	NO
1. Did the firm request expedited review?		✓
2. Did we grant expedited review?		✓
3. Have you verified that the Document is labeled Class III for GMP purposes?	✓	<del>✓</del>
4. If, not, has POS been notified?	✓	
5. Is the product a device?	✓	
6. Is the device exempt from 510(k) by regulation or policy?		✓
7. Is the device subject to review by CDRH?	✓	
8. Are you aware that this device has been the subject of a previous NSE decision?		✓
9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?	N/A	A
10. Are you aware of the submitter being the subject of an integrity investigation?		✓
11. If, yes, consult the ODE Integrity Officer.		
12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.	N/A	A

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

November 15, 2000

DEPUY ORTHOPAEDICS, INC.  
P.O. BOX 988  
WARSAW, IN 46581  
ATTN: LYNNETTE WHITAKER

510(k) Number: K003523  
Received: 15-NOV-2000  
Product: DEPUY PINNACLE  
METAL-ON-METAL  
ACETABULAR CUP  
LINERS

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.**

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman  
Consumer Safety Officer  
Premarket Notification Staff



# **SPECIAL 510(k): DEVICE MODIFICATION**

**Pinnacle 36mm Metal-On-Metal  
Acetabular Cup Liners**

**(modification of the Pinnacle Metal-On-Metal  
Acetabular Cup Liners, K002883)**

700 Orthopaedic Drive Warsaw, IN 46581

20  
SKIP  
II OR



**DePuy Orthopaedics, Inc.**

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

Tel: +1 (219) 267 8143  
Fax: +1 (219) 267 7196

## Special 510(k): Device Modification

November 13, 2000

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

**Reference:** DePuy Pinnacle Metal-On-Metal Acetabular Cup; K002883; Cleared October 13, 2000

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate on the DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners, as a **Special 510(k): Device Modification**. The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are a minor design modification of the Pinnacle Metal-On-Metal Acetabular Cup Liners that were cleared in K002883.

*The indications of use for the device have not changed from those cleared in K002883.*

DePuy believes that this modification is eligible for the Special 510(k) process since the product has the same fundamental scientific technology and intended use as the predicate device.

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

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at (219) 371-4903.

Sincerely,

Lynnette Whitaker, RAC  
Manager, Regulatory Affairs  
DePuy Orthopaedics, Inc.

RECEIVED

NOV 15 1 20 PM '00

FDA/CDRH/ODE/DMC

0000001

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0000002

**SUMMARY OF SAFETY AND EFFECTIVENESS**

**DePuy Orthopaedics, Inc.**

**NAME OF FIRM:**

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

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

**510(k) CONTACT:**

Lynnette Whitaker  
Manager, Regulatory Affairs

**TRADE NAME:**

DePuy Pinnacle Metal-On-Metal Acetabular Cup  
Liners

**COMMON NAME:**

Acetabular Cup Prosthesis

**CLASSIFICATION:**

888.3330 Hip joint metal/metal semi-constrained, with  
an uncemented acetabular component, prosthesis

**DEVICE PRODUCT CODE:**

87 JDM

**SUBSTANTIALLY EQUIVALENT  
DEVICES:**

DePuy Pinnacle Metal-On-Metal Acetabular Cup  
Inter-Op™ Durasul™ Acetabular Inserts, Sulzer  
Orthopaedics, Inc.

**DEVICE DESCRIPTION AND INTENDED USE:**

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 36mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

It is indicated for use as the acetabular component 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, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 36mm diameter Co-Cr-Mo femoral heads only.

**BASIS OF SUBSTANTIAL EQUIVALENCE:**

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are nearly identical to the Pinnacle Metal-On-Metal Acetabular Cup Liners that were cleared previously. The intended use, articular surface characteristics, material and locking mechanism with the outer shell are the same. The only minor change to the cup is to inner diameter of the cup, which is now 36mm.

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510(k) Number (if known) K003523

Device Name DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component 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, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 36mm diameter Co-Cr-Mo femoral heads only.

-----  
Concurrence of CDRH, Office of Device Evaluation

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The Counter Use

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**DePuy Orthopaedics, Inc.**

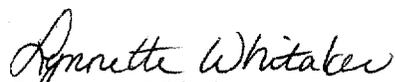
700 Orthopaedic Drive  
PO Box 988  
Warsaw, Indiana 46581-0988  
USA

Tel: +1 (219) 267 8143  
Fax: +1 (219) 267 7196

November 13, 2000

**TRUTHFUL AND ACCURATE STATEMENT**

Pursuant to 21 CFR 807.87(j), I, Lynnette Whitaker, certify that to the best of my knowledge and belief and based upon the data and information submitted to me in the course of my responsibilities as Manager of Regulatory Affairs of DePuy Orthopaedics, Inc., and in reliance thereupon, the data and information submitted in this premarket notification are truthful and accurate and that no facts material for a review of the substantial equivalence of this device have been knowingly omitted from this submission.

  
Lynnette Whitaker  
Manager, Regulatory Affairs  
DePuy Orthopaedics, Inc.

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**DePuy Orthopaedics, Inc.**

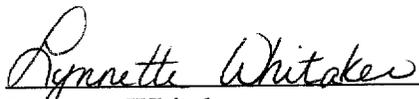
700 Orthopaedic Drive  
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Warsaw, Indiana 46581-0988  
USA

Tel: +1 (219) 267 8143  
Fax: +1 (219) 267 7196

November 13, 2000

**PREMARKET NOTIFICATION  
CLASS III CERTIFICATION AND SUMMARY  
(As Required by 21 CFR 807.94)**

I certify that, in my capacity as Manager of Regulatory Affairs 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.

  
\_\_\_\_\_  
Lynette Whitaker

11-13-00  
\_\_\_\_\_  
Date

\_\_\_\_\_  
(Premarket Notification [510(k)] Number)

DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners

0000006

## **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.

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## SPECIAL 510(k): DEVICE MODIFICATION

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., P.O. Box 988, Warsaw IN, 46581-0988, hereby submits the following information as a special 510(k) for a design modification of the DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners, originally cleared in K002883. The modified acetabular cup liners will be labeled as DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners and are intended for use with the DePuy Pinnacle Acetabular Shells.

### **I. ADMINISTRATIVE INFORMATION**

#### **A. LABELED MANUFACTURER AND SPONSOR OF THE 510(k) SUBMISSION**

DePuy Orthopaedics, Inc.  
P.O. Box 988  
Warsaw, IN 46581-0988  
Establishment Registration Number: 1818910

#### **B. MANUFACTURING LOCATION**

DePuy International Ltd.  
St. Anthony's Road  
Leeds LS11 8DT  
England  
Tel: +44 (113) 270 0461  
Fax: +44 (113) 272 4101

#### **C. CONTRACT STERILIZER**

(b)(4)

#### **D. CONTACT PERSON**

Lynnette Whitaker  
Manager, Regulatory Affairs  
DePuy Orthopaedics, Inc.  
(219) 371-4903  
FAX (219) 371-4940

0000008

## II. DEVICE IDENTIFICATION

### A. PROPRIETARY NAME

Pinnacle Metal-On-Metal Acetabular Cup Liners

### B. COMMON NAME

Total Hip Replacement System

### C. CLASSIFICATION NAME AND REFERENCE

888.3330: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. Class III

### D. DEVICE PRODUCT CODE

87 JDM

## III. PREDICATE DEVICE INFORMATION

The predicate devices are the Pinnacle Metal-On-Metal Acetabular Cup Liners, cleared in K002883 on October 13, 2000.

Polyethylene Acetabular Cup Liners have previously been cleared using inner diameters of up to 46mm. Therefore the Inter-Op Durasul Acetabular Inserts marketed by Sulzer Orthopaedics, Inc., cleared via K993259 on March 10, 2000, are also predicate devices. Predicate Device information is included in Exhibit 6.

## IV. LABELING AND INTENDED USE

Representative draft labels and draft Instructions for Use are provided in Exhibit 3.

The same package insert will be used with both the Pinnacle 28mm and 36mm inner diameter MOM Acetabular Shell components. The only changes made to the Instructions for Use are editorial changes to allow the use of a 36mm femoral head with the 36mm acetabular liner. No changes have been made to the Indications, Contraindications, Warnings, Precautions, or Adverse Effects.

already cleared?

### Intended Use

The Pinnacle Metal-On-Metal Acetabular Cups are indicated for use as the acetabular component 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, *protrusio acetabuli*, slipped capital

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femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle 36mm Metal-On-Metal Acetabular Cups are intended for use with DePuy 36mm diameter Co-Cr-Mo femoral heads only.

This is the **same intended use** that was previously cleared for the Pinnacle MOM Acetabular Cup Liners in K002883.

## V. DEVICE DESCRIPTION AND COMPARISON

The Pinnacle MOM Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 36mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available 36mm diameter prosthetic femoral heads.

The following list compares the Pinnacle 36mm MOM Acetabular Cup Liner with the Pinnacle ~~28mm MOM~~ Acetabular Cup Liners that were cleared in K002883:

- Same indications;
- Same articular surface requirements (larger inner diameter, same effective radius, roundness  $5\mu$  or less);
- Same material specification;
- Same femoral head articulation mechanism;
- Same locking mechanism with acetabular shell (taper lock with same taper angle);
- Same sterilization method and SAL;
- Same packaging;
- Similar labels and package insert;

### Modifications:

- Change to the inner diameter size of the acetabular shell, the inner diameter will include a 36mm size, in addition to the currently cleared 28mm inner diameter size.

Part numbers, descriptions, and engineering prints of the Pinnacle 36mm MOM liners are provided in Exhibit 1. A reference engineering print of the Pinnacle 28mm inner diameter MOM liner is also provided in Exhibit 1 for comparison.

A list of femoral head components that are compatible with the Pinnacle 36mm MOM Acetabular Cup Liners is provided in Exhibit 2.

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**VI. SUBSTANTIAL EQUIVALENCE**

Due to the similarities in intended use, material and design listed above, DePuy believes that the Pinnacle 36mm MOM Acetabular Cup Liners are substantially equivalent to the Pinnacle 28mm MOM Acetabular Cup Liners that were previously cleared in K002883.

Acetabular Cup Liners have previously been cleared in polyethylene materials having inner diameters of up to 46mm, and articulating with similarly sized femoral heads. The Inter-Op Durasul Acetabular Inserts marketed by Sulzer Orthopaedics were cleared in K993259 for liners with an inner diameter as great as 46mm. The 36mm Pinnacle MOM Acetabular Cup Liners are also substantially equivalent to the Durasul Inserts, as they articulate using similarly sized 36mm liner and femoral head.

**VII. SUMMARY OF DESIGN CONTROL ACTIVITIES**

(b)(4)

**Verification Tests**

<b>Modification</b>	<b>Test Performed</b>	<b>Acceptance Criteria</b>
Change in size to inner diameter of inserts to 36mm as opposed to previous size of 28mm inner diameter.	(b)(4)	

Test results are on file and available for review at DePuy. A declaration of conformity with design controls is provided in Exhibit 5.

**0000011**

**EXHIBIT 1**

**Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners**

<b>Pinnacle Shell Outer Diameter</b>	<b>Pinnacle MOM 36mm Neutral Liner</b>
52mm	1218-87-352
54mm	1218-87-354
56mm	1218-87-356
58mm	1218-87-358
60mm	1218-87-360
62mm	1218-87-362
64mm	1218-87-364
66mm	1218-87-366

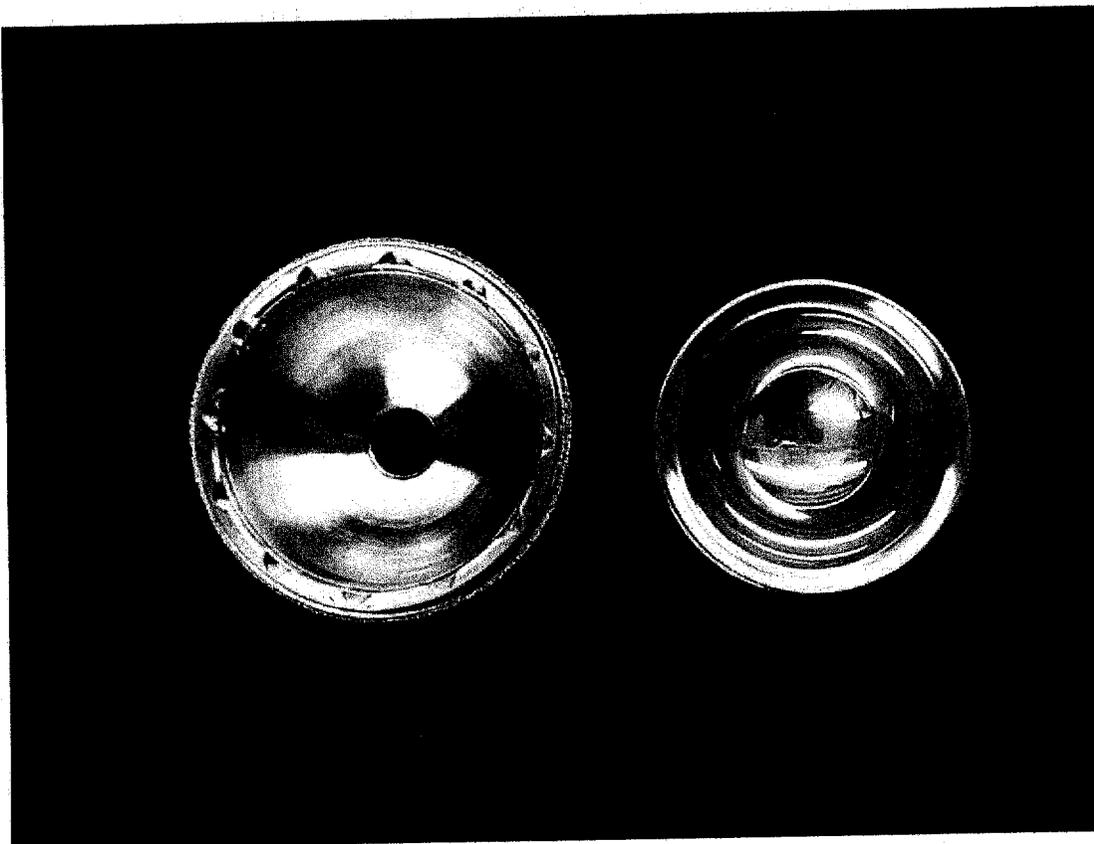
**0000012**

Pages 49 through 56 redacted for the following reasons:

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Pages 49-56 contain schematic drawings considered proprietary under Exemption 4.

**EXHIBIT 1**

**PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS**

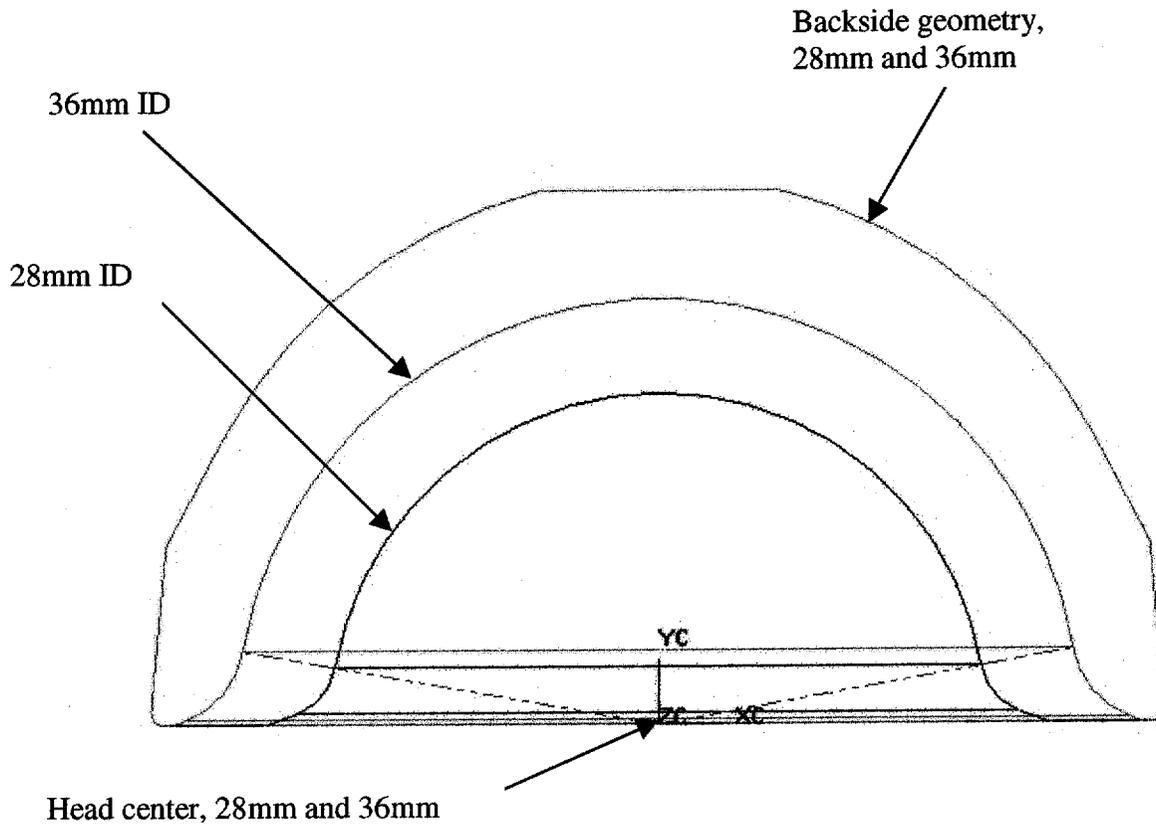


Pinnacle Acetabular Shell (left) and Metal-On-Metal Liner (right)



Pinnacle Acetabular Shell and Metal-On-Metal Liner, Assembled

**0000021**



- 0000022

Pinnacle 28 mm Liner - For reference only!

(b)(4)

**EXHIBIT 2**

**COMPATIBLE COMPONENTS**

**PINNACLE ACETABULAR SHELLS  
(cleared in K001534)**

<b>Acetabular Shell Diameter</b>	<b>Pinnacle 100 Shell (No Holes)</b>	<b>Pinnacle 300 Shell (Tri-Spiked)</b>	<b>Pinnacle Sector Shell (Cluster)</b>
52mm	1217-01-052	1217-03-052	1217-02-052
54mm	1217-01-054	1217-03-054	1217-02-054
56mm	1217-01-056	1217-03-056	1217-02-056
58mm	1217-01-058	1217-03-058	1217-02-058
60mm	1217-01-060	1217-03-060	1217-02-060
62mm	1217-01-062	1217-03-062	1217-02-062
64mm	1217-01-064	1217-03-064	1217-02-064
66mm	1217-01-066	1217-03-066	1217-02-066

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**EXHIBIT 2**

**COMPATIBLE COMPONENTS**

**DEPUY 36mm FEMORAL HEADS**

(b)(4)

<b>Part Number</b>	<b>Description</b>	<b>Cleared In:</b>
1365-31-000	S-ROM 36mm +0 Femoral Head	K851422
1365-32-000	S-ROM 36mm +3 Femoral Head	K851422
1365-33-000	S-ROM 36mm +6 Femoral Head	K851422
1365-34-000	S-ROM 36mm +9 Femoral Head	K851422
1365-35-000	S-ROM 36mm +12 Femoral Head	K851422
1365-50-000	Articul/eze Ball 36mm -2	K980513
1365-51-000	Articul/eze Ball 36mm +1.5	K980513
1365-52-000	Articul/eze Ball 36mm +5	K980513
1365-53-000	Articul/eze Ball 36mm +8.5	K980513
1365-54-000	Articul/eze Ball 36mm +12	K980513

(b)(4)

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**EXHIBIT 3**  
**REPRESENTATIVE DRAFT LABEL**

**REF: 1218-89-XXX**

**Lot: XXXXX**

**Pinnacle Metal Insert**

**36mm Inner Diameter**

**Size X**

**Co-Cr-Mo**

**Sterile Unless Damaged or Opened**

**Rx Only.**

DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, IN 46580

**0000026**

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## Metal-On-Metal Acetabular Cups

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

### Description

The DePuy Ultima and Pinnacle Metal-On-Metal (MOM) Acetabular Cup Systems are both comprised of a metal acetabular shell and a metal acetabular cup insert. In both MOM acetabular cup systems, the metal insert mechanically locks with the metal shell via a taper junction. (Delete last line)

**Do not mix Metal-on-Metal inserts and shells from different systems. Ultima MOM Acetabular Cup Inserts can be used only with Ultima MOM Acetabular Shells. Pinnacle MOM Acetabular Cup Inserts can be used only with Pinnacle Acetabular Shells.**

### Indications

The Ultima and Pinnacle Metal-On-Metal Acetabular Cups are indicated for use as the acetabular component 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, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

**The Ultima and Pinnacle Metal-On-Metal Acetabular Cups are intended for use with DePuy 28mm and 36mm diameter Co-Cr-Mo femoral heads labeled for metal-on-metal use only. Inserts with a 28mm inner diameter should be used with 28mm femoral heads only. Inserts with a 36mm inner diameter should be used with 36mm femoral heads only.**

(b)(4)

### Information for Use

An instrumentation system, as well as a system of trial components, is available to assure proper fit and alignment of the prosthesis. Correct fit and alignment will reduce stresses at interface surfaces to enhance implant fixation. The surgeon should refer to the appropriate surgical technique manual on use of the instrument system and implantation of the prosthesis. A special instrument is provided to enable the surgeon to remove the insert once it has been fitted in place. For the Ultima system only, it is recommended that a reamer of the same size designation as the shell is used since this will provide a 1.5mm diametral press fit.

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### **Contraindications**

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

### **Warnings**

Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental or occupational conditions will likely result in extreme stresses to the implant may result in premature failure due to loosening, fracture or wear. Postoperative care is extremely important. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion and activity levels permissible. Early motion and load bearing should be carefully monitored.

This implant should not be used with other manufacturers' components. Use of components other than those recommended could lead to loosening, wear, fracture during assembly and premature failure. Use the Ultima Metal-On-Metal Shell only with the Ultima Metal-On-Metal insert. Use the Pinnacle Metal-On-Metal insert only with the Pinnacle Acetabular Shell.

The inner diameter of the Metal-On-Metal insert must correspond to the hip head size. Use of an insert with a non-matching hip head size (e.g. 28mm inner diameter insert with a 22mm head) will result in accelerated wear and early failure. *Inserts with a 28mm inner diameter should be used with 28mm femoral heads labeled for metal-on-metal use only. Inserts with a 36mm inner diameter should be used with 36mm femoral heads labeled for metal-on-metal use only.*

### **Precautions**

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

An implant should never be re-used. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.

Likewise, a new implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces.

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When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

The highly polished bore of the insert should not come into contact with abrasive surfaces, as this may damage the bore and affect performance. In addition, all mating surfaces should be clean before assembly to ensure proper seating. If the insert is not properly seated into the metal on metal shell it may become loose.

#### **Adverse Effects**

Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements. Subclinical nerve damage has also been reported more frequently, often associated with surgical trauma. Dislocation and subluxation resulting from improper positioning and/or muscle and fibrous tissue laxity may also occur, as may loosening and subsequent failure of the total hip prosthesis.

Histological reactions have been reported as an apparent response to exposure to a foreign material. The actual clinical significance of these reactions is unknown.

Implanted metal alloys release metallic ions into the body. In situations where bone cement is not used, higher ion release due to increased surface area of a porous coated prosthesis is possible.

There have been reports of failure of bone to grow into porous surfaces and fix components. Shedding or fragmentation of the porous surface has been reported, with potential for release of metallic debris into the joint space. Radiolucencies of bone adjacent to porous surfaces have been noted, although the clinical significance of this observation is uncertain in many cases.

**Serious adverse effects may necessitate surgical intervention.**

#### **Sterility and Handling**

The components of the Ultima and Pinnacle Metal-On-Metal Acetabular Cups are supplied sterile by exposure to gamma irradiation.

**DO NOT RESTERILIZE and DO NOT USE if the package is damaged or broken and sterility may be compromised.**

Components may not be resterilized by the hospital because of the possibility of damaging the articulating and interfacing surfaces of the implant and/or damaging or contaminating the porous surface.

The care and handling of porous coated implants demands greater attention because of the increased potential for particulate and microbiological contamination. Body fluids, tissues and particulate matter adhere to the beaded surface. Therefore, it is critical to minimize handling of the prosthesis.

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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.

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Comparison of Pinnacle 28mm and 36mm metal inserts

Risk analysis method used to assess differences

	Pinnacle 28mm	Pinnacle 36mm
<b>Indications for use</b>	The acetabular component 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. Also, patients with congenital hip dysplasia, protrusio acetabuli, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.	SAME
<b>Device description</b>	Metal liner that assembles into a metal shell.	SAME
<b>Shell</b>	Titanium alloy porous coated shell with apical hole and 3 dome screw holes	SAME
<b>Shell material</b>	Ti-6AL-4V with commercially pure titanium porous coating	SAME
<b>Locking of liner into shell</b>	10 degree included angle taper junction.	SAME
<b>Liner material</b>	Wrought Co-Cr-Mo alloy	SAME
<b>Articulation requirements</b>	40-80 microns clearance on diameter, roundness 5 microns or less	SAME
<b>Inner diameter</b>	28mm nominal	36mm nominal
<b>Sterilization</b>	Gamma	SAME
<b>Use with femoral heads</b>	DePuy S-ROM, PFC, and Articulzeze 28mm diameter Co-Cr-Mo femoral heads.	DePuy S-ROM and Articulzeze 36mm diameter Co-Cr-Mo femoral heads.
<b>Liner styles</b>	Neutral only	SAME
<b>Liner sizes</b>	Each shell OD has a corresponding insert	SAME

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**Risk analysis method used to assess differences**   **Verification/validation activity**   **Pass/Fail Criteria**

**Pinnacle**

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**EXHIBIT 5**

**DePuy Orthopaedics, Inc.**

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

Tel: +1 (219) 267 8143  
Fax: +1 (219) 267 7196

**DECLARATION OF CONFORMITY WITH DESIGN CONTROLS**

**Verification Activities**

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

Leanne Turner 11/13/00  
Leanne Turner  
Product Development Engineer

**Manufacturing Facility**

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

N. Heck 11-13-00  
Natalie Heck  
Design Quality Engineer  
DePuy Orthopaedics, Inc.

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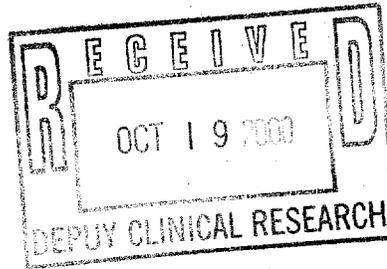
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OCT 13 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Cheryl K. Hastings  
Director, Regulatory Affairs  
DePuy Orthopaedics, Inc.  
700 Orthopaedic Drive  
Warsaw, Indiana 46581-0988



Re: K002883  
Trade Name: Pinnacle Metal-On-Metal Acetabular Cup Liners  
Regulatory Class: III  
Product Codes: JDM and KWA  
Dated: September 13, 2000  
Received: September 15, 2000

Dear Ms. Hastings:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

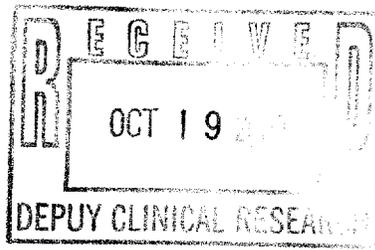
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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Page 2 - Ms. Cheryl K. Hastings



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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten".

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

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### 510(k) SUMMARY

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 CFR 807, this is to serve as a Summary of Safety and Effectiveness for line additions to the Inter-Op™ Durasul™ Acetabular components and CoCr Femoral Heads.

**Submitter:** Sulzer Orthopedics Inc.  
9900 Spectrum Drive  
Austin, Texas 78717  
(512) 432-9900

**Date:** September 17, 1999

**Contact Person:** Mitchell Dhority, RAC  
Manager, Regulatory and Clinical Affairs

**Classification Name:** Hip joint metal/polymer/metal semi-constrained porous coated uncemented prosthesis, 21 CFR 888.3358

**Common/Usual Name:** Total Hip Prosthesis, Semi-constrained

**Trade/Proprietary Name:** Sulzer Orthopedics Inter-Op™ Durasul™ Acetabular Inserts and CoCr Femoral Heads

### PRODUCT DESCRIPTION

The Sulzer Orthopedics Inter-Op Durasul Acetabular Inserts were originally cleared via 510(k) K983509. The purpose of the present submission is to gain notice of substantial equivalence for line additions to these previously cleared insert components and corresponding metallic heads. More specifically, this includes decreased thicknesses (down to 5mm) of the previously cleared Inter-Op Durasul Standard Acetabular Insert design for use with 28, 32, 38mm and 46mm CoCr femoral heads.

### SPECIFIC DIAGNOSTIC INDICATIONS

Diagnostic indications for use of this device include:

- patient conditions of noninflammatory degenerative joint disease (NIDJD); e.g., avascular necrosis, osteoarthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
- those patients with failed previous surgery where pain, deformity, or dysfunction persists.
- revision of a previously failed arthroplasty.

### SUBSTANTIAL EQUIVALENCE

The Inter-Op Durasul Standard Acetabular insert is substantially equivalent and identical in intended use, function, material and general overall design to those products cleared under K983509. These are modular components that are manufactured from the same Durasul cross-linked polyethylene, interface with the same Inter-Op Acetabular Shells and metallic heads and are used to resurface the acetabulum during total hip arthroplasty in the same indications. The main difference is the decreased polyethylene insert thickness (down to 5mm) and increase in diameter of the corresponding head sizes that will be offered.

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Wear, contact stress, fatigue, and locking mechanism integrity testing all indicated that these line additions would perform as intended and similar to legally marketed products. The results of *in vitro* wear tests have not been shown to correlate with clinical wear mechanisms

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 10 2000

Mr. Mitchell Dhority, RAC  
Manager, Regulatory and Clinical Affairs  
Sulzer Orthopedics, Inc.  
9900 Spectrum Drive  
Austin, Texas 78717

Re: K993259

Trade Name: Sulzer Orthopedics Inter-Op™ Durasul™ Acetabular Inserts and CoCr  
Femoral Heads

Regulatory Class: II

Product Code: LPH and JDI

Dated: January 14, 2000

Received: January 18, 2000

Dear Mr. Dhority:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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Page 2 - Mr. Mitchell Dhority, RAC

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

Sincerely yours,



*for* James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

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510(k) Number (if known): K993259

Device Name: Inter-Op Durasul Acetabular Components/CoCr Heads - Line Additions

**Indications for Use:**

The Inter-Op Durasul Acetabular Components and CoCr Femoral Heads are intended for use in treatment of the following:

1. Advanced joint destruction resulting from degenerative, posttraumatic or rheumatoid arthritis.
2. Fracture or avascular necrosis of the femoral head.
3. Failed previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemiarthroplasty and total hip replacement.

**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Harold Jager*

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K993259

Prescription Use Yes

OR

Over-the Counter Use No

(Optional Format 1-2-96)

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FDA/CDRH IMAGING SYSTEM

Page Count Discrepancy Information

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Page after page 41 was misnumbered.

Verifiers Initials SW