U.S. Department of Health & Human Services

Food and Drug Administration

FOIA RESPONSE

USER:	(arp)
FOLDER:	K062426 - 243 pages (FOI:01101466)
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:	May 11, 2011
DATE PRINTED:	May 11, 2011
Note:	Non-Releasable Working Copy

K062426

DEC 15 2006

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Anne M. Schuler Sr. Regulatory Affairs Associate
DATE PREPARED:	August 17, 2006
TRADE NAME:	DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners
COMMON NAME:	Acetabular Cup Liner
CLASSIFICATION:	Hip joint metal/metal semi-constrained with an uncemented acetabular component prosthesis (per 21 CFR 888.3330), Class III Device
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners (K003523, cleared December 13, 2000) DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners (K002883, cleared Ocotober 13, 2000) DePuy ASR Modular Acetabular Cup System (K040627, cleared August 5, 2005)

DEVICE INFORMATION:

A. DEVICE DESCRIPTION

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with Pinnacle Acetabular Shells that have been cleared previously. The liners currently are offered with inner diameters (ID) of 28-36mm, this modification is to add 40 and 44mm Ids and to add a 36mm liner with a outer diameter (OD) of 50mm. The liners are offered in a neutral style only. The subject Pinnacle MOM liner is mechanically locked with the shell via a taper junction which is identical to the taper junction used for the cleared 28 and 36mm liners and articulates with previously cleared M-Spec metal prosthetic femoral heads.

B. INTENDED USE AND INDICATIONS

Intended Use

The subject Pinnacle Metal-On-Metal Liners are intended to be used with the DePuy Pinnacle metal acetabular shells to resurface the acetabular socket in cementless total hip arthroplasty.

Indications

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 Metal-On-Metal Acetabular Cup Liners are intended for use with DePuyPinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

C. BASIS OF SUBSTANTIAL EQUIVALENCE:

The modified Pinnacle Metal-On-Metal Acetabular Cup Liners have the same intended use, indications, manufacturing method, sterilization and packaging as the Pinnacle 36mm and 28mm Acetabular Liners cleared in K003523 and K002883 and the same intended use and indications as the ASR Modular Acetabular Cup System cleared in K040627. The design of the modified Pinnacle Metal-On-Metal Acetabular Cup Liners is similar to the design of the previously cleared Pinnacle Metal-On-Metal liners. The modified liners are offered in a range of sizes (inner and outer diameters) that fall within the range of sizes previously cleared for the ASR Modular Acetabular Cup System. Based on similarities in design, intended use, indications, manufacturing methods, sterilization and packaging DePuy believes that the Pinnacle Metal-On-Metal Acetabular Cup Liners are substantially equivalent to the previously cleared Pinnacle 36 and 28mm metal Acetabular Liners.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics Inc.
% Ms. Kathy Harris
Director of Regulatory Affairs
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

DEC 15 2006

Re: K062426
Trade/Device Name: DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: December 1, 2006
Received: December 4, 2006

Dear Ms. Harris:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K062426
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 Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062426

Document Cover Sheet:

Date of Submission:	17-AUG-2006
Description:	DEPUY PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS
Date of Scan:	26-DEC-2006
Document Prep:	SJR4 12/26/06
Scanner:	SJR4 12/27/06
Image Quality Reviewer:	JHM4 2/7/07

K062426-K6049

FSR0801-000

Document Expected	Page # Start	Page # End	Page In Doc	Indexer
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Indications for Use 15-DEC-2006	3	3	2	
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510K Decision Tree	5	5	2	
Reviewer Notes 15-DEC-2006	6	28	24	
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Correspondence 26-OCT-2006	44	45	3	
Reviewer Notes 26-OCT-2006	46	75	31	
SUPP 001 05-OCT-2006	76	136	62	
Contents 05-OCT-2006	76	136	62	

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Correspondence 27-SEP-2006	137	138	3	✓
Reviewer Notes 26-SEP-2006	139	157	20	✓
Acknowledgement Letter 21-AUG-2006	158	161	5	✓
Original 17-AUG-2006	162	232	72	✓
Cover Page 17-AUG-2006	162	162	2	✓
Medical Device User Fee Cover Sheet 17-AUG-2006	163	163	2	✓
Cover Letter 17-AUG-2006	164	164	2	✓
Contents 17-AUG-2006	165	232	69	✓
Total documents: 15				✓
Total document pages: 232				✓
Total separator pages: 18				✓
Total Scan pages: 251				✓

QC Signature NXCY 4/25/07

QC Bar Code Sticker

Document Cover Sheet:

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QC Signature

QC Bar Code Sticker

April 28, 2009

Food and Drug Administration
Rockville MD 20857

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

Re: Premarket Notification Number: K062426

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,

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

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics Inc.
% Ms. Kathy Harris
Director of Regulatory Affairs
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

DEC 15 2006

Re: K062426
Trade/Device Name: DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis
Regulatory Class: Class III
Product Code: KWA
Dated: December 1, 2006
Received: December 4, 2006

Dear Ms. Harris:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K062426
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 Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062426

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

November 30, 2006

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Device: DEPUY PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS

Extended Until: 26-DEC-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold fo up to a maximum of 180 days from the date of the AI request.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

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

DePuy
a Johnson & Johnson company

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

November 21, 2006

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

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a Johnson & Johnson company

November 21, 2006

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

(b)(4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

October 26, 2006

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Product: DEPUY PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240)276-4040.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 27, 2006

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Product: DEPUY PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

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If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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September 05, 2006

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Received: 01-SEP-2006
Product: DEPUY PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS

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

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

Please note the following documents as they relate to 510(k) review: 1)Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k))Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2)Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3)Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

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

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsma/dsmastaf.html. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

August 21, 2006

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Received: 18-AUG-2006
Product: DEPUY PINNACLE
User Fee ID Number: 6027007AL
ACETABULAR CUP
LINERS

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), 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 all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail	By Private Courier(e.g.,Fed Ex, UPS, etc.)
Food and Drug Administration P.O. Box 956733 St. Louis, MO 63195-6733.	U.S. Bank 956733 1005 Convention Plaza St. Louis, MO 63101 (314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

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

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-fee number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at 301-827-2860. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

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

K062426

DePuy
a Johnson & Johnson company

Special 510(k):

Device Modification

PMC

AUG 1 8 2006

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

(Modification to DePuy 36mm Pinnacle Metal-On-Metal Acetabular Cup Liners, K003523)

K10

OR

Class II

700 Orthopaedic Drive Warsaw, IN 46580

162

Form Approved: OMB No. 0910-511 Expiration Date: August 31, 2005. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: **MD6027007-956733**
Write the Payment Identification number on your check.

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

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

-->

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

DEPUY ORTHOPAEDICS INC
700 Orthopaedic Drive
Warsaw IN 46582
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
352109957

2. CONTACT NAME
Rhonda Myer

2.1 E-MAIL ADDRESS
rmyer7@dpyus.jnj.com

2.2 TELEPHONE NUMBER (Include Area code)
574-371-4927

2.3 FACSIMILE (FAX) NUMBER (Include Area code)
574-371-4987

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

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)

3.1 Select one of the types below
[X] Original Application

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

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business

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

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under secion 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

[ ] YES [X] NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005)
$3,833.00

09-Aug-2006

Form FDA 3601 (08/2003)

Close Window

0000001

DePuy
a Johnson & Johnson company

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

August 17, 2006

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 Liners

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate for the DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners, as a **Special 510(k): Device Modification**. The modifications to the existing Pinnacle Metal-On-Metal Acetabular Cup Liners (K003523) are the addition of 2 larger size liners (40 and 44mm ID) and a the addition of a 36mm liner with a decreased outer diameter of 50mm **The indications for the device remain the same as those cleared in the predicate 510(k) submissions**.

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(b), 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 (574) 372-7098 or be e-mail at aschuler@dpyus.jnj.com.

Sincerely,

Anne M Schuler

Anne M. Schuler
Senior Regulatory Affairs Associate
DePuy Orthopaedics, Inc.

K10

0000002

Table of Contents

Indications for Use

510(k) Number (if known): _____
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 Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

0000004

Truthful and Accuracy Statement

In accordance with 21 CFR §807.87 (j), I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

Carmen L Shuler

Sr Regulatory Affairs Associate

August 17, 2006

Date

0000005

Special 510(k)

Declaration of Conformity with Design Controls

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Verification Activities

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

Rebecca Noftz
Project Engineer, Hips
DePuy Orthopaedics, Inc.

8/17/06
Date

Manufacturing Facility

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

Edmund Frazee
Quality Assurance Engineer
DePuy Orthopaedics, Inc.

17-AUG-06
Date

0000006

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. P.O. Box 988 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(k) CONTACT:	Anne M. Schuler Sr. Regulatory Affairs Associate
DATE PREPARED:	August 17, 2006
TRADE NAME:	DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners
COMMON NAME:	Acetabular Cup Liner
CLASSIFICATION:	Hip joint metal/metal semi-constrained with an uncemented acetabular component prosthesis (per 21 CFR 888.3330), Class III Device
DEVICE PRODUCT CODE:	87 KWA
SUBSTANTIALLY EQUIVALENT DEVICE(S):	DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners (K003523, cleared December 13, 2000) DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners (K002883, cleared Ocotober 13, 2000) DePuy ASR Modular Acetabular Cup System (K040627, cleared August 5, 2005)

DEVICE INFORMATION:

A. DEVICE DESCRIPTION

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with Pinnacle Acetabular Shells that have been cleared previously. The liners currently are offered with inner diameters (ID) of 28-36mm, this modification is to add 40 and 44mm Ids and to add a 36mm liner with a outer diameter (OD) of 50mm. The liners are offered in a neutral style only. The subject Pinnacle MOM liner is mechanically locked with the shell via a taper junction which is identical to the taper junction used for the cleared 28 and 36mm liners and articulates with previously cleared M-Spec metal prosthetic femoral heads.

B. INTENDED USE AND INDICATIONS

Intended Use

The subject Pinnacle Metal-On-Metal Liners are intended to be used with the DePuy Pinnacle metal acetabular shells to resurface the acetabular socket in cementless total hip arthroplasty.

Indications

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 Metal-On-Metal Acetabular Cup Liners are intended for use with DePuyPinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

C. BASIS OF SUBSTANTIAL EQUIVALENCE:

The modified Pinnacle Metal-On-Metal Acetabular Cup Liners have the same intended use, indications, manufacturing method, sterilization and packaging as the Pinnacle 36mm and 28mm Acetabular Liners cleared in K003523 and K002883 and the same intended use and indications as the ASR Modular Acetabular Cup System cleared in K040627. The design of the modified Pinnacle Metal-On-Metal Acetabular Cup Liners is similar to the design of the previously cleared Pinnacle Metal-On-Metal liners. The modified liners are offered in a range of sizes (inner and outer diameters) that fall within the range of sizes previously cleared for the ASR Modular Acetabular Cup System. Based on similarities in design, intended use, indications, manufacturing methods, sterilization and packaging DePuy believes that the Pinnacle Metal-On-Metal Acetabular Cup Liners are substantially equivalent to the previously cleared Pinnacle 36 and 28mm metal Acetabular Liners.

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

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

Anne M. Schuler

Anne M. Schuler

August 17, 2006

Date

(Premarket Notification [510(k)] Number)

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

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.

Special 510(k):
PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS

Section I

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 premarket notification for the Pinnacle Metal-on-Metal Acetabular Cup Liners.

I. ADMINISTRATIVE INFORMATION

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

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

B. CONTACT PERSON

Anne M. Schuler
Sr. Regulatory Affairs Associate
DePuy Orthopaedics, Inc.
(574) 372-7098
FAX (574) 371-4987

II. DEVICE IDENTIFICATION

A. PROPRIETARY NAME

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liner

B. COMMON NAME

Acetabular Cup Liner

C. CLASSIFICATION NAME AND REFERENCE

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

D. DEVICE PRODUCT CODES

87 KWA

III. COMPLIANCE WITH SPECIAL CONTROLS

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

IV. STERILITY AND PACKAGING

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

(b)(4)

V. PREDICATE DEVICE INFORMATION

The predicate devices for this submission are:

- DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners cleared in K003523, December 13, 2000
- DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners cleared in K002883, Ocotober 13, 2000
- DePuy ASR Modular Acetabular Cup System cleared in K040627 August 5, 2005

VI. 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 Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

These are the **same indications for use** that were previously cleared for the Pinnacle MOM Acetabular Cup Liners in K003523 and K002883.

VII. INTENDED USE

The subject Pinnacle Metal-On-Metal Liners are intended to be used with the DePuy Pinnacle metal acetabular shells to resurface the acetabular socket in cementless total hip arthroplasty.

VIII. LABELING AND INSTRUCTIONS FOR USE

Representative draft labels and draft Instructions for Use (IFU) are provided in Exhibit IV.

The IFU is the same as the one currently 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 40 and 44mm femoral heads with the 40 and 44mm acetabular liners. No changes have been made to the Indications, Contraindications, Warnings, Precautions, or Adverse Effects.

IX. ENGINEERING DRAWINGS AND PART NUMBERS

Engineering drawings are provided in Exhibit II. Part numbers are provided in Exhibit I .

DEVICE DESCRIPTION

The Pinnacle Metal-On-Metal Acetabular Cup Liner is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular component is provided as two separate units, a previously cleared porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner manufactured from wrought Co-Cr-Mo metal alloy, which locks into the outer shell via a taper junction. The liner component articulates with a metal femoral head of an appropriate diameter.

The current Pinnacle Metal-On-Metal Liners are offered with inner diameters (ID) of 28 and 36mm. The 28mm liners have an outer diameter (OD) range of 48-66mm and the 36mm liners have an OD range of 52-66mm. Both are offered in a neutral style only. The 28mm liners were cleared in K002883 and the 36mm liners cleared in K003523. The subject liners are geometrically identical to the previously cleared 28 and 36mm liners with the following modifications:

- Increased ID to 40mm with an OD range of 56-60mm
- Increased ID to 44mm with an OD range of 62-66mm
- Decreased OD of 36 mm liner to 50mm

The larger ID size subject liners fall within the range of sizes cleared in the DePuy ASR Modular Acetabular Cup System (K040627). The ASR System consists of a one-piece metal acetabular cup which mates with a metal femoral head. There are no separate liners to this system as the liners are integral to the one piece acetabular cups. The ID range of metal cups cleared for this system is 38.6 – 54.6 mm.

The 40 and 44mm subject liners are designed to fit DePuy Pinnacle metal acetabular shells with an OD range of 56-66mm. The 36mm subject liner is to be used with the 50mm Pinnacle metal acetabular shells. They are locked into the shells via a taper junction which is identical to the taper junction used for the cleared 28 and 36mm liners. The 40 and 44 mm liners are intended for use with DePuy 40 and 44 mm M-Spec Co-Cr-Mo femoral heads previously cleared for use with 40 and 44mm polyethylene liners in K060031. The 36 mm liner is intended for use with the 36 mm Co-Cr-Mo heads cleared for use with metal liners in K003523. A list of compatible components is provided in Exhibit III.

Representative photographs of the subject liners are shown in figures 1 and 2.

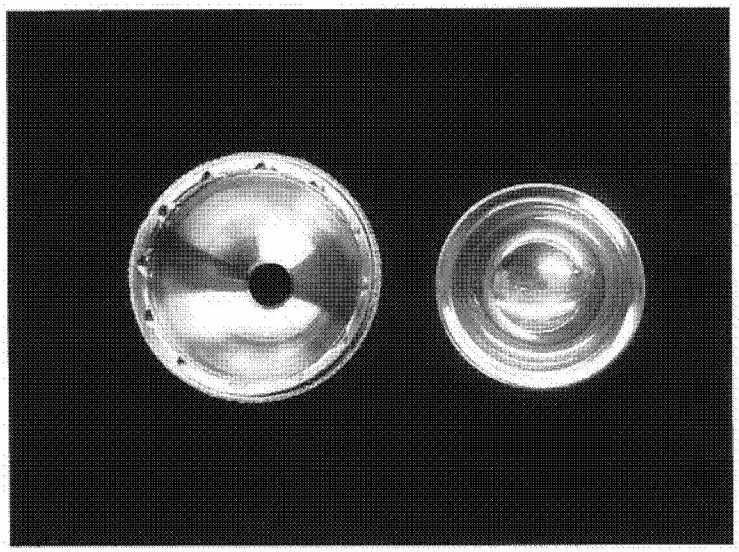


Fig. 1 Pinnacle Acetabular Shell (left) and Metal-On-Metal Liner (right)

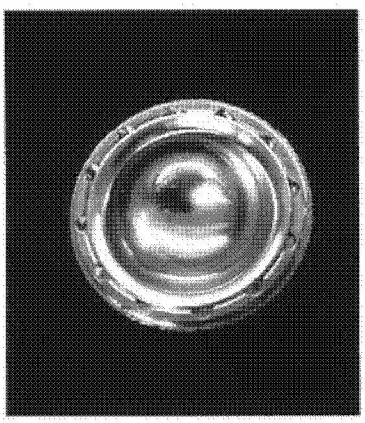


Fig. 2 Pinnacle Acetabular Shell and Metal-On-Metal Liner, Assembled

In metal-on-metal hip implants the clearance between the head and liner interface is critical to ensure that the bearing surfaces receive adequate lubrication for wear reduction. It is known that in modern metal-on-metal hip implants a fluid film lubrication may occur where a thin microscopic layer of lubricant completely separates the head and cup liner bearing surfaces thus protecting the articulating surfaces during relative motion. By protecting these surfaces, the fluid film lubrication plays a role in reducing the wear of metal-on-metal bearings. The diametrical clearances for the subject liners with compatible femoral head are the same as those for similar size components of the ASR system and the 36 mm Pinnacle metal liner (See Table 1). Therefore, it is expected that the fluid film lubricant layer produced with the subject liners will be the same as that for the previously cleared ASR Modular Acetabular Cup System (K040627) and the 36mm Pinnacle metal liner (K003523) indicating the subject liners will have similar wear rates. (b)(4)

(b)(4)

Table 1: DIAMETRICAL CLEARANCES FOR SUBJECT DEVICES AND PREVIOUSLY CLEARED DEVICES

Clearance (microns)	Pinnacle 40mm	Pinnacle 44mm	Pinnacle 36mm (K003523)	ASR 39mm (K040627)	ASR 41mm (K040627)	ASR 43mm (K040627)	ASR 45mm (K040627)
Min	80	80	80	80	80	80	80
Max	120	120	120	120	120	120	120

DIFFERENCES AND SIMILARITIES:

The similarities and differences between the DePuy and the predicate devices are listed in Table 2.

Table 2. Similarities and Differences Between the Subject and Predicate Devices

Characteristics	Subject Device	Predicate Device #1	Predicate Device #2	Predicate Device #3
Device Name	DePuy Pinnacle Metal Acetabular Cup Liner	DePuy Pinnacle 36 mm Metal Acetabular Cup Liner (K003523)	DePuy Pinnacle 28mm Metal Acetabular Cup Liner (K002883)	DePuy ASR Modular Acetabular Cup System (K040627)
Material	Wrought Co-Cr-Mo Alloy	Wrought Co-Cr-Mo Alloy	Wrought Co-Cr-Mo Alloy	Cast Co-Cr-Mo Alloy
Design	Separate liner which locks into metal acetabular shel, Neutral Style only	Separate liner which locks into metal acetabular shell Neutral Style only	Separate liner which locks into metal acetabular shell Neutral Style only	One piece metal acetabular cup, no separate liner
Locking Mechanism	Taper Lock	Taper Lock	Taper Lock	N/A
Intended Use	Total Hip Arthroplasty	Total Hip Arthroplasty	Total Hip Arthroplasty	Total Hip Arthroplasty
Sizes (mm): **Inner Diamaeter (ID)** **Outer Diameter (OD)**	ID = 36,40,44 OD = 50,56,58,60,62,64, 66	ID = 36 OD = 52,54,56,58,60,62,64, 66	ID = 28 OD = 48,50,52,54,56,58,60,62, 64,66,68	ID = 38.6,40.6,42.6,44.6,45.6, 48.6,50.6,52.6,54.6 OD = 44,46,48,50,52,54,56,58, 60,62
Sterilization	Gamma	Gamma	Gamma	Gamma
Packaging	(b)(4)			

Special 510(k)

Section IV

SUMMARY OF DESIGN CONTROL ACTIVITIES:

The Design verification activities conducted for the Pinnacle Metal-On-Metal Acetabular Liners were performed based on the possible failure modes of the device. Table 2 lists the modifications that were made to the device, the associated risks from the changes, verification activities performed to evaluate the risks, acceptance criteria and a summary of the results of the testing.

Table 2. Device Modifications, Risks, & Design Control Activities

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
Increased Inner Diameter of liner to 40 and 44 mm	(b)(4)			

Decreased Outer Diameter of 36mm liner to 50mm	(b)(4)

Special 510(k)

Section V

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The modified Pinnacle Metal-On-Metal Acetabular Cup Liners have the same intended use, indications, manufacturing method, sterilization and packaging as the Pinnacle 36mm and 28mm Acetabular Liners cleared in K003523 and K002883 and the same intended use and indications as the ASR Modular Acetabular Cup System cleared in K040627. The design of the modified Pinnacle Metal-On-Metal Acetabular Cup Liners is similar to the design of the previously cleared Pinnacle Metal-On-Metal liners. The modified liners are offered in a range of sizes (inner and outer diameters) that falls within the range of sizes previously cleared for the ASR Modular Acetabular Cup System. Based on similarities in design, intended use, indications, manufacturing methods, sterilization and packaging DePuy believes that the Pinnacle Metal-On-Metal Acetabular Cup Liners are substantially equivalent to the previously cleared Pinnacle 36 and 28mm metal Acetabular Liners.

Clearance letters for the predicate devices are provided in Exhibit VI.

EXHIBIT I

Part Numbers

DePuy Pinnacle Metal-On-Metal Acetabular Cup liners

Description	Part Number
Pinnacle metal ins neut 36ID x 50OD	1218-87-350
Pinnacle metal ins neut 40ID x 56OD	1218-87-456
Pinnacle metal ins neut 40ID x 58OD	1218-87-458
Pinnacle metal ins neut 40ID x 60OD	1218-87-460
Pinnacle metal ins neut 44ID x 62OD	1218-87-462
Pinnacle metal ins neut 44ID x 64OD	1218-87-464
Pinnacle metal ins neut 44ID x 66OD	1218-87-466

EXHIBIT II

Engineering Drawings

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

EXHIBIT III

PINNACLE METAL LINER COMPATIBLE COMPONENTS

DePuy Femoral Heads

Description	Cleared In:
12/14 taper 40-44mm M Spec Co-Cr-Mo Femoral Heads	K060031
11/13 taper 40-44mm M Spec Head Co-Cr-Mo Femoral Heads	K060031
S-ROM 36mm Femoral Heads	K851422, K003523
Articul/eze Ball 36mm Heads	K980513, K003523

DePuy Acetabular Shells

Description	Cleared In:
Pinnacle 100 Series Shells	K001534, K003523
Pinnacle 300 Series Shells	K001534, K003523
Pinnacle Multi-hole Shells	K000306* K001534*
Pinnacle Sector Shells	K001534, K003523
Pinnacle HA Sector	K031495
Pinnacle HA 100	K031495
Standard Profile Shells	K033338
Deep Profile Shells	K033338

(b)(4)

EXHIBIT IV

Draft Labels and Instructions for Use

DRAFT LABELS

0000034

196

(b)(4)

LABEL – MAIN PRODUCT

(b)(4)

0000035

197

(b)(4)

LABEL – INNER

REF 1218-87-350 LOT 123456789 2006-06 STERILE R

PINNACLE™

metal insert

Neutral	36mmID x 50mmOD

insert en métal Neutre 36mmID x 50mmOD

Metalleinlage Neutral 36mmID x 50mmOD

metalen insertie Neutraal 36mmID x 50mmOD

inserto metallico Neutro 36mmID x 50mmOD

inserto metálico Neutro 36mmID x 50mmOD

insert de metal Neutro 36mmID x 50mmOD

金属製インサート ニュートラル 36mmID x 50mmOD

MATL COBALT CHROME Rx Only CE 0086

DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, IN 46581-0988, USA

LABEL – DISTRIBUTION & PATIENT

REF 1218-87-350 LOT 123456789 2006-06

PINNACLE™ Neutral

metal insert 36mmID x 50mmOD

DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, IN 46581-0988, USA STERILE R

(b)(4)

0000036

(b)(4)

LABEL – MAIN PRODUCT

REF 1218-87-456 LOT 123456789 2006-06 STERILE R

PINNACLE™
metal insert

Neutral	40mmID x 56mmOD	

MATL COBALT CHROME

CE 0086

Use only with DePuy femoral heads designated for use with metal inserts

Insert en métal Neutre 40mmID x 56mmOD
A n'utiliser qu'avec les têtes fémorales DePuy, conçues pour être employées avec des inserts en métal

Metalleinlage Neutral 40mmID x 56mmOD
Nur mit DePuy Femurköpfen, die ausdrücklich für den Einsatz mit Metalleinlagen vorgesehen sind, verwenden

metalen insertie Neutraal 40mmID x 56mmOD
Uitsluitend gebruiken met DePuy femurkoppen bestemd voor gebruik met metalen inzetstukken

Inserto metallico Neutro 40mmID x 56mmOD
Da utilizzarsi esclusivamente con le teste femorali DePuy indicate per l'uso con impianti metallici

Inserto metálico Neutro 40mmID x 56mmOD
Usar sólo con las cabezas femorales DePuy designadas para su uso con insertos metálicos

Insert de metal Neutro 40mmID x 56mmOD
Utilize apenas com cabeças femorais DePuy indicadas para utilização com inserts de metal

金属製インサート ニュートラル 40mmID x 56mmOD
金属製インサートとの使用を目的としたデピュー社製大腿骨ヘッドとのみご使用下さい。

Používejte pouze s s femorálními hlavicemi typu DePuy vyvinutými pro použití s kovovými implantáty
Csak DePuy fémbetétes femur fejekkel használható!
Do użycia tylko z główkami kości udowej DePuy przeznaczonymi do użycia z metalowymi wkładkami
Používajte len s femorálnymi hlavicami DePuy určenými na použitie s kovovými vložkami

DePuy, DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, In 46581-0988, USA

℞ Only

MADE IN UK

(b)(4)

0000037

(b)(4)

LABEL – INNER

REF 1218-87-456 LOT 123456789 2006-06 STERILE R

PINNACLE™

metal insert

Neutral	40mmID x 56mmOD

insert en métal Neutre 40mmID x 56mmOD

Metalleinlage Neutral 40mmID x 56mmOD

metalen insertie Neutraal 40mmID x 56mmOD

inserto metallico Neutro 40mmID x 56mmOD

inserto metálico Neutro 40mmID x 56mmOD

insert de metal Neutro 40mmID x 56mmOD

金属製インサート ニュートラル 40mmID x 56mmOD

MATL COBALT CHROME Rx Only 0086

DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, In 46581-0988, USA

LABEL – DISTRIBUTION & PATIENT

REF 1218-87-456 LOT 123456789 2006-06

PINNACLE™ Neutral

metal insert 40mmID x 56mmOD

DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, In 46581-0988, USA STERILE R

(b)(4)

0000038

200

(b)(4)

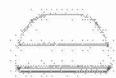
LABEL – MAIN PRODUCT

REF 1218-87-458 LOT 123456789 2006-06 STERILE R

PINNACLE™

metal insert

Neutral	40mmID x 58mmOD	



MATL COBALT CHROME

CE 0086

Use only with DePuy femoral heads designated for use with metal inserts

Insert en métal: Neutre 40mmID x 58mmOD
A n'utiliser qu'avec les têtes fémorales DePuy conçues pour être employées avec des inserts en métal

Metalleinlage, Neutral 40mmID x 58mmOD
Nur mit DePuy Femurköpfen, die ausdrücklich für den Einsatz mit Metalleinlagen vorgesehen sind, verwenden

metalen insertie: Neutraal 40mmID x 58mmOD
Uitsluitend gebruiken met DePuy femurkoppen bestemd voor gebruik met metalen inzetstukken.

Inserto metallico: Neutro 40mmID x 58mmOD
Da utilizzarsi esclusivamente con le teste femorali DePuy indicate per l'uso con impianti metallici

Inserto metálico: Neutro 40mmID x 58mmOD
Usar sólo con las cabezas femorales DePuy designadas para su uso con insertos metálicos

Insert de metal: Neutro 40mmID x 58mmOD
Utilize apenas com cabeças femorais DePuy indicadas para utilização com inserts de metal

金属製[illegible] 40mmID x 58mmOD
金属製[illegible]

Používejte pouze s s femorálními hlavicemi typu DePuy vyvinutými pro použití s kovovými implantáty
Csak DePuy fémbetétes femur fejekkel használható
Do użycia tylko z główkami kości udowej DePuy przeznaczonymi do użycia z metalowymi wkładkami
Používajte len s femorálnymi hlavicami DePuy určenými na použitie s kovovými vložkami

DePuy. DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, IN 46581-0988 USA
MADE IN UK

Rx Only

(b)(4)

(b)(4)

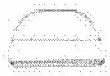
LABEL – INNER

REF 1218-87-458 LOT 123456789 2006-06 STERILE R

PINNACLE™

metal insert

Neutral | 40mmID x 58mmOD



insert en metal Neutre 40mmID x 58mmOD

Metalleinlage Neutral 40mmID x 58mmOD

metalen insertie Neutraal 40mmID x 58mmOD

inserto metallico Neutro 40mmID x 58mmOD

inserto metálico Neutro 40mmID x 58mmOD

insert de métal Neutre 40mmID x 58mmOD

[illegible] 40mmID x 58mmOD

MATL COBALT CHROME

Only

CE 0086

DePuy

DePuy Orthopaedics 700 Orthopaedic Drive Warsaw, IN 46581-0988 USA

LABEL – DISTRIBUTION & PATIENT

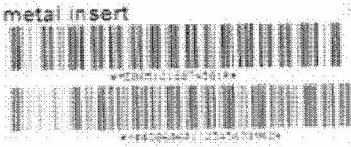
REF 1218-87-458 LOT 123456789 2006-06

PINNACLE™

metal insert

Neutral

40mmID x 58mmOD



DePuy DePuy Orthopaedics 700 Orthopaedic Drive Warsaw, IN 46581-0988 USA STERILE R

(b)(4)

202

(b)(4)

LABEL – MAIN PRODUCT

REF 1218-87-460 LOT 123456789 2006-06 STERILE R

PINNACLE™
metal insert

Neutral	40mmID x 60mmOD	

MATL COBALT CHROME

CE 0086

Use only with DePuy femoral heads designated for use with metal inserts

insert en métal Neutre 40mmID x 60mmOD
A n'utiliser qu'avec les têtes fémorales DePuy, conçues pour être employées avec des inserts en métal

Metalleinlage Neutral 40mmID x 60mmOD
Nur mit DePuy Femurköpfen, die ausdrücklich für den Einsatz mit Metalleinlagen vorgesehen sind, verwenden.

metalen insertie Neutraal 40mmID x 60mmOD
Uitsluitend gebruiken met DePuy femurkoppen bestemd voor gebruik met metalen inzetstukken

inserto metallico Neutro 40mmID x 60mmOD
Da utilizzarsi esclusivamente con le teste femorali DePuy indicate per l'uso con impianti metallici

inserto metálico Neutro 40mmID x 60mmOD
Usar sólo con las cabezas femorales DePuy designadas para su uso con insertos metálicos

insert de metal Neutro 40mmID x 60mmOD
Utilize apenas com cabeças femorais DePuy indicadas para utilização com inserts de metal

金属製インサート ニュートラル 40mmID x 60mmOD
金属製インサットとの使用を目的にデザインされたDePuy大腿骨ヘッドとのみ使用すること

Používejte pouze s femorálními hlavicemi typu DePuy vyvinutými pro použití s kovovými implantáty
Csak DePuy fémbetétes femur fejekkel használható
Do użycia tylko z główkami kości udowej DePuy przeznaczonymi do użycia z metalowymi wkładkami
Používajte len s femorálnymi hlavicami DePuy určenými na použitie s kovovými vložkami

DePuy, DePuy Orthopaedics, 700 Orthopaedic Drive Warsaw, IN 46581-0988, USA

℞ Only

MADE IN UK

(b)(4)

203

(b)(4)

LABEL – INNER

REF 1218-87-460 LOT 123456789 2006-06 STERILE R

PINNACLE™

metal insert

Neutral | 40mmID x 60mmOD

insert en métal Neutre 40mmID x 60mmOD

Metalleinlage Neutral 40mmID x 60mmOD

metalen insertie Neutraal 40mmID x 60mmOD

inserto metallico Neutro 40mmID x 60mmOD

inserto metálico Neutro 40mmID x 60mmOD

insert de metal Neutro 40mmID x 60mmOD

金属製インサート ニュートラル 40mmID x 60mmOD

MATL COBALT CHROME Rx Only 0086

DePuy DePuy Orthopaedics, 700 Orthopaedic Drive Warsaw, IN 46581-0988 USA

LABEL – DISTRIBUTION & PATIENT

REF 1218-87-460 LOT 123456789 2006-06

PINNACLE™ Neutral

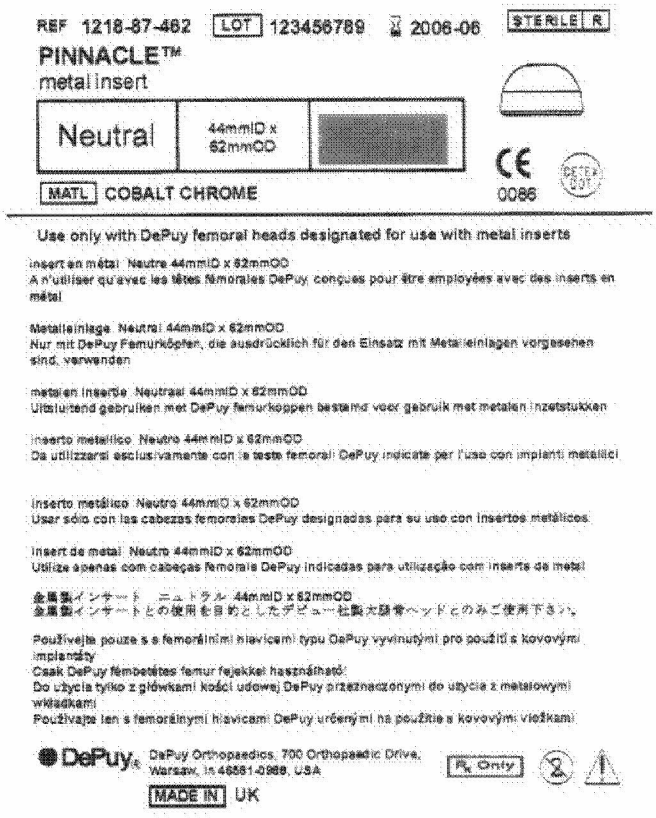
metal insert 40mmID x 60mmOD

DePuy DePuy Orthopaedics, 700 Orthopaedic Drive Warsaw, IN 46581-0988 USA STERILE R

(b)(4)

(b)(4)

LABEL – MAIN PRODUCT



(b)(4)

(b)(4)

LABEL – INNER

REF 1218-87-462 LOT 123456789 2006-06 STERILE R

PINNACLE™

metal insert

Neutral	44mmID x 62mmOD

insert en métal Neutre 44mmID x 62mmOD

Metalleinlage Neutral 44mmID x 62mmOD

metalen insertie Neutraal 44mmID x 62mmOD

inserto metallico Neutro 44mmID x 62mmOD

inserto metálico Neutro 44mmID x 62mmOD

insert de metal Neutro 44mmID x 62mmOD

金属製インサート ニュートラル 44mmID x 62mmOD

MATL COBALT CHROME

℞ Only

0086

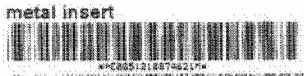
DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, IN 46581-0988, USA

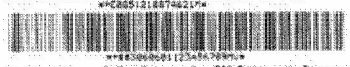
LABEL – DISTRIBUTION & PATIENT

REF 1218-87-462 LOT 123456789 2006-06

PINNACLE™ Neutral

metal insert 44mmID x 62mmOD





DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, IN 46581-0988, USA

STERILE R

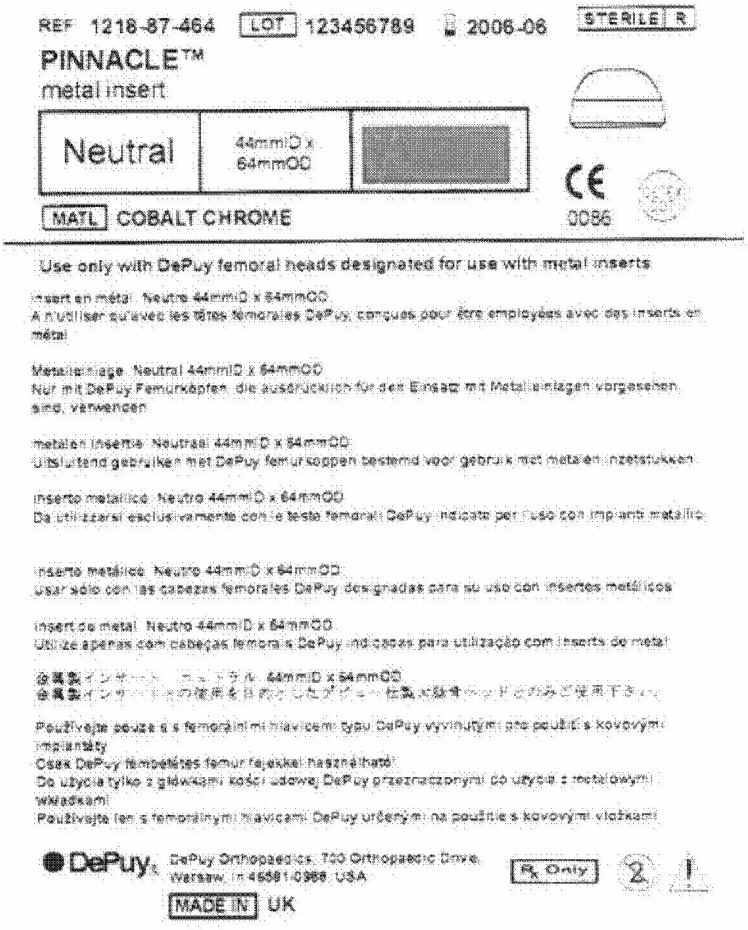
(b)(4)

0000044

206

(b)(4)

LABEL – MAIN PRODUCT



(b)(4)

207

(b)(4)

LABEL – INNER

REF 1218-87-464 LOT 123456789 2006-06 STERILE R

PINNACLE™

metal insert

Neutral	44mmID x 64mmOD

insert en métal Neutre 44mmID x 64mmOD

Metalleinlage Neutral 44mmID x 64mmOD

metalen insertie Neutraal 44mmID x 64mmOD

inserto metallico Neutro 44mmID x 64mmOD

inserto metálico Neutro 44mmID x 64mmOD

insert de métal Neutro 44mmID x 64mmOD

金属製インサート ニュートラル 44mmID x 64mmOD

MATL COBALT CHROME Rx Only 2 1 CE 0086

DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, IN 46581-0988, USA

LABEL – DISTRIBUTION & PATIENT

REF 1218-87-464 LOT 123456789 2006-06

PINNACLE™ Neutral

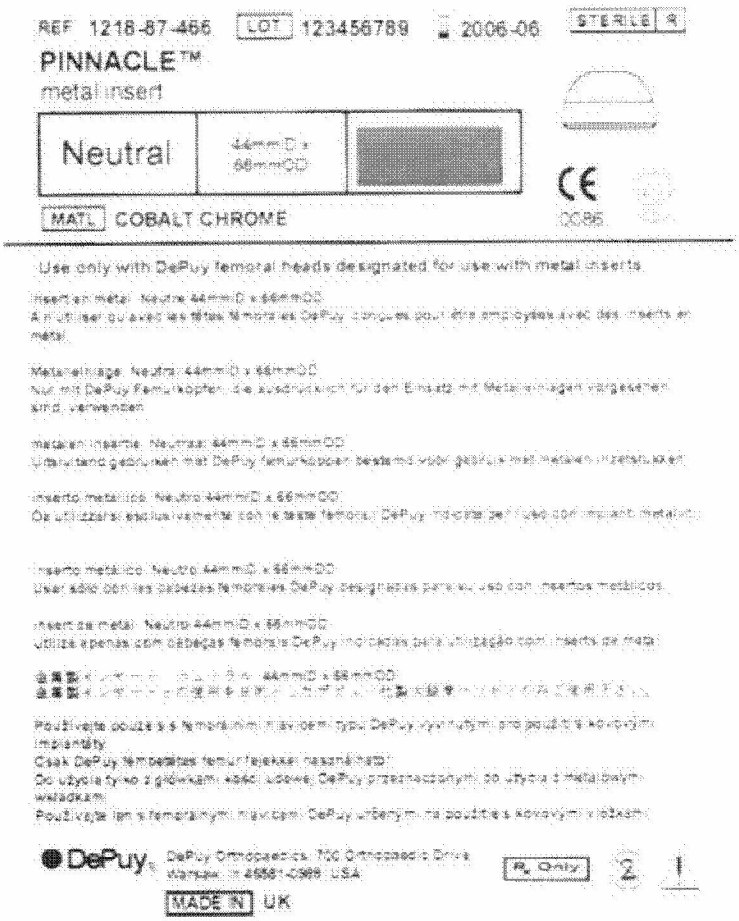
metal insert 44mmID x 64mmOD

DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, IN 46581-0988, USA STERILE R

(b)(4)

(b)(4)

LABEL – MAIN PRODUCT



(b)(4)

(b)(4)

LABEL – INNER

REF 1218-87-466 LOT 123456789 2006-06 STERILE R

PINNACLE™

metal insert

Neutral | 44mmID x 66mmOD

insert en metal Neutre 44mmID x 66mmOD

Metalleinlage Neutral 44mmID x 66mmOD

metalen inserte Neutraal 44mmID x 66mmOD

inserto metálico Neutro 44mmID x 66mmOD

inserto metálico Neutro 44mmID x 66mmOD

insert de metal Neutro 44mmID x 66mmOD

44mmID x 66mmOD

MATL COBALT CHROME Rx Only 2 1 CE 0086

DePuy DePuy Orthopaedics 700 Orthopaedic Drive Warsaw IN 46581-0988 USA

LABEL – DISTRIBUTION & PATIENT

REF 1218-87-466 LOT 123456789 2006-06

PINNACLE™

metal insert

Neutral

44mmID x 66mmOD

DePuy DePuy Orthopaedics 700 Orthopaedic Drive Warsaw IN 46581-0988 USA STERILE R

(b)(4)

DRAFT INSTRUCTIONS FOR USE (IFU)

DePuy Pinnacle Acetabular Metal Inserts

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

Description

The DePuy Pinnacle Acetabular Cup System is comprised of a metal acetabular shell designed to accept alternative bearing inserts. The Pinnacle metal insert mechanically locks with the metal shell via a taper junction.

Do not mix inserts and shells from different systems. Pinnacle Acetabular Cup Inserts can be used only with Pinnacle Acetabular Shells.

Indications

Pinnacle 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.

For metal-on-metal articulation, Pinnacle Acetabular Inserts are intended for use only with DePuy 28mm, 36mm, 40mm and 44mm diameter Co-Cr-Mo femoral heads labelled for metal-on-metal use. 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. Inserts with a 40mm inner diameter should be used with the 40mm femoral heads only. Inserts with a 44mm inner diameter should be used with the 44mm 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.

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 Pinnacle metal insert only with the Pinnacle Acetabular Shell.

The inner diameter of the 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.

Metal-on-metal articulation must utilise DePuy heads especially designed for this purpose

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 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

Pinnacle acetabular metal inserts 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.

EXHIBIT V

(b)(4)

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

(b)(4) Test Data

EXHIBIT VI

Clearance Letters for Predicate Devices

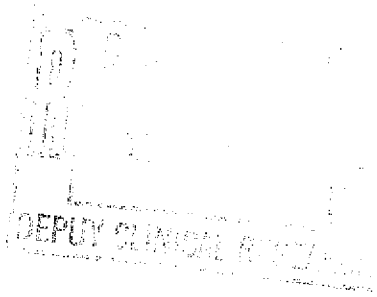
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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.

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.

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

Sincerely yours,

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

Enclosure

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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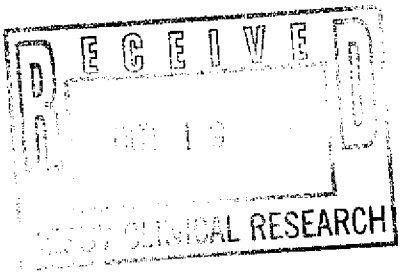


Ms. Cheryl K. Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

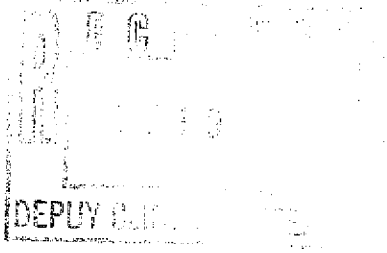
Re: K002883
Trade Name: Pinnacle Metal-On-Metal Acetabular Cup Liners
Regulatory Class: III
Product Codes: JDM and KWA
Dated: September 13, 2000
Received: September 15, 2000

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.



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

Sincerely yours,

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

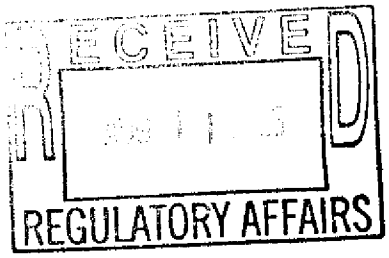
Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 5 - 2005



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

Re: K040627
Trade/Device Name: DePuy ASR™ Modular Acetabular Cup System
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA
Dated: May 23, 2005
Received: May 24, 2005

Dear Ms. Heck:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Gantenberg

Subject: 510(k) Number K062426/S1

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

Is this device subject to Section 522 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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

- ☑ A 510(k) summary OR ☐ A 510(k) statement
- ☑ The required certification and summary for class III devices
- ☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) CP-N

Animal Tissue Source ☐ YES ☒ NO 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: KWA 87- III

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

Review: (Branch Chief) [signature] OTDB (Branch Code) 12/15/06 (Date)

Final Review: (Division Director) [signature] 12/15/06 (Date)

Revised: 4/2/03

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

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Subject: 510(k) Number K062426/S1

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- ☑ Requires additional information (other than refuse to accept).
- ☐ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

- ☑ A 510(k) summary OR ☐ A 510(k) statement
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- ☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) CP-N

Animal Tissue Source ☐ YES ☒ NO 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 day

Predicate Product Code with class: KWA 87-III

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

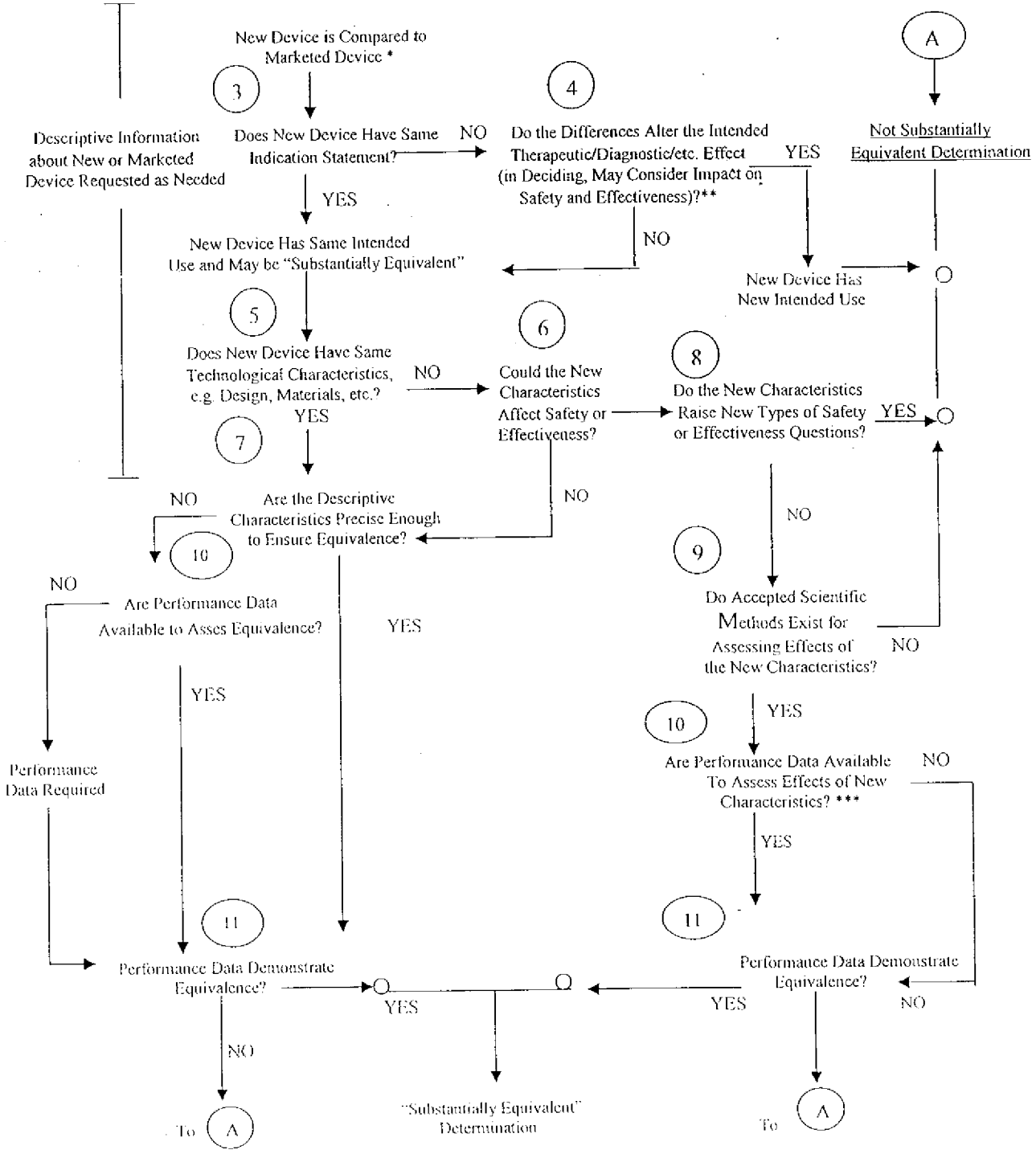
Review: (Branch Chief) _____ OJD3 (Branch Code) 10/26/06 (Date)

Final Review: for (Division Director) _____ 10/26/06 (Date)

Revised:4/2/03

46

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

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

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.

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 over-the-counter 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 th 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?		
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)?		
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.		

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Indications for Use

510(k) Number (if known): K062426
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 Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

EPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

Reviewer(s) - Name(s) Gantenberg

Subject: 510(k) Number K062426

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

Is this device subject to Section 522 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

Truthful and Accurate Statement ☐ Requested ☑ Enclosed

- ☑ A 510(k) summary OR ☐ A 510(k) statement
- ☑ The required certification and summary for class III devices
- ☑ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) CP-N

Animal Tissue Source ☐ YES ☒ NO 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: KWA 87-III

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

Review: [signature] (Branch Chief) OJD13 (Branch Code) 9/26/06 (Date)

Final Review: for [signature] (Division Director) 9/26/06 (Date)

4/2/03

139

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? 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)?		
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.		

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K062426

The cover letter clearly identifies the type of 510(k) submission as (Check the appropriate box):

☒ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☐ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	X	
Table of Contents.	X	
Truthful and Accurate Statement.	X	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	X	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	X	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	X	
Statement of Indications for Use that is on a separate page in the premarket submission.	X	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate.	X	
510(k) Summary or 510(k) Statement.	X	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		X
Identification of legally marketed predicate device. *	X	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	X	
Class III Certification and Summary. **		NA
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		NA
510(k) Kit Certification ***		NA

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	X	
A description of the modified device and a comparison to the sponsor's predicate device.	X	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	X	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.	X	
A Design Control Activities Summary that includes the following elements (a-c):		
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.		X
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		X
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		X
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	X	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
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. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the H drive.]		

For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening X Yes ____ No
Reviewer: Julie Gantenberg
Concurrence by Review Branch: [signature]

Date: 9/26/04

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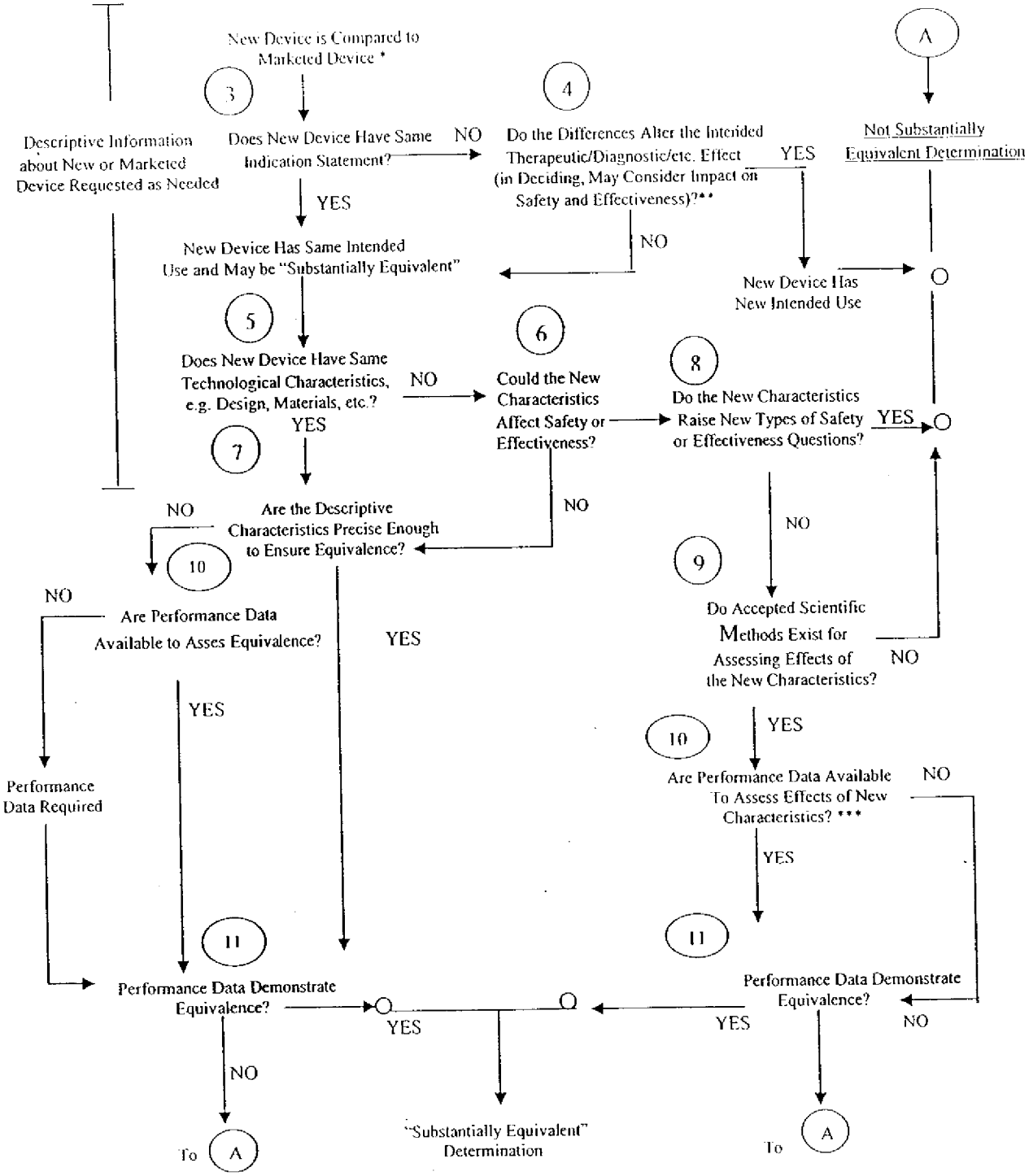
The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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

K_____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

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

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.

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 over-the-counter 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

B(5) Pre-deisional

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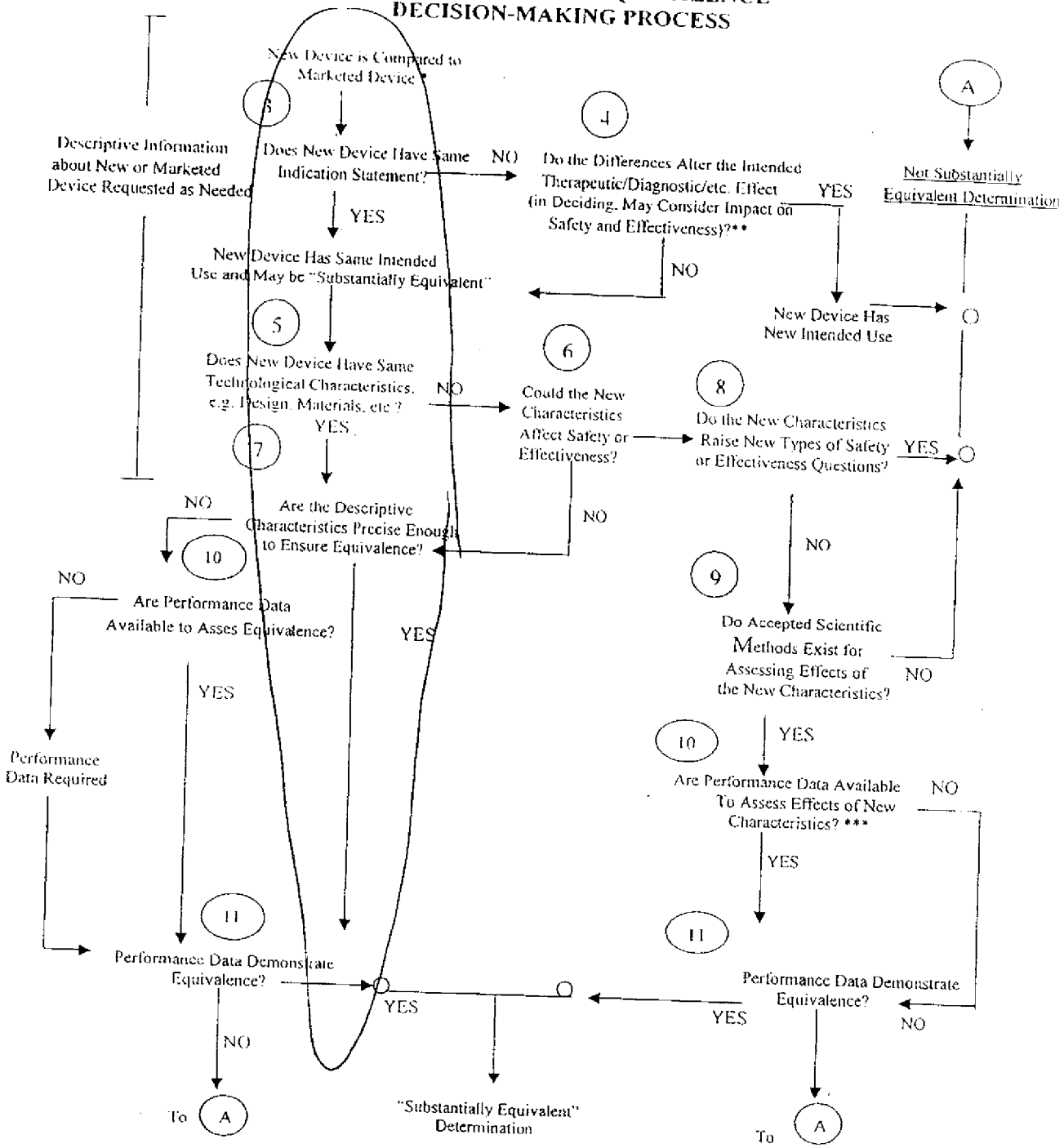
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



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5

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

October 06, 2006

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Product: DEPUY PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. 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 one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

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

510(k): Premarket Notification

October 5, 2006

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

K062426/S1

DePuy
a Johnson & Johnson company

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

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PINNACLE XL INSERT TOLERANCE ANALYSIS

FDA cleared | calculated

cleared

Insert Dimensions				
Size	ID (A) - radius from print (inches)			
	min (MMC)	nominal	tolerance	max (LMC)
36x50	0.7104	0.7106	+/- .0002	0.7108
36x52	0.7104	0.7106	+/- .0002	0.7108
40x56	0.7892	0.7894	+/- .0002	0.7896
40x58	0.7892	0.7894	+/- .0002	0.7896
40x60	0.7892	0.7894	+/- .0002	0.7896
44x62	0.8679	0.8681	+/- .0002	0.8683
44x64	0.8679	0.8681	+/- .0002	0.8683
44x66	0.8679	0.8681	+/- .0002	0.8683

Product Used for Analysis	
Product Description	Product Number
Inserts	
36x50	121887350
36x52	121887352
40x56	121887456
40x58	121887458
44x60	121887460
44x62	121887462
44x64	121887464
44x66	121887466
Heads	
36 mm M-Spec -2 offset	136550000
40 mm M-Spec -2 offset	136504000
44 mm M-Spec -2 offset	136560000

Head Dimensions							
Size	OD (A) - diameter from print (inches)				OD radius (inches)		
	min (LMC)	nominal	tolerance	max (MMC)	min (LMC)	nominal	max (MMC)
36mm	1.4169	1.4173	+/- .0004	1.4177	0.7085	0.7087	0.7089
40mm	1.5744	1.5748	+/- .0004	1.5752	0.7872	0.7874	0.7876
44mm	1.7319	1.7323	+/- .0004	1.7327	0.8660	0.8662	0.8664

*The Head OD radius was calculated by dividing the OD diameter on the print in half. This was necessary for the clearance calculation

DIMENSIONAL ANALYSIS

The smallest clearance was calculated by subtracting the Head Maximum Material Condition (maximum OD radius) from the Insert Maximum Material Condition (minimum ID radius) ==
INSERT MMC - HEAD MMC
The largest clearance was calculated by subtracting the Head Least Material Condition (minimum OD radius) from the Insert Least Material Condition (maximum ID radius) == INSERT LMC - HEAD LMC

			To convert the clearances to mm the radii were multipled by 25.4 1 inch = 25.4 mm		To convert the clearances to um, the radii were multiplied by 1000. 1 mm = 1000um		To convert the clearances to diameter, the radii in um was multiplied by 2 diameter = 2 x radius	
Insert Size	Insert ID-Head OD		(Insert ID - Head OD) x 25.4		(Insert ID-Head OD) x 25.4 x 1000		((Insert ID-Head OD) x 25.4 x 1000) x2)	
	Smallest Radial Clearance (in)	Largest Radial Clearance (in)	Smallest Radial Clearance (mm)	Largest Radial Clearance (mm)	Smallest Radial Clearance (um)	Largest Radial Clearance (um)	Smallest Diamotrical Clearance (um)**	Largest Diametrical Clearance (um)**
36x52	0.00155	0.00235	0.03937	0.05969	39.37	59.69	79	119
36x50	0.00155	0.00235	0.03937	0.05969	39.37	59.69	79	119
40x56	0.00160	0.00240	0.04064	0.06096	40.64	60.96	81	122
40x58	0.00160	0.00240	0.04064	0.06096	40.64	60.96	81	122
40x60	0.00160	0.00240	0.04064	0.06096	40.64	60.96	81	122
44x62	0.00155	0.00235	0.03937	0.05969	39.37	59.69	79	119
44x64	0.00155	0.00235	0.03937	0.05969	39.37	59.69	79	119
44x66	0.00155	0.00235	0.03937	0.05969	39.37	59.69	79	119

FEMORAL HEAD DRAWINGS

B(4) Drawings

B(4) Drawings

B(4) Drawings

EXHIBIT 3
COMPATIBLE COMPONENTS

DePuy Femoral Heads

Description	Cleared In:
12/14 taper 40 and 44mm M Spec Co-Cr-Mo Femoral Heads	K060031
11/13 taper 40 and 44mm M Spec Head Co-Cr-Mo Femoral Heads	K060031
36mm S-ROM M Spec Co-Cr-Mo Heads	K851422, K003523
36mm Articul/eze M Spec Co-Cr-Mo Heads	K980513, K003523

DePuy Acetabular Shells

Description	Cleared In:
Pinnacle 100 Series Shells	K001534, K003523
Pinnacle 300 Series Shells	K001534, K003523
Pinnacle Multi-hole Shells	K000306* K001534*
Pinnacle Sector Shells	K001534, K003523
Pinnacle HA Sector	K031495
Pinnacle HA 100	K031495
Pinnacle Standard Profile Shells	K033338
Pinnacle Deep Profile Shells	K033338

(b)(4)

DePuy Compatible Stems

Description	Material	Taper	Cleared In
AML Hip Stem	CoCrMo	12/14	K012364, K003800, K030979, K040627* K061833
Prodigy Hip Stem	CoCrMo	12/14	K914078, K000207 K001778, K040627*
Replica Hip Stem	CoCrMo	12/14	K934334, K003875 K040627*
Vision Solution Std	CoCrMo	12/14	K953703, K953694 K033338, K040627*
Summit Porous Hip Stem	Ti	12/14	K000306, K001991 K011489, K030122, K040627*
Trilock Std Hip Stem	CoCrMo	12/14	K001982, K010367 K869331, K974740 K040627*
Endurance Total Hip Stem	CoCrMo	12/14	K942370 K040627*
Luster Total Hip Stem	CoCrMo	12/14	K983136 K040627*
Summit Cemented Hip Stem	CoCrMo	12/14	K013352, K023453 K040627*
Uni-Rom Hip Stem	Ti	11/13	K974331 K040627*
SROM Hip Stem	Ti	11/13	K851422, K954935, K961939, K040627* K061221
Corail AMT	Ti	12/14	K042992*

* This 510k cleared the stem family for use with metal heads and liners

(b)(4) Test Data

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DePuy Pinnacle Acetabular Metal Inserts

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

Description

The DePuy Pinnacle Acetabular Cup System is comprised of a metal acetabular shell designed to accept alternative bearing inserts. The Pinnacle metal insert mechanically locks with the metal shell via a taper junction.

Do not mix inserts and shells from different systems. Pinnacle Acetabular Cup Inserts can be used only with Pinnacle Acetabular Shells.

Indications

Pinnacle 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 Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

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.

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

For metal-on-metal articulation, Pinnacle Acetabular Inserts are intended for use only with DePuy 28mm, 36mm, 40mm and 44mm diameter M-Spec Co-Cr-Mo femoral heads labelled for metal-on-metal use. 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. Inserts with a 40mm inner diameter should be used with the 40mm femoral heads only. Inserts with a 44mm inner diameter should be used with the 44mm femoral heads only.

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 Pinnacle metal insert only with the Pinnacle Acetabular Shell.
The inner diameter of the 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.
Metal-on-metal articulation must utilise DePuy heads especially designed for this purpose

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 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

Pinnacle acetabular metal inserts 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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

December 04, 2006

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Product: DEPUY PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS

The additional information you have submitted has been received.

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Sincerely yours,

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

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