



USER: CURTSINGER, MARGARET A (mac)

FOLDER: K002883 - 65 pages (FOI:10008002)

COMPANY: DEPUY ORTHOPAEDICS, INC.
(DEPUORTHA)

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

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

DATE REQUESTED: Fri Dec 17 24:00:00 2010

DATE PRINTED: Thu Feb 03 14:53:57 2011

Note: Releasable Version

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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: Cheryl Hastings
Director, Regulatory Affairs

TRADE NAME: DePuy Pinnacle Metal-On-Metal Acetabular Cup
Liners

COMMON NAME: Acetabular Cup Prosthesis

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

DEVICE PRODUCT CODE: 87 JDM

**SUBSTANTIALLY EQUIVALENT
DEVICES:** DePuy Ultima Metal-On-Metal Acetabular Cup

DEVICE DESCRIPTION AND INTENDED USE:

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 28mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

It is indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 28mm diameter Co-Cr-Mo femoral heads only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are nearly identical to the Ultima Metal-On-Metal Acetabular Cup Liners that were cleared previously. The intended use, articular surface, material and locking mechanism with the outer shell are the same. The only changes are minor design changes that allow the liners to be used with the Pinnacle Acetabular Shells that have been cleared previously.

0000004



OCT 13 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

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

Dear Ms. Hastings:

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

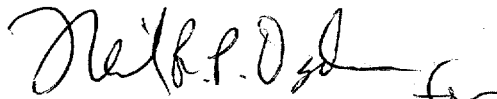
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

Page 2 - Ms. Cheryl K. Hastings

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

Sincerely yours,



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

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known) K002883

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 28mm diameter Co-Cr-Mo femoral heads only.

MLO [signature]
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002883

Concurrence of CDRH, Office of Device Evaluation

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use

0000005

K002883-A1



DePuy Orthopaedics, Inc.

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

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

October 6, 2000

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

Attn: Ted Stevens

Reference: Additional Information for K002883, Ultima MOM Special 510(k)

Dear Ted:

As requested, enclosed are 2 copies of a revised Truthful and Accuracy Statement for this 510(k). Thank you for your review of this information.

Sincerely,

Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.

RECEIVED
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FOIA/09/19/00/240

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JK36



DePuy Orthopaedics, Inc.

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

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

October 6, 2000

**TRUTHFUL AND ACCURATE STATEMENT
PREMARKET NOTIFICATION**

Pursuant to 21 CFR 807.87(j), I certify that in my capacity as Director of Regulatory Affairs of DePuy Orthopaedics, Inc., 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.

A handwritten signature in cursive script that reads "Cheryl Hastings".

Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.

DePuy Orthopaedics, Inc.

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

Tel: +1 (219) 267 8143
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Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.



AFFIDAVIT

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

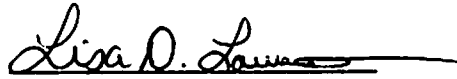
I am the Records Management Officer, for the Center for Devices and Radiological Health, Food and Drug Administration.

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

A comprehensive search of CDRH file systems has been conducted. The following pages for file K002883 cannot be located and therefore cannot be produced for this request.

• Correspondence

Pages 1 and 2


CDR Lisa D. Lawrence


County of Montgomery
State of Maryland

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


Notary Public

My Commission Expires 9/20/2018.

AFFIDAVIT

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

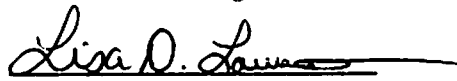
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Notary Public

My Commission Expires 9/20/2018.

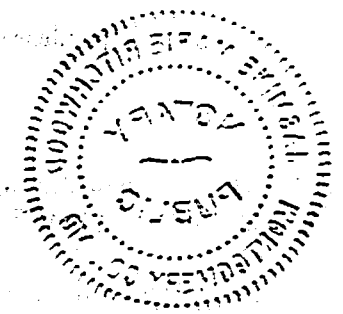
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OCT 13 2000

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9200 Corporate Boulevard
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DePuy Orthopaedics, Inc.
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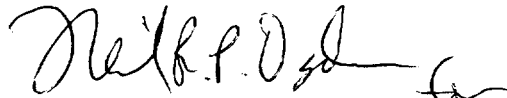
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Sincerely yours,

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

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

Director

Division of General, Restorative and

Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known) K002883

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

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Nko firman
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002883

Concurrence of CDRH, Office of Device Evaluation

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

0000005

3

Memorandum

From: Reviewer(s) - Name(s) Theodore R Stevens *HW*

Subject: 510(k) Number K 002883

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

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

De Novo Classification Candidate?

YES NO

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

YES NO

Is this device subject to Postmarket Surveillance?

YES NO

Is this device subject to the Tracking Regulation?

YES NO

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

YES NO

Is this a prescription device?

YES NO

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

YES NO

Special 510(k)?

YES NO

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

This 510(k) contains:

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

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

The required certification and summary for class III devices

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

Material of Biological Origin YES NO

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

- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

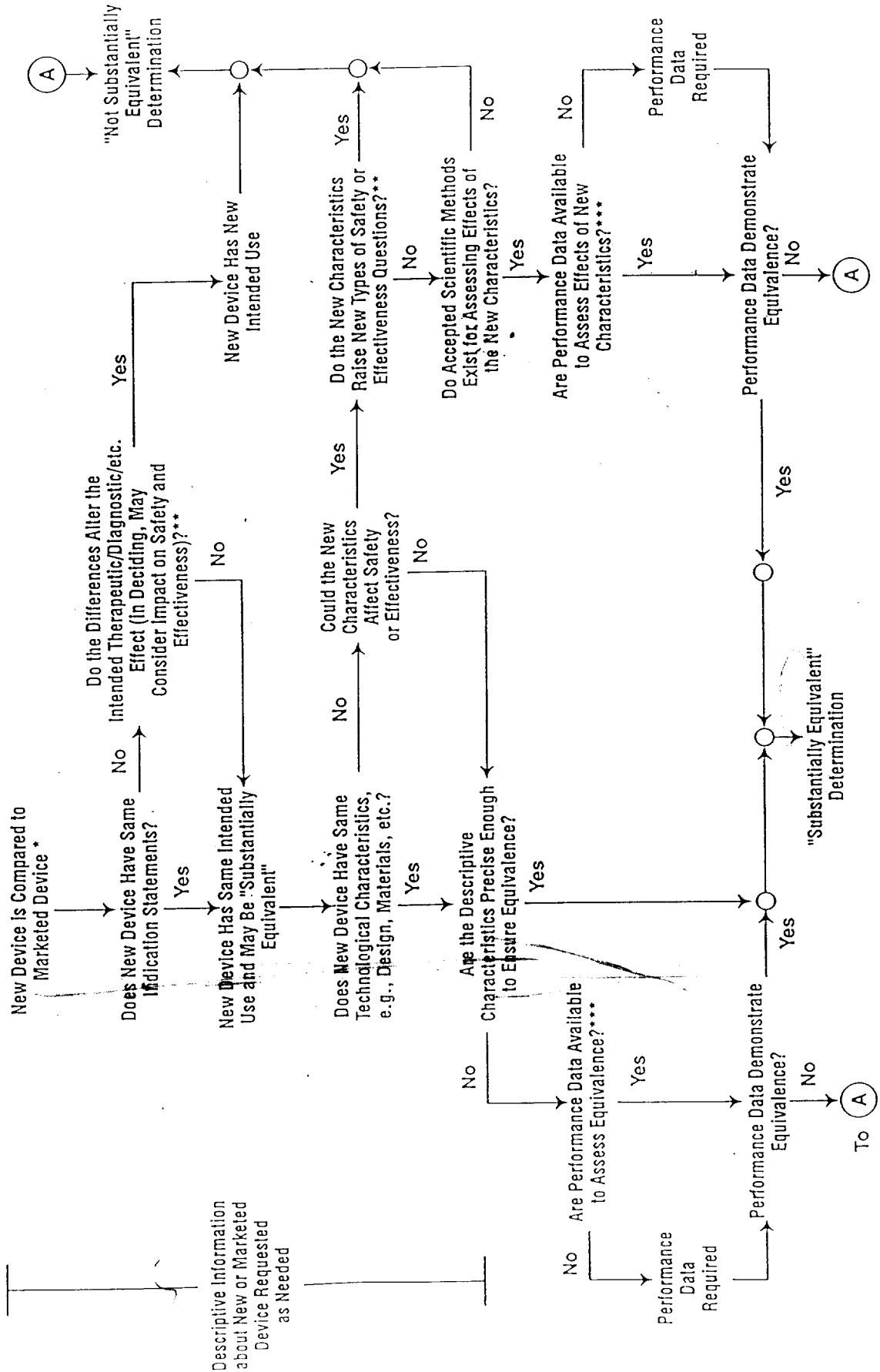
Review: [Signature] (Date) 10/12/00

Final Review: [Signature] (Date) 10/13/00

(Division Director)

Revised: 8/17/99

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



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

** This Decision is Normally Based on Descriptive Information Alone, But Limiting Information Is Sometimes Required.

*** Data in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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

To: THE FILE

RE: DOCUMENT NUMBER #K002883

HW

Manufacturer: DePuy

Device Name: DePuy Pinnacle Metal-on-Metal Atabular Cup Liners

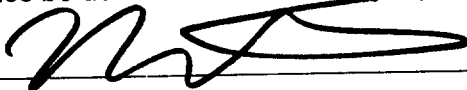
Original 510(k): K001532

Change being instituted: Backside, non-locking section of liner modified to match dome on Pinnacle shells, proportional sizing of shells.

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

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

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



10/10/00
(Reviewer's Signature)

(Date)

revised:3/27/98

Screening Checklist

For all Premarket Notification 510(k) Submissions

Device Name: <u>Parade Hip Implants</u>					K 202583		
Submitter (Company): <u>DePuy</u>							
Items which should be included <i>(circle missing & needed information)</i>	SPECIAL		A B B R E V I A T E D		T R A D I T I O N A L		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"							
b) "Abbreviated 510(k)"							
c) Traditional 510(k)							
	GO TO # 2,3		GO TO # 2,4,5		GO TO #2, 5		
2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS							
✓ IF ITEM IS NEEDED							
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)							
		NA		YES		NO	
		SPECIALS		ABBREVIATED		TRADITIONAL	
		YES	NO	YES	NO	YES	
		YES	NO	YES	NO	AND IS MISSING	
a) trade name, classification name, establishment registration number, device class							
b) OR a statement that the device is not yet classified							
c) identification of legally marketed equivalent device							
d) compliance with Section 514 - performance standards							
e) address of manufacturer							
f) Truthful and Accurate Statement							
g) Indications for Use enclosure							
h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES)							
i) Class III Certification & Summary (FOR ALL CLASS III DEVICES)							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
k) Proposed Labeling:							
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) Labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing							
vi) safety characteristics							
m) If kit, kit certification							
3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE							
a) Name & 510(k) number of legally marketed (unmodified) predicate device							
b) STATEMENT - INTENDED USE AND INDICATIONS FOR							
* If no - STOP not a special							

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

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

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

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

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

Passed Screening Yes No
 Date: 10/12/00

Reviewer: [Signature]
 Concurrence by Review Branch: [Signature]

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 #191-2 and Federal Register 90N0332, September 10, 1991.		

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 15, 2000

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O. BOX 988
WARSAW, IN 46581
ATTN: CHERYL K. HASTINGS

510(k) Number: K002883
Received: 15-SEP-2000
Product: PINNACLE
METAL-ON-METAL
ACETABULAR CUP
LINERS

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

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

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

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

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff

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K 002883



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

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

**(modification of the Ultima Metal-On-Metal
Acetabular Cup Liners, K001523)**

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Special 510(k): Device Modification

September 13, 2000

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

DePuy Orthopaedics, Inc.

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

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

Reference: DePuy Ultima Metal-On-Metal Acetabular Cup; K001523; Cleared August 10, 2000

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate on the DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners, as a **Special 510(k): Device Modification**. The Pinnacle Metal-On-Metal Acetabular Cup Liners are a minor design modification of the Ultima Metal-On-Metal Acetabular Cup Liners that were cleared in K001523.

The indications of use for the device have not changed from those cleared in K001523.

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

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

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at (219) 371-4901.

Sincerely,

Cheryl K. Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.

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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: Cheryl Hastings
Director, Regulatory Affairs

TRADE NAME: DePuy Pinnacle Metal-On-Metal Acetabular Cup
Liners

COMMON NAME: Acetabular Cup Prosthesis

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

DEVICE PRODUCT CODE: 87 JDM

**SUBSTANTIALLY EQUIVALENT
DEVICES:** DePuy Ultima Metal-On-Metal Acetabular Cup

DEVICE DESCRIPTION AND INTENDED USE:

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 28mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

It is indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 28mm diameter Co-Cr-Mo femoral heads only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are nearly identical to the Ultima Metal-On-Metal Acetabular Cup Liners that were cleared previously. The intended use, articular surface, material and locking mechanism with the outer shell are the same. The only changes are minor design changes that allow the liners to be used with the Pinnacle Acetabular Shells that have been cleared previously.

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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: Cheryl Hastings
Director, Regulatory Affairs

TRADE NAME: DePuy Pinnacle Metal-On-Metal Acetabular Cup
Liners

COMMON NAME: Acetabular Cup Prosthesis

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

DEVICE PRODUCT CODE: 87 JDM

**SUBSTANTIALLY EQUIVALENT
DEVICES:** DePuy Ultima Metal-On-Metal Acetabular Cup

DEVICE DESCRIPTION AND INTENDED USE:

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 28mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

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The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and 28mm diameter Co-Cr-Mo femoral heads only.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are nearly identical to the Ultima Metal-On-Metal Acetabular Cup Liners that were cleared previously. The intended use, articular surface, material and locking mechanism with the outer shell are the same. The only changes are minor design changes that allow the liners to be used with the Pinnacle Acetabular Shells that have been cleared previously.

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510(k) Number (if known) K002883

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 28mm diameter Co-Cr-Mo femoral heads only.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

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DePuy Orthopaedics, Inc.

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

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

September 13, 2000

TRUTHFUL AND ACCURATE STATEMENT

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

Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.

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DePuy Orthopaedics, Inc.

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Warsaw, Indiana 46581-0988
USA

Tel: +1 (219) 267 8143

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September 13, 2000

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

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

Cheryl K Hastings
Cheryl K. Hastings

Sept. 13, 2000
Date

(Premarket Notification [510(k)] Number)

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

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SUMMARY OF THE TYPES AND CAUSES OF SAFETY OR EFFECTIVENESS PROBLEMS

METAL-ON-METAL TOTAL HIP SYSTEMS

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

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

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

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

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

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

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SPECIAL 510(k): DEVICE MODIFICATION

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations and the Safe Medical Devices Act of 1990; DePuy Orthopaedics Inc., P.O. Box 988, Warsaw IN, 46581-0988, hereby submits the following information as a special 510(k) for a design modification of the DePuy Ultima Metal-On-Metal Acetabular Cup Liners, originally cleared in K001523. The modified acetabular cup liners will be labeled as DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners and are intended for use with the DePuy Pinnacle Acetabular Shells.

I. ADMINISTRATIVE INFORMATION

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

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

B. MANUFACTURING LOCATION

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

C. CONTRACT STERILIZER

(b) (4)



D. CONTACT PERSON

Cheryl Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
(219) 371-4901
FAX (219) 371-4940

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II. DEVICE IDENTIFICATION

- A. **PROPRIETARY NAME**
Pinnacle Metal-On-Metal Acetabular Cup Liners
- B. **COMMON NAME**
Total Hip Replacement System
- C. **CLASSIFICATION NAME AND REFERENCE**
888.3330: Hip joint, metal/metal semi-constrained, with an uncemented acetabular component, prosthesis. Class III
- D. **DEVICE PRODUCT CODE**
87 JDM

III. PREDICATE DEVICE INFORMATION

The predicate devices are the Ultima Metal-On-Metal Acetabular Cup Liners, cleared in K001523 on August 10, 2000.

IV. LABELING AND INTENDED USE

Representative draft labels and draft Instructions for Use are provided in Exhibit 3. The following changes have been made to the labels, compared to those provided and cleared in K001523. The tradename and part numbers have been changed to differentiate the Pinnacle MOM Acetabular Cup Liners from the Ultima MOM Acetabular Cup Liners.

The same package insert will be used with both the Ultima and the Pinnacle MOM Acetabular Shell components. The only changes made to the Instructions for Use are editorial changes to allow the use of the same package insert for both systems and the addition of the following statement: **“Do not mix Metal-on-Metal liners and shells from different systems. Ultima MOM Acetabular Cup Liners can be used only with Ultima MOM Acetabular Shells. Pinnacle MOM Acetabular Cup Liners can be used only with Pinnacle Acetabular Shells.”** No changes have been made to the Indications, Contraindications, Warnings, Precautions, or Adverse Effects.

Intended Use

The Pinnacle Metal-On-Metal Acetabular Cups are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital

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

The Pinnacle Metal-On-Metal Acetabular Cups are intended for use with DePuy 28mm diameter Co-Cr-Mo femoral heads only.

This is the **same intended use** that was previously cleared for the Ultima® MOM Acetabular Cup Liners in K001523.

V. DEVICE DESCRIPTION AND COMPARISON

The Pinnacle MOM Acetabular Cup Liner is a metal liner that is intended for use with the Pinnacle Acetabular Shells that have been cleared previously. The liner has a 28mm inner diameter and is offered in a neutral style only. The Pinnacle MOM liner is mechanically locked with the shell via a taper junction, and articulates with commercially available prosthetic femoral heads.

The following list compares the Pinnacle MOM Acetabular Cup Liner with the Ultima MOM Acetabular Cup Liners that were cleared in K001523:

- Same indications;
- Same articular surface requirements (same inner diameter, 40-80 μ clearance on diameter, roundness 5 μ or less);
- Same material specification;
- Same femoral head articulation;
- Same locking mechanism with acetabular shell (taper lock with same taper angle);
- Same sterilization method and SAL;
- Same packaging;
- Similar labels and package insert;

Modifications:

- The Pinnacle MOM Liners will be offered in a neutral style only. The Ultima MOM Liners are offered in both neutral and 10 degree augmented styles.
- The backside of the Pinnacle MOM Liners has been modified to match the Pinnacle Acetabular Shells. The dome of the Pinnacle liners is a radius rather than a stepped series of flats as used on the Ultima liners. In both cases (Pinnacle and Ultima) the liner locks into the shell using the taper at the rim of the liner and shell. The dome of the liner does not actually touch the shell but maintains a specific clearance with the shell (see graphic in Exhibit 1). The

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geometry of the liner dome, therefore, does not impact locking of the shell and liner.

- Each Pinnacle Acetabular Shell outer diameter size mates with a unique Pinnacle MOM Acetabular Liner size. In the Ultima System one liner size mates with multiple shell sizes. To accommodate this sizing change, the outer diameter of the Pinnacle MOM liner increases between sizes to mate with the corresponding Pinnacle shell inner diameter.
- Change in part numbers and tradename.

Part numbers, descriptions, and engineering prints of the Pinnacle MOM liners, a graphic of a Pinnacle liner assembled with a Pinnacle Acetabular Shell, and an overlay demonstrating the similarities between the Pinnacle and Ultima MOM liners are provided in Exhibit 1. A reference engineering print of the Ultima MOM liner is also provided in Exhibit 1 for comparison.

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

VI. SUBSTANTIAL EQUIVALENCE

Due to the similarities in intended use, material and design listed above, DePuy believes that the Pinnacle MOM Acetabular Cup Liners are substantially equivalent to the Ultima MOM Acetabular Cup Liners that were previously cleared in K001523.

VII. SUMMARY OF DESIGN CONTROL ACTIVITIES

A Design Failure Mode and Effects Analysis (DFMEA) was performed. Copies of the Design Control plan and DFMEA are provided in Exhibit 4.

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The design verification tests that were performed as a result of the Design Control Plan and DFMEA are listed below.

Verification Tests

(b) (4)



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

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EXHIBIT 1

Pinnacle Metal-On-Metal Acetabular Cup Liners

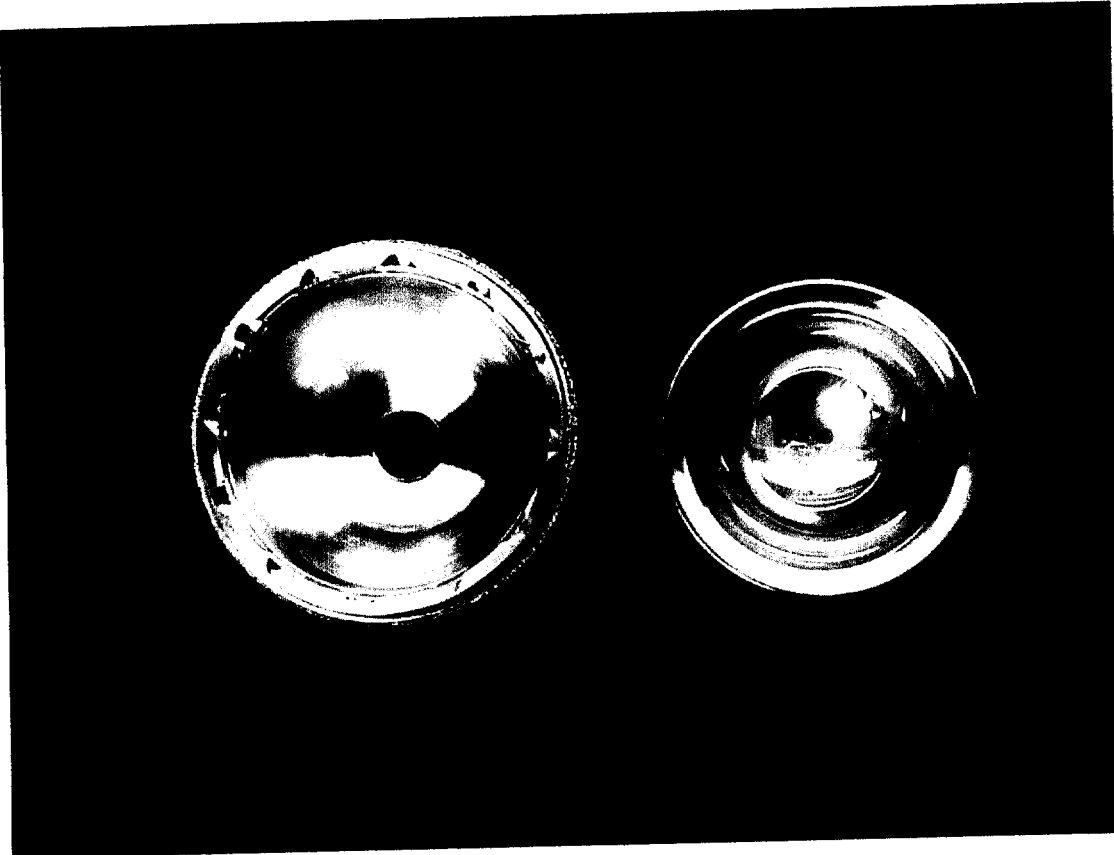
Pinnacle Shell Outer Diameter	Pinnacle MOM 28mm Neutral Liner
48mm	1218-89-148
50mm	1218-89-150
52mm	1218-89-152
54mm	1218-89-154
56mm	1218-89-156
58mm	1218-89-158
60mm	1218-89-160
62mm	1218-89-162
64mm	1218-89-164
66mm	1218-89-166

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EXHIBIT 1

PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS



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

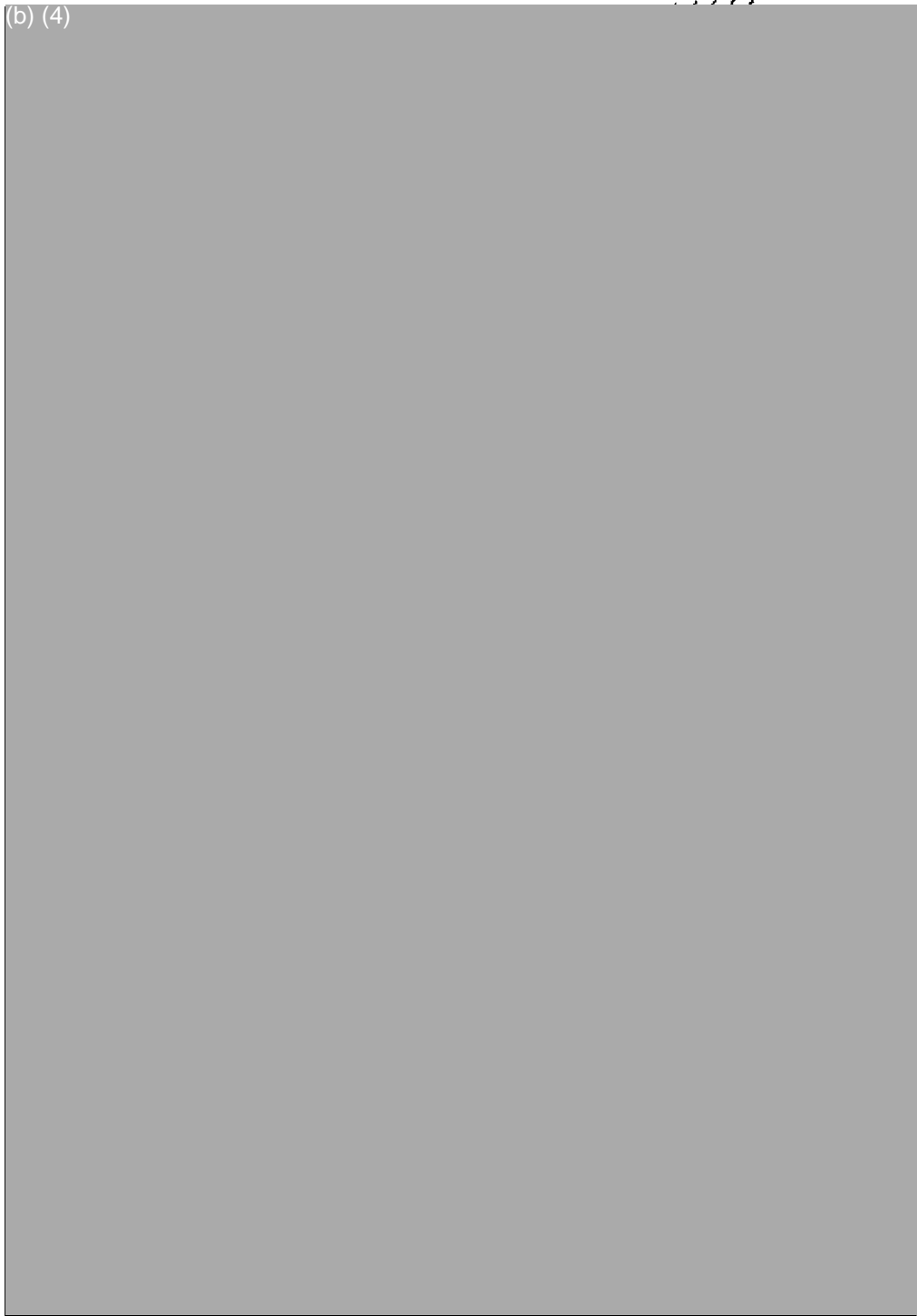


Pinnacle Acetabular Shell and Metal-On-Metal Liner, Assembled

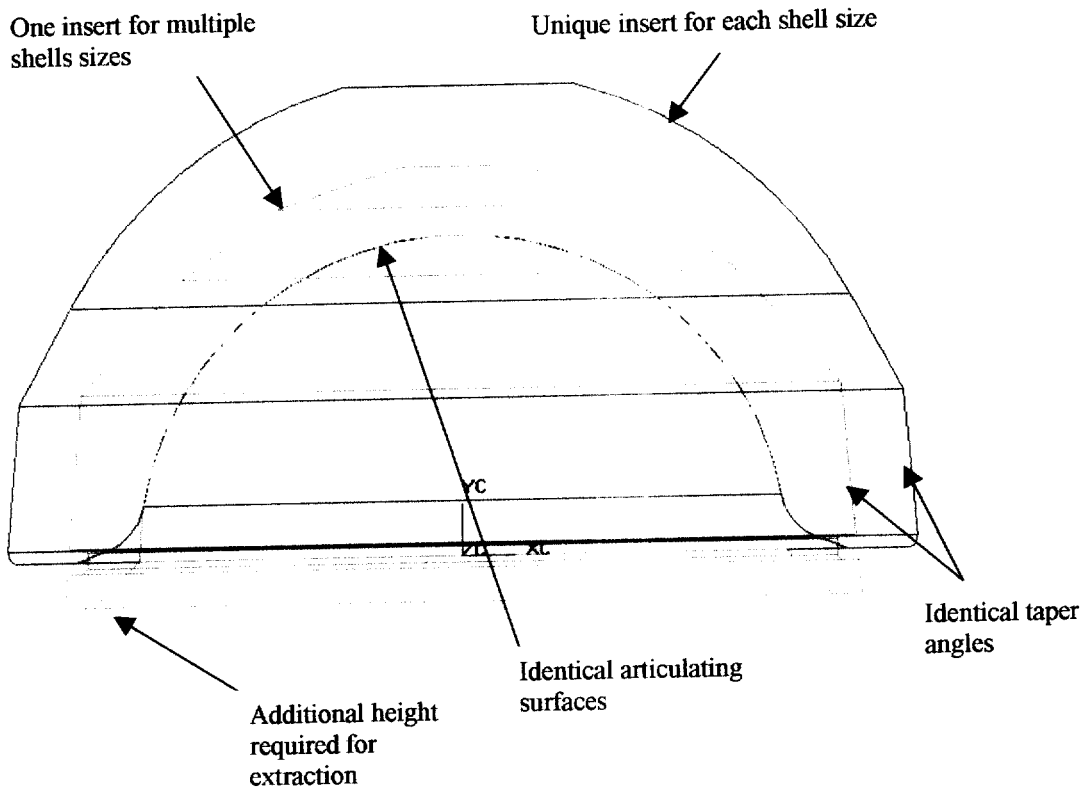
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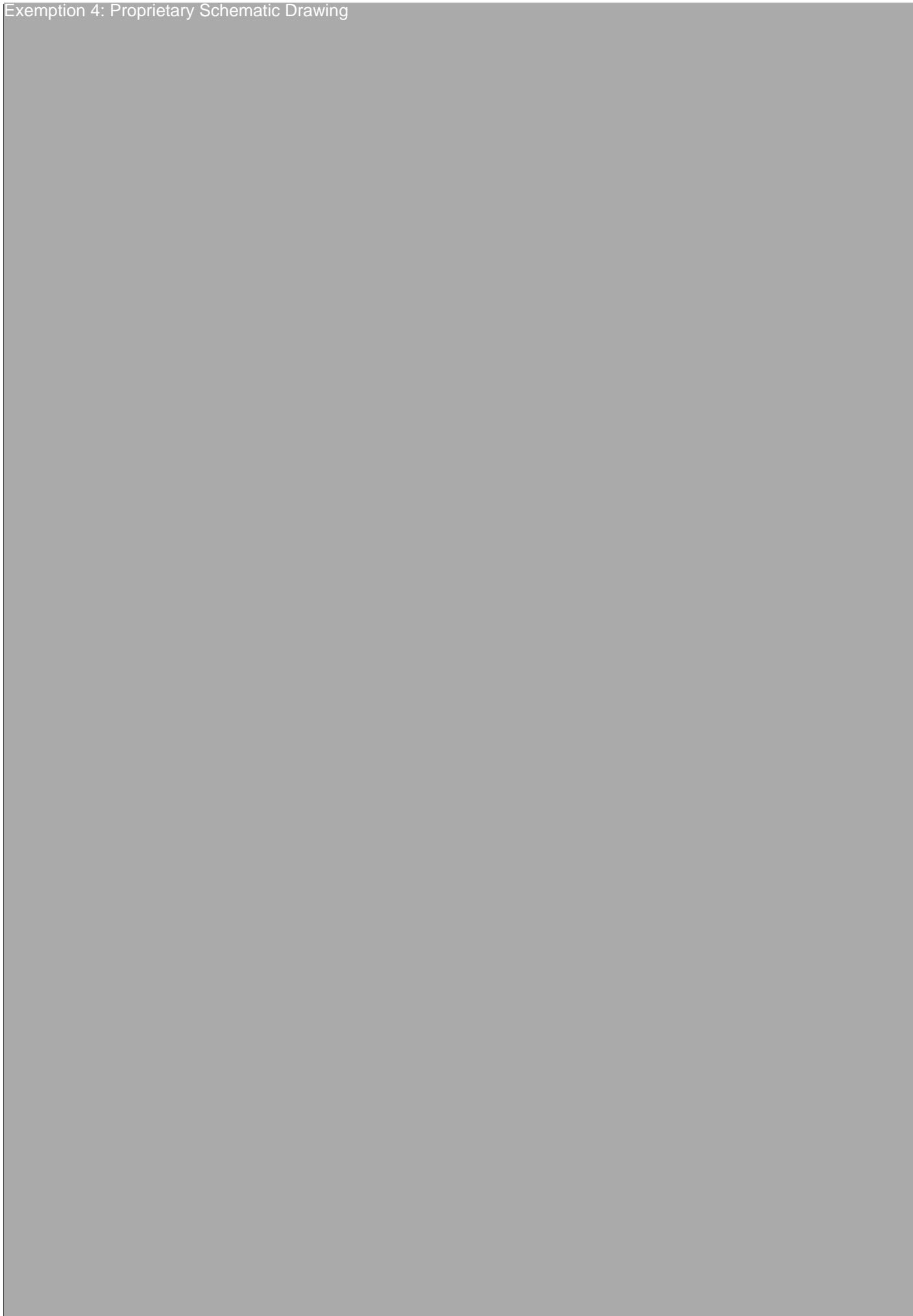
(b) (4)

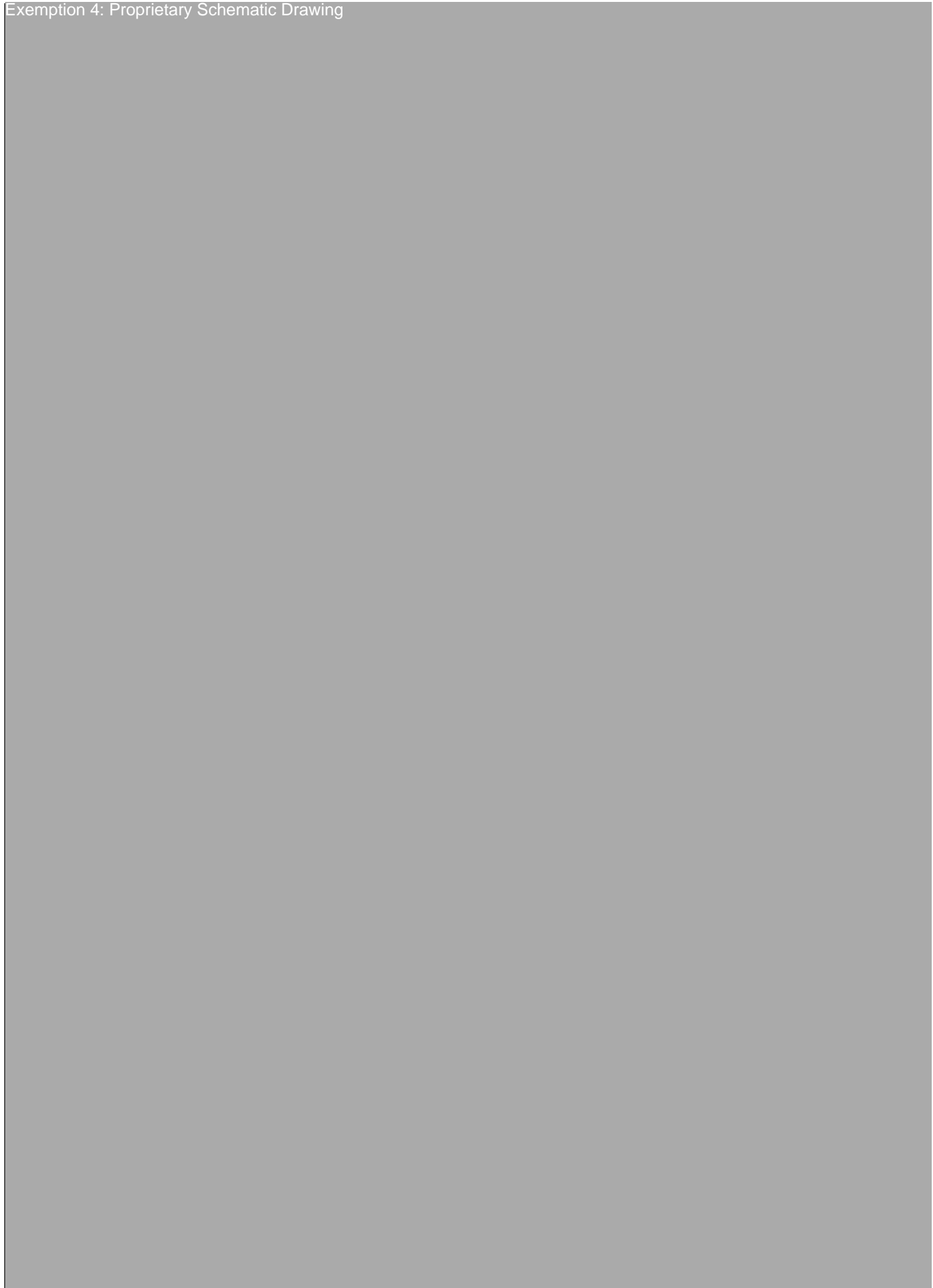


Pinnacle Liner assembled with Pinnacle Shell (b) (4)



ULTIMA/Pinnacle Metal Insert Geometry Similarities/Differences
(Pinnacle in blue, ULTIMA in green)

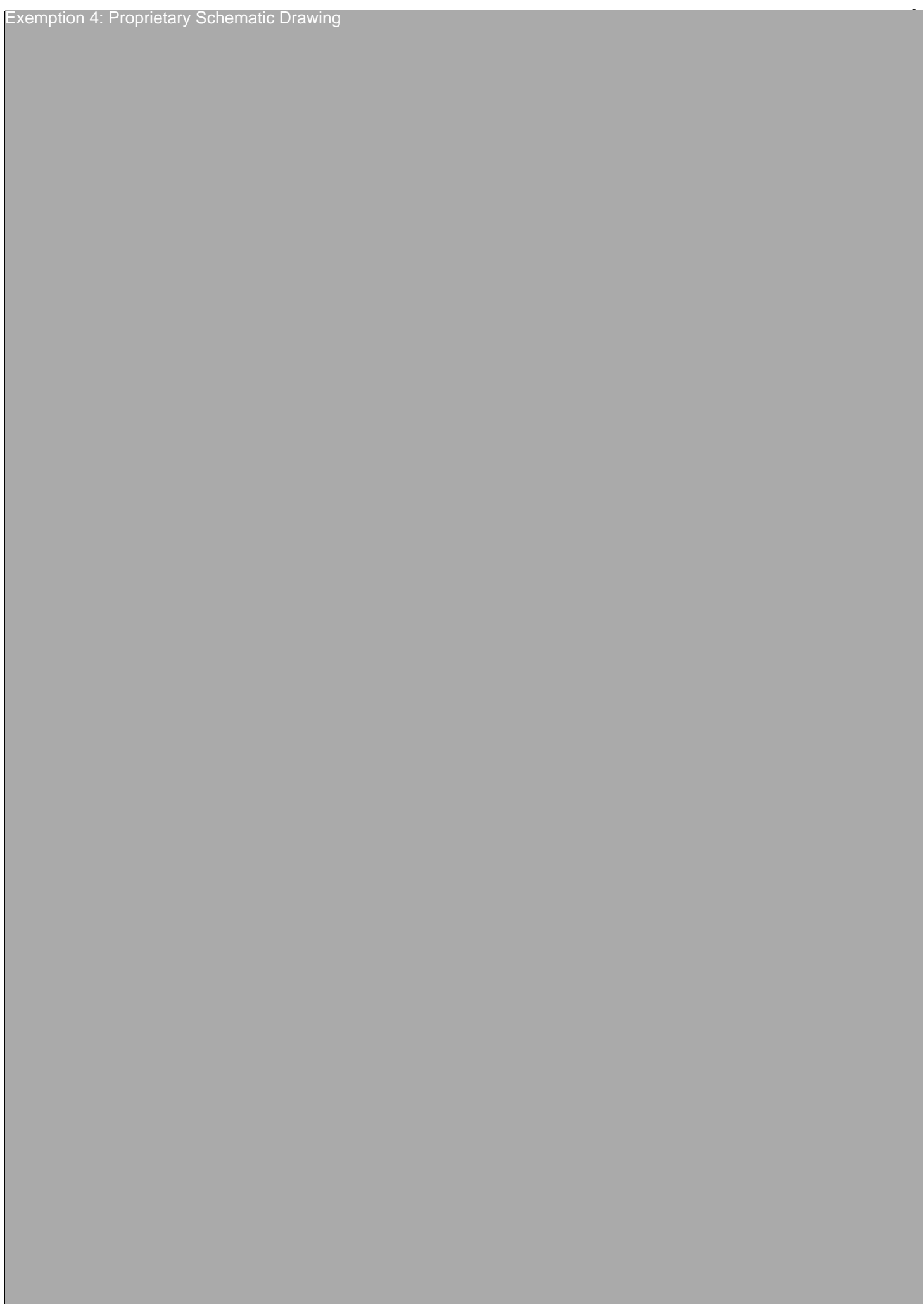




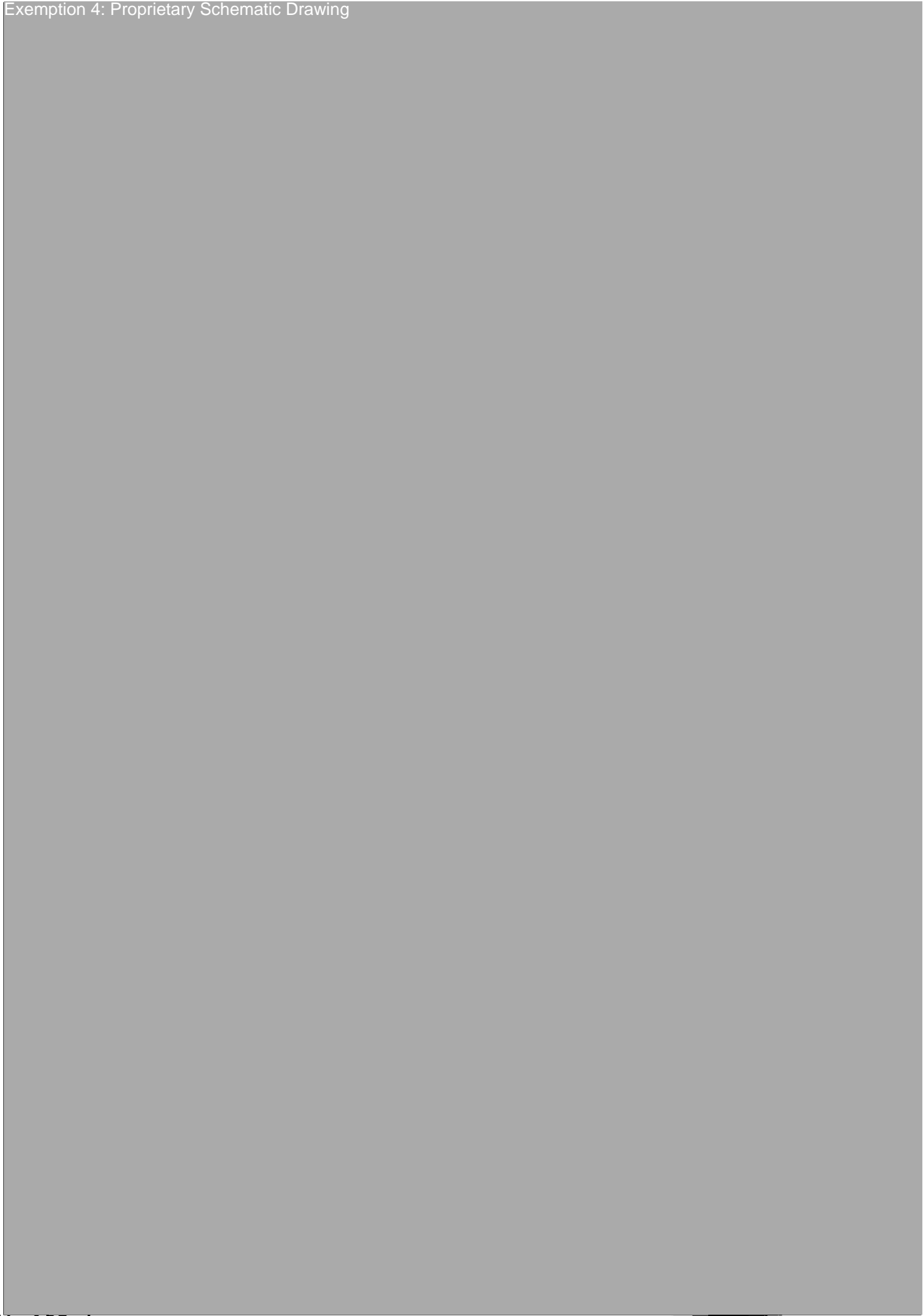






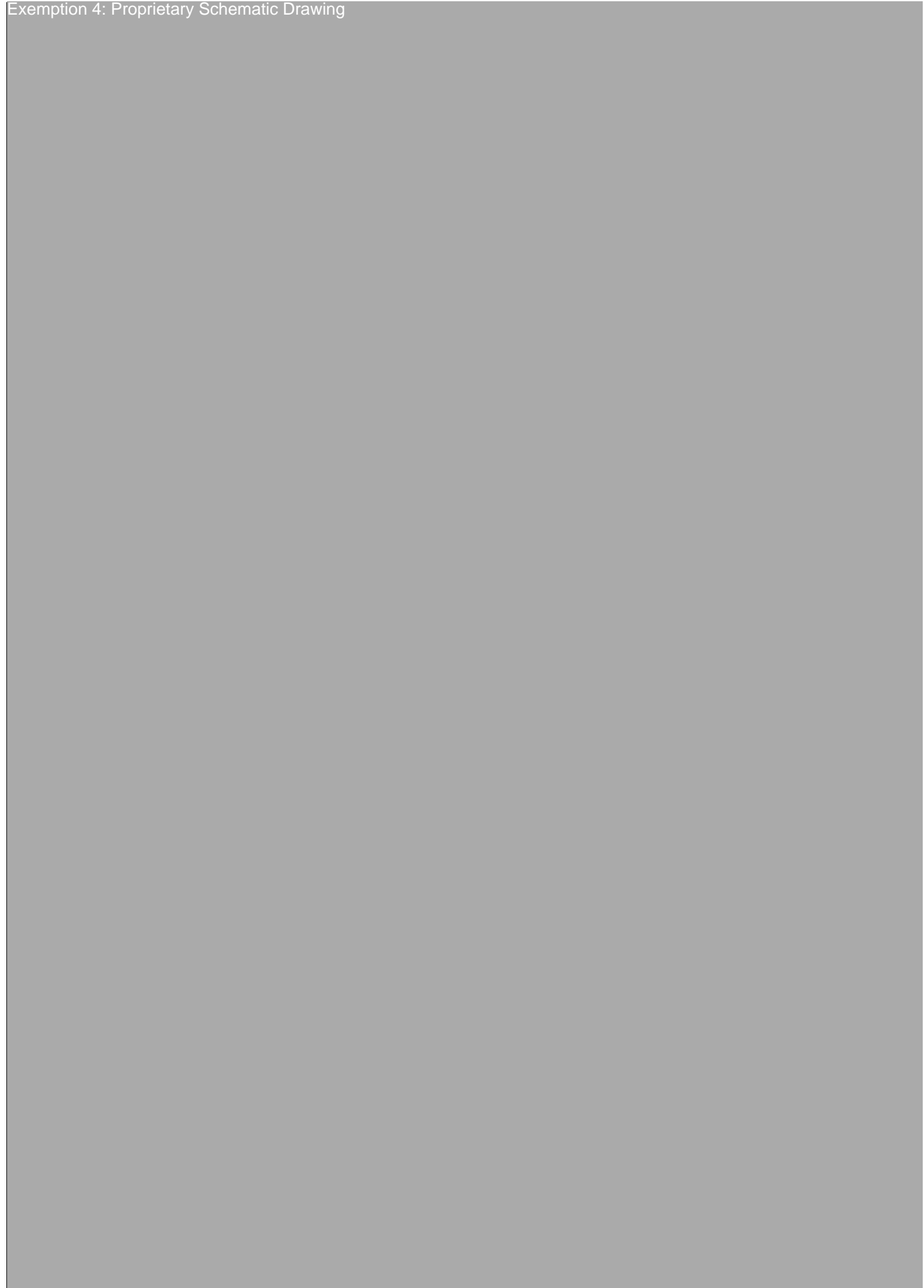






Exemption 4: Proprietary Schematic Drawing





Exemption 4: Proprietary Schematic Drawing



EXHIBIT 2

COMPATIBLE COMPONENTS

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

Acetabular Shell Diameter	Pinnacle 100 Shell (No Holes)	Pinnacle 300 Shell (Tri-Spiked)	Pinnacle Sector Shell (Cluster)
48mm	1217-01-048	1217-03-048	1217-02-048
50mm	1217-01-050	1217-03-050	1217-02-050
52mm	1217-01-052	1217-03-052	1217-02-052
54mm	1217-01-054	1217-03-054	1217-02-054
56mm	1217-01-056	1217-03-056	1217-02-056
58mm	1217-01-058	1217-03-058	1217-02-058
60mm	1217-01-060	1217-03-060	1217-02-060
62mm	1217-01-062	1217-03-062	1217-02-062
64mm	1217-01-064	1217-03-064	1217-02-064
66mm	1217-01-066	1217-03-066	1217-02-066

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EXHIBIT 2

COMPATIBLE COMPONENTS

DEPUY 28mm FEMORAL HEADS

Part Number	Description	Cleared In:
85-9913	S-ROM 28mm +0 Femoral Head	K851422
85-9915	S-ROM 28mm +6 Femoral Head	K851422
85-9916	S-ROM 28mm +12 Femoral Head	K851422
85-9847	PFC 28mm +0 Femoral Head	K893872
85-9848	PFC 28mm +5 Femoral Head	K893872
85-9849	PFC 28mm +10 Femoral Head	K893872

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EXHIBIT 3
REPRESENTATIVE DRAFT LABEL

REF: 1218-89-XXX

Lot: XXXXX

Pinnacle Metal Insert

Size X

Co-Cr-Mo

Sterile Unless Damaged or Opened

Rx Only.

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

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DRAFT PACKAGE INSERT

Metal-On-Metal Acetabular Cups

Rx Only

Description

The DePuy Ultima and Pinnacle Metal-On-Metal (MOM) Acetabular Cup Systems are both comprised of a metal acetabular shell and a metal acetabular cup liner. In both MOM acetabular cup systems, the metal liner mechanically locks with the metal shell via a taper junction. Both systems articulate with commercially available prosthetic femoral heads.

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

Indications

The Ultima and Pinnacle Metal-On-Metal Acetabular Cups are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Ultima and Pinnacle Metal-On-Metal Acetabular Cups are intended for use with DePuy 28mm diameter 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. For the Ultima system only, it is recommended that a reamer of the same size designation as the shell is used since this will provide a 1.5mm diametral press fit.

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Contraindications

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

Warnings

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

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

The inner diameter of the Metal-On-Metal insert must correspond to the hip head size. Use of an insert with a non-matching hip head size (e.g. 28mm inner diameter insert with a 22mm head) will result in accelerated wear and early failure. Use only with DePuy 28mm diameter Co-Cr-Mo femoral heads.

Precautions

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

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

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

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

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

Adverse Effects

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

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

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

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

Serious adverse effects may necessitate surgical intervention.

Sterility and Handling

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

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

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

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

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

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Pinnacle MUM Design Control Plan

Design Control Plan			Mfg. Process Control Plan			
Design Inputs	Design Outputs	Criticality (Function, Safety, Aesthetics)	Verification/Validation	Mfg. Process	Process Normal or Special	Verification/Validation
(b) (4)						

SEP

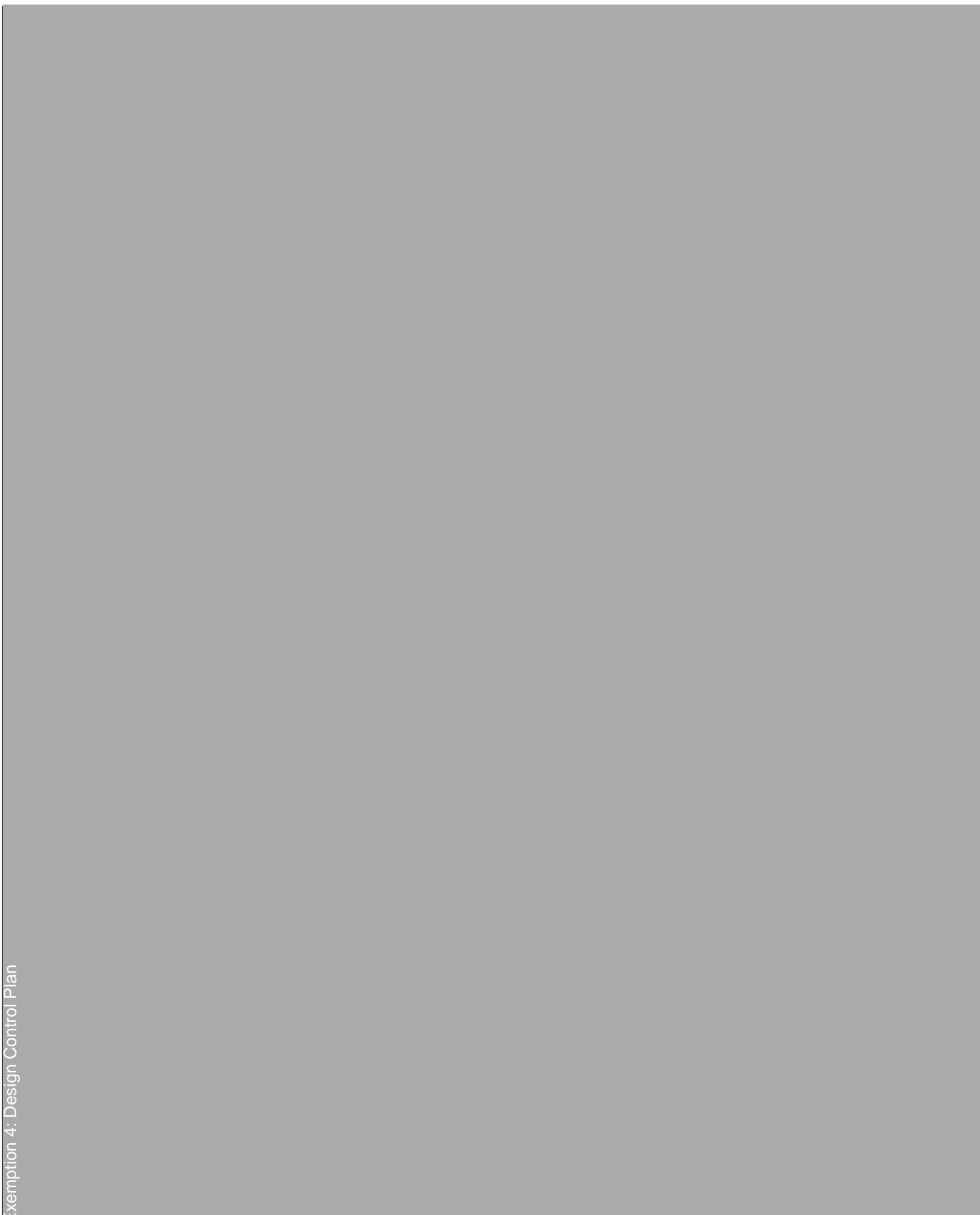
Exemption 4: Design Control Plan



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09/05/2000

LT Turner



Exemption 4: Design Control Plan



(b)
(4)
Revision A, 08/10/00

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EXHIBIT 5

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

Verification Activities

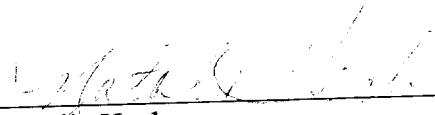
To the best of my knowledge, the verification activities, as required by the risk analysis, for this modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.



Leanne Turner
Product Development Engineer

Manufacturing Facility

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



Natalie Heck
Design Quality Engineer
DePuy Orthopaedics, Inc.