

JUL 12 2005

1/3

510(k) Summary of Safety and Effectiveness**Line Extension to the BioloX® Delta Ceramic Femoral Heads**

Proprietary Name: BioloX® Delta Ceramic Femoral Heads

Common Name: Artificial femoral head component

Proposed Regulatory Class: Class II

Classification: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353.

Device Product Code: 87 LZO: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented.

For Information contact: Karen Ariemma, Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430
Telephone: (201) 831-5718
Fax: (201) 831-6038
Email: karen.ariemma@stryker.com

Date Summary Prepared: June 13, 2005

Device Description

The subject BioloX® Delta Ceramic Femoral Heads mate with Howmedica Osteonics' C-Taper femoral stems fabricated from Titanium or CoCr alloys. The BioloX® Delta Ceramic Femoral Heads are available in 28, 32 and 36 mm diameters and a variety of neck offsets.

Device Modification

This submission adds additional femoral heads (36 mm diameter -5.0 mm offset heads and 36 mm diameter +7.5 mm offset heads) and allows for use of the BioloX® Delta Ceramic Femoral Heads with the Trident® X3™ Acetabular inserts.

Indications for Use

The subject devices are single use devices. They are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures. They can be used with all Howmedica Osteonics C-Taper* hip stems made from Titanium or CoCr alloys. When used as a total hip replacement, they are intended for use only with Howmedica Osteonics polyethylene bearing surfaces.

Indications for Use as a Bipolar

- Femoral head/neck fractures or non-unions,
- Aseptic necrosis of the femoral head,
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations that indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum,
- Salvage of failed total hip arthroplasty.

Indications for Use as a Total Hip:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

* The term "C-Taper" includes both the original C-Taper design, and the modified C-Taper design first introduced on the hip stems found Substantially Equivalent via K982032.

Substantial Equivalence

The features of the new components are substantially equivalent to the predicate devices based on similarities in intended use, materials and design. Mechanical testing demonstrates substantial equivalence of the new components to the predicate devices in regards to mechanical strength. In addition, the intended use, material, manufacturing methods, packaging, and sterilization of the predicate and new components are identical.



JUL 12 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Ariemma
Senior Regulatory Affairs Specialist
Stryker Howmedica Osteonics
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051588

Trade/Device Name: Line Extension to BioloX[®] Delta Ceramic Femoral Heads

Regulation Number: 21 CFR 888.3353

Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class: Class II

Product Code: LZO

Dated: June 13, 2005

Received: June 15, 2005

Dear Ms. Ariemma:

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

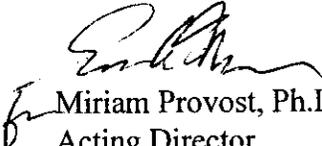
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: BioloX[®] Delta Ceramic Femoral Heads

The subject devices are single use devices. They are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures. They can be used with all Howmedica Osteonics C-Taper* hip stems made from Titanium or CoCr alloys. When used as a total hip replacement, they are intended for use only with Howmedica Osteonics polyethylene bearing surfaces.

Indications for Use as a Bipolar

- Femoral head/neck fractures or non-unions,
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Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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



Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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

510(k) Number K051588



JUL 12 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Karen Ariemma
Senior Regulatory Affairs Specialist
Stryker Howmedica Osteonics
325 Corporate Drive
Mahwah, New Jersey 07430

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Miriam Provost, Ph.D.
Acting Director
Division of General, Restorative
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Office of Device Evaluation
Center for Devices and
Radiological Health

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

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

510(k) Number K051588

June 15, 2005

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

HOWMEDICA OSTEONICS CORP
325 CORPORATE DR.
MAHWAH, NJ 07430
ATTN: KAREN ARIEMMA

510(k) Number: K051588
Received: 15-JUN-2005
Product: BIOLOX DELTA CERAMIC
FEMORAL HEADS

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 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 May 21, 2004, FDA issued a 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. Please review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

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 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.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/cdrh/devadvice/>". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA 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
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K051588

stryker

Howmedica
OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

Via Federal Express

June 13, 2005

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

6/15/05 JUN 15 A 9:55
6/15/05/10:05/10:18

Re: Special 510(k) Notification: Line Extension to the Biolox[®] Delta Ceramic Femoral Heads

Ladies and Gentlemen:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and in conformance with Title 21 of the Code of Federal Regulations Part 807 (21 CFR 807), Subpart E, this 510(k) Premarket Notification is being submitted prior to the date when Howmedica Osteonics Corp. proposes to introduce into interstate commerce a modification to the Biolox[®] Delta Ceramic Femoral Heads which was cleared via 510(k) K041940.

This submission contains methods, data, and analysis of these data which Howmedica Osteonics Corp. considers "Trade Secret" and commercially privileged and confidential to Howmedica Osteonics Corp. In accordance with 21 CFR §20.61, this information may not be disclosed to the public in accordance with the Freedom of Information (FOI) Act.

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OR
II 14

To the best of Howmedica Osteonics' knowledge and belief, all data and information contained herein are truthful and accurate, and no facts material to the subject determination have been omitted. Although the modification to the Biolox[®] Delta Ceramic Femoral Heads is substantially equivalent to the predicate device within the meaning of Section 513(i)(1)(A) of the Federal Food, Drug and Cosmetic Act, nothing in this submission in any way reflects upon the completely unrelated federal patent law "doctrine of equivalents".

The Indications for Use Form, Truthful and Accuracy Statement and Medical Device User Fee Cover Sheet immediately follow this letter.

Your early attention to this submission is appreciated. Please refer any questions regarding this submission to Karen Ariemma at (201) 831-5718.

Sincerely,

Howmedica Osteonics Corp.

A handwritten signature in black ink, appearing to read "Karen Ariemma". The signature is fluid and cursive, with a large initial "K" and "A".

Karen Ariemma

Senior Regulatory Affairs Specialist

Indications for Use

510(k) Number (if known): _____

Device Name: Bilox[®] Delta Ceramic Femoral Heads

The subject devices are single use devices. They are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures. They can be used with all Howmedica Osteonics C-Taper* hip stems made from Titanium or CoCr alloys. When used as a total hip replacement, they are intended for use only with Howmedica Osteonics polyethylene bearing surfaces.

Indications for Use as a Bipolar

- Femoral head/neck fractures or non-unions,
- Aseptic necrosis of the femoral head,
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations that indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum,
- Salvage of failed total hip arthroplasty.

Indications for Use as a Total Hip:

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Prescription Use X AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

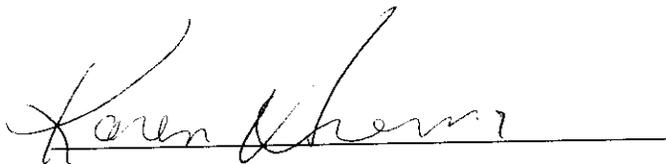
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Premarket Notification
Truthful and Accurate Statement
[as required by 21 CFR 807.87(k)]

I certify that, in my capacity as Senior Regulatory Affairs Specialist for Howmedica Osteonics Corp., I believe to the best of my knowledge that all information and data submitted in this premarket notification [510(k)] are truthful and accurate and that no material facts have been willfully omitted.



Karen Ariemma

Senior Regulatory Affairs Specialist

6 / 13 / 2005

Date

| | |
|---|--|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET | PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret Process 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 submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a 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 transfers.
6. Include a copy of the completed 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) HOWMEDICA OSTEONICS CORP. 325 CORPORATE DRIVE MAHWAH, NJ 07430 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 222183590 | 2. CONTACT NAME KAREN ARIEMMA 2.1 E-MAIL ADDRESS karen.ariemma@stryker.com 2.2 TELEPHONE NUMBER (Include Area Code) 201-831-5718 2.3 FACSIMILE (FAX) NUMBER (Include Area Code) 201-831-6038 |
|---|---|

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/oc/mdufma>)

| | |
|--|--|
| <p><u>Select an application type:</u></p> <input checked="" type="checkbox"/> Premarket notification (510(k)); except for third party reviews <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) | <p><u>3.1 Select one of the types below:</u></p> <input checked="" type="checkbox"/> Original Application <p><u>Supplement Types:</u></p> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 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

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.

| | |
|---|--|
| <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only | <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> 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 NO

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

(b)(4)Trade Secret

SPECIAL 510(k) PREMARKET NOTIFICATION

**LINE EXTENSION TO THE BIOLOX[®] DELTA CERAMIC
FEMORAL HEADS**

**Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430**

June 13, 2005

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| Name and Address of the Distributor of the Device:..... | 6 |
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510(k) Summary of Safety and Effectiveness
Line Extension to the BioloX® Delta Ceramic Femoral Heads

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Indications for Use as a Total Hip:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

* The term "C-Taper" includes both the original C-Taper design, and the modified C-Taper design first introduced on the hip stems found Substantially Equivalent via K982032.

Substantial Equivalence

The features of the new components are substantially equivalent to the predicate devices based on similarities in intended use, materials and design. Mechanical testing demonstrates substantial equivalence of the new components to the predicate devices in regards to mechanical strength. In addition, the intended use, material, manufacturing methods, packaging, and sterilization of the predicate and new components are identical.

SECTION I
ADMINISTRATIVE INFORMATION

Manufacturer Identification

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
325 Corporate Drive, Mahwah, NJ 07430
Establishment Registration Number: 2249697

Name and Address of the Manufacturers of the Device:

Howmedica Osteonics Corp.
325 Corporate Drive, Mahwah, NJ 07430
Establishment Registration Number: 2249697

Stryker Ireland Ltd.
I.D.A. Industrial Estate
Carrigtwohill, County Cork, Ireland
Registration Number: 9616696

Name and Address of the Distributor of the Device:

Howmedica Osteonics Corp.
325 Corporate Drive, Mahwah, NJ 07430
Establishment Registration Number: 2249697

Contact Person:

Karen Ariemma, Senior Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430
Telephone: (201) 831-5718
Fax: (201) 831-6038
Email: karen.ariemma@stryker.com

SECTION II
DEVICE IDENTIFICATION

Device Identification

Proprietary Name: Biolox[®] Delta Ceramic Femoral Heads

Common Name: Artificial femoral head component

Proposed Regulatory Class: Class II

Classification: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21 CFR §888.3353.

Device Product Code: 87 LZO: Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented.

SECTION III
DEVICE DESCRIPTIVE INFORMATION

Introduction

This Special 510(k) submission is intended to address a line extension to the Biolo[®] Delta Ceramic Femoral Heads. This submission adds additional femoral heads (36 mm diameter ~~-2.5~~^{-5.0 mm} mm offset heads and 36 mm diameter +7.5 mm offset heads) and allows for use of the Biolo[®] Delta Ceramic Femoral Heads with the Trident[®] X3[™] Acetabular inserts.

Device History and Description

The Biolo[®] Delta Ceramic Femoral Heads were determined substantially equivalent via 510(k) K041940. The Biolo[®] Delta Ceramic Femoral Heads can be used with Howmedica Osteonics' femoral C-Tapered stems fabricated from Titanium alloy and Cobalt Chromium Alloy. The Biolo[®] Delta Ceramic Femoral Heads were cleared for use with Howmedica Osteonics' N₂Vac and Crossfire[®] Acetabular Inserts. The Biolo[®] Delta Ceramic Femoral Heads are available in the following sizes:

- 28mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm,
- 32mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm,
- 36mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm.

Description of Device Modification

The line extension to the Biolo[®] Delta Ceramic Femoral Heads involves two changes. These changes are described below.

36 mm diameter Biolo[®] Delta Ceramic Femoral Heads, -5 mm and +7.5 mm offset

The predicate 36 mm diameter Biolo[®] Delta Ceramic Femoral Heads were available in the following offsets: -2.5, 0, +2.5 and +5 mm. The subject components are 36 mm diameter -5 mm offset and 36 mm diameter +7.5 mm offset Biolo[®] Delta Ceramic Femoral Heads. Refer to subject component list in Appendix A-1, page 19, and the engineering drawings in Appendix A-2, page 20.

Use of the Biolo[®] Delta Ceramic Femoral Heads with the Trident[®] X3[™] Acetabular

The Trident[®] X3[™] Acetabular Inserts were determined substantially equivalent via K033716.

The Trident® X3™ Acetabular Inserts are fabricated from X3™ Ultra High Molecular Weight Polyethylene (UHMWPE) and sterilized via gas plasma sterilization. This submission seeks to allow use of the BioloX® Delta Ceramic Femoral Heads with Trident® X3™ Acetabular Inserts. The Acetabular liner compatibility chart has been updated to include Trident® X3™ Acetabular Inserts and is included as Appendix A-3, page 22.

Indications for Use

The subject devices are single use devices. They are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures. They can be used with all Howmedica Osteonics C-Taper* hip stems made from Titanium or CoCr alloys. When used as a total hip replacement, they are intended for use only with Howmedica Osteonics polyethylene bearing surfaces.

Indications for Use as a Bipolar

- Femoral head/neck fractures or non-unions,
- Aseptic necrosis of the femoral head,
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations that indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum,
- Salvage of failed total hip arthroplasty.

Indications for Use as a Total Hip:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as

indicated by deficiencies in the acetabulum.

* The term "C-Taper" includes both the original C-Taper design, and the modified C-Taper design first introduced on the hip stems found Substantially Equivalent via K982032.

Materials

The subject Biolox[®] Delta Ceramic Femoral Heads are fabricated from Zirconia Toughened Alumina (ZTA) (b)(4)Trade Secret Process

[Redacted text block containing multiple lines of blacked-out information]

Design Control

Analyses were performed to evaluate the potential risks associated with the changes made to the Biolox[®] Delta Ceramic Femoral Heads. Mechanical testing was used to assess whether the subject device falls within pre-established acceptance criteria. The overall risk analysis method used was FMEA. (b)(4)Trade Secret Process

[Redacted text block containing multiple lines of blacked-out information]

(b)(4) Trade Secret Process [Redacted]

Use of the BioloX[®] Delta Ceramic Femoral Heads with the Trident[®] X3[™] Acetabular

Testing was performed to characterize the wear performance of BioloX[®] Delta Ceramic Femoral Heads on Trident[®] X3[™] UHMWPE Acetabular inserts. (b)(4) Trade Secret Process [Redacted]

[Redacted]

Table 1: Chart of Potential Risks

| Device Modification | Risk | Verification Activity | Acceptance Criteria | Results of Verification |
|-----------------------------|------|-----------------------|---------------------|-------------------------|
| (b)(4) Trade Secret Process | | | | |

Declaration of Conformity

A Declaration of Conformity stating each of the following may be found in Appendix D, page 57.

- 1) A statement 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 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.

Scientific Technology

A Statement of Scientific Technology and Indications may be found in Appendix E, page 59.

Sterility Information

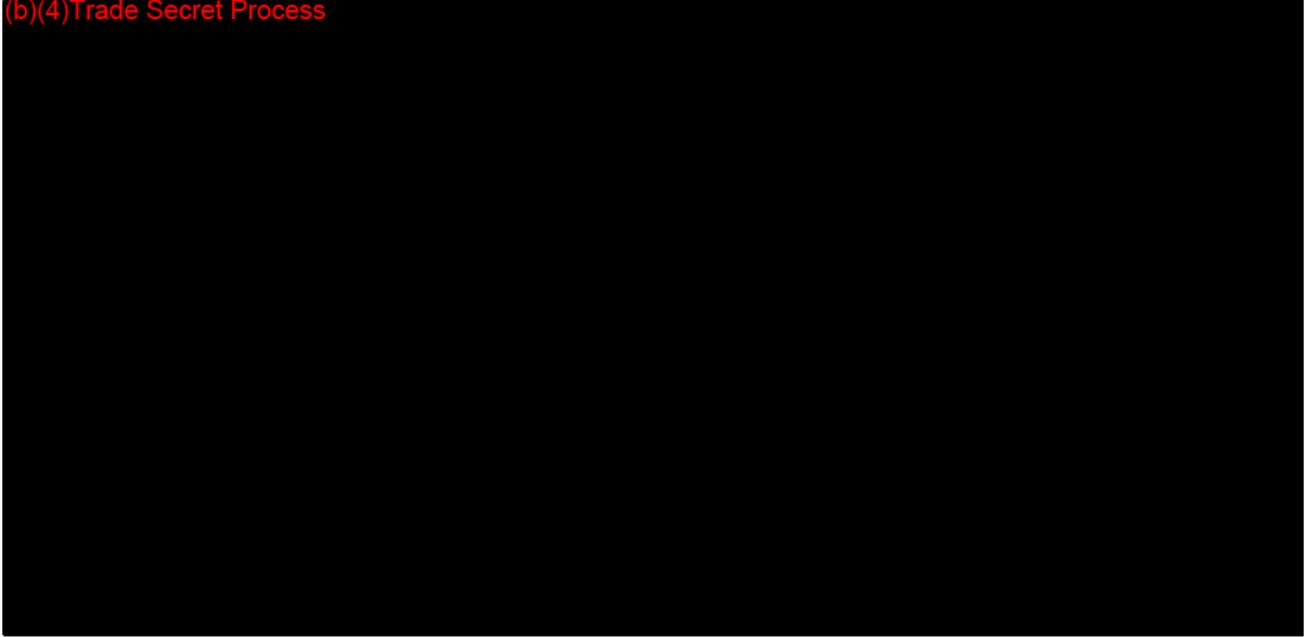
(b) [Redacted]
(4) Trade Secret Process [Redacted]
[Redacted]
[Redacted]
[Redacted]

Sterilization Method:
Gamma Irradiation - Cobalt 60 Isotope
Dose 25kGy
Validated according to ANSI/AAMI/ISO 11137
SAL - 10⁻⁶

Sterilization/Packaging Information

(b)(4) Trade Secret Process [Redacted]
[Redacted] [Redacted]
[Redacted] [Redacted]

(b)(4) Trade Secret Process



Labeling

Refer to Appendix B for product labeling and instructions for use for BioloX[®] Delta Ceramic Femoral Heads. The instructions for use were not changed as a result of this line extension.

APPENDICES

APPENDIX A COMPONENT INFORMATION

APPENDIX B PACKAGING INFORMATION

APPENDIX C MECHANICAL TESTING

APPENDIX D DECLARATION OF CONFORMITY

APPENDIX E STATEMENT OF SCIENTIFIC TECHNOLOGY

APPENDIX F

[REDACTED] (b)
(4) Trade

APPENDIX A: COMPONENT INFORMATION

- A-1 Catalog Numbers for the Subject BioloX[®] Delta Ceramic Femoral Heads
- A-2 Engineering Drawings for the Subject BioloX[®] Delta Ceramic Femoral Heads
- A-3 Acetabular Insert Compatibility Chart

Appendix A-1: Catalog Numbers for the Subject Biolo^x® Delta Ceramic Femoral Heads

| CATALOG NO. | DESCRIPTION/CHARACTERISTICS |
|-------------|---|
| 18-36-5 | Biolo ^x ® Delta Ceramic Femoral Heads, 36 mm diameter, -5 mm offset |
| 18-3675 | Biolo ^x ® Delta Ceramic Femoral Heads, 36 mm diameter, +7.5mm offset |

Appendix A-2
Engineering Drawings for the Subject BioloX[®] Delta Ceramic Femoral Heads

- CONFIDENTIAL -

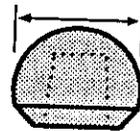
Appendix A-3
Acetabular Insert Compatibility Chart

| | |
|------------------------------------|---|
| K033716 | Trident [®] X3 [™] Acetabular Inserts |
| K020497 | Trident [®] Crossfire [®] Elevated Rim Liners |
| K021911, K991952, K983502 | Trident [®] Crossfire [®] Poly Liners, 10° or 0° profile |
| K021911, K991952, K983502 | Trident [®] Crossfire [®] Eccentric Poly Liners, 10° or 0° profile |
| K983382, K991952 | Trident [®] Poly Liners, 10° or 0° profile |
| K983382, K991952 | Trident [®] Eccentric Poly Liners |
| P960047 | Trident [®] Constrained Insert |
| K974685 | Crossfire [®] Series II Inserts (2041C, 2042C, 2043C, S2301, S2302) |
| K943054, K990849 | Series II Inserts, and Series II Eccentric Inserts |
| K890197 | Constrained Liner |
| K850352 | Series I Inserts |
| K993352 K903362 | System 12 Inserts (Standard and Crossfire) |
| K803192 | All Poly Cup |
| K001956 | Trident [®] All Poly Cup |
| K010310 | Crossfire Trident [®] All Poly Cup |
| K800207 | UH1 |
| K861105, K972792 | Centrax Bipolar |
| K921384, K852153, K963612, K920831 | PCA Acetabular Insert |
| K851565 | Precision Acetabular Components |

APPENDIX B: PACKAGING INFORMATION

- B-1** Draft Labels for the Subject Components
- B-2** Draft Package Insert for the Subject Components

Appendix B-1
Draft Label for the Subject Components

Catalog No. **18-3675**
BIOLOX® delta Ceramic
C-Taper Head **36mm**
+7.5 

- Zirconia Toughened Alumina
- In the U.S.A., Do Not Use with Ceramic Inserts

Howmedica Osteonics Corp.
Stryker Ireland
Carrigtwohill Industrial Estate
Carrigtwohill, County Cork
Ireland



H8251836750H



\$\$8010610CASECASECAH1

Authorized Representative in Europe
Stryker France
ZAC Satolas Green Pusignan
Av de Satolas Green 69881 Meyzieu
Cedex France

| | |
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| 2010-06 | ZrO2 |

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CAUTION: Federal Law(USA) restricts this device to sale by or on the order of a Physician

Appendix B-2
Draft Package Insert for the Subject Components

4350 rev 9 – draft

Howmedica Osteonics® Trident® Acetabular Component System and Howmedica Osteonics® Alumina and BioloX® Delta Ceramic Heads English

Description

The Howmedica Osteonics Trident® Acetabular Component System consists of a metal acetabular shell and the choice of any Trident® acetabular bearing insert. The shells are available with a variety of surface enhancements including Arc Deposition with or without Hydroxylapatite surface treatment. The shells are intended for cementless fixation within the prepared acetabulum. The Howmedica Osteonics Trident® acetabular UHMWPE inserts may be used with any Howmedica Osteonics stem of compatible head size, with suitable stem size and style to achieve total reconstructive replacement of the hip joint. The dome hole plugs are optional devices which are available to seal the Howmedica Osteonics acetabular shell. The plugs are to be threaded into the dome holes of the shell.

The Crossfire® Polyethylene Acetabular Inserts show a 90% reduction in gravimetric wear rate versus the same Acetabular inserts fabricated from standard polyethylene. Testing was performed under multi-axial hip joint simulation for 5 million cycles, using a 28-mm CoCr articulating counterface and a bovine calf serum lubricant. The results of in-vitro hip wear simulator tests have not been shown to quantitatively predict clinical wear performance. Consult with Howmedica Osteonics as to the status of clinical evaluation.

Compatibility

Shell-to-Insert

- Trident shells can be used with Trident polyethylene and Trident ceramic inserts. Please see the additional package insert addressing ceramic on ceramic articulation.

Insert-to-Head

- Howmedica Osteonics polyethylene inserts can be used with all Howmedica Osteonics metal or ceramic heads.
- Outside the U.S., the Howmedica Osteonics ceramic inserts can be used with either Howmedica Osteonics alumina or BioloX® Delta ceramic heads.
- Within the U.S., the Howmedica Osteonics ceramic inserts can be used **only** with the Howmedica Osteonics alumina ceramic heads.

Head-to-Stem

- Howmedica Osteonics C-taper Alumina Ceramic Heads can be used with Howmedica Osteonics C-taper titanium stems. When used with adaptor sleeve 17-0000E, the C-taper alumina heads can be used with Howmedica Osteonics V40™ taper titanium stems and V40™ taper CoCr stems. When used with adaptor sleeve 1034-0000J, the C-taper alumina heads can be used with Howmedica Osteonics Morse taper titanium stems and Morse taper CoCr stems.
- Howmedica Osteonics V40™ Alumina Ceramic Heads (series 6565-0-xxx) can be used with Howmedica Osteonics V40™ titanium and V40™ stainless steel stems.
- Howmedica Osteonics C-taper BioloX® Delta Ceramic Heads can be used with Howmedica Osteonics C-taper titanium or C-taper CoCr stems.

Acetabular Bone Screws

- Howmedica Osteonics 6.5mm or 5.5mm bone screws can be used with the dome screw holes of the acetabular shells.

Materials:

- ASTM F-620 Titanium 6Al-4V ELI Alloy Acetabular Shell, Acetabular Insert Sleeve
- ASTM F-67 CP Titanium Arc-Deposited Coating, Dome Hole Plugs
- ASTM F-1185 Hydroxylapatite Hydroxylapatite Powder
- ASTM F-603 Aluminum Oxide (Al₂O₃) Alumina Ceramic Head
- Zirconia-Toughened Aluminum Oxide Delta Ceramic Head
- ASTM F-648 Ultra-High Molecular Weight Polyethylene (UHMWPE) Acetabular Bearing Insert

Indications

Indications for Use as a Bipolar

- Femoral head/neck fractures or non-unions,
- Aseptic necrosis of the femoral head,
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.
- Pathological conditions or age considerations that indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum,
- Salvage of failed total hip arthroplasty.

Indications for Use as a Total Hip:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty or other procedure,
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results,
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies of the acetabulum.

Contraindications

- Any active or suspected latent infection in or about the hip joint.
- Any mental or neuromuscular disorder which would create an unacceptable risk of prosthesis instability, prosthesis fixation failure, or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis.
- Skeletal immaturity.

Warnings

- Do not reassemble a ceramic head and stem. Once a ceramic head has been assembled to a stem taper, it should never be reassembled to that stem or subsequently assembled to any other stem. In addition, a ceramic head should only be assembled to an unused stem taper. Once a stem taper has been assembled to any femoral head, it should never be subsequently assembled to any ceramic head

component due to deformation of the stem's taper locking mechanism during initial stem/head assembly.

- Do not allow polished bearing areas and machined taper surfaces to come in contact with hard or abrasive surfaces, as scratching or in any way damaging these surfaces can significantly affect the structural integrity.
- Clean bearing surfaces of debris prior to assembly as foreign particles may cause accelerated bearing wear, which may lead to early failure of the device. Clean and dry machine taper surfaces to ensure proper seating and assembly.
- Do not substitute another manufacturer's device for any of the Howmedica Osteonics Trident[®] System components because design, material, or tolerance differences may lead to premature device and/or functional failure. Components of the system have been specifically designed to work together. Any such use will negate the responsibility of Howmedica Osteonics for the performance of the resulting mixed component implant.
- Howmedica Osteonics strongly advises against the use of another manufacturer's bone screws with any Howmedica Osteonics Acetabular System component, due to variations which exist between screw head and screw seat configurations.
- Do not handle the hydroxylapatite treated regions as it may compromise the sterility or cause failure under load.
- Do not use V40[™] alumina heads with CoCr stems.
- Do not use C-Taper alumina heads with CoCr stems without an adaptor sleeve.
- Do not use C-Taper alumina heads with Stainless Steel (Orthinox[™]) stems.
- Avoid excessive verticalization of shell, which may accelerate bearing wear.
- Do not contour or bend an implant because it may reduce its fatigue strength and cause failure under load.
- Do not implant in obese patients because additional loading may lead to loss of fixation or device failure.
- Improper seating of the head may result in a discrepancy in neck length, component disassociation and/or dislocation.
- Ensure appropriate selection of bone screw length and location to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall can result in internal bleeding and possible damage to vital organs.
- Discard all damaged or mishandled implants. Never reuse an implant, even though it may appear undamaged. It may have small defects and internal stress patterns which may lead to early failure of the device.
- **Do not resterilize.**

Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the device. Physicians must instruct patients in the limitations of the prosthesis, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. If the patient is involved in an occupation or activity which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device, or both. The prosthesis will not restore function to the level

expected with normal healthy bone, and the physician must advise the patient against having unrealistic functional expectations.

- Appropriate selection, placement and fixation of the total hip components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanic and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions and warnings for this product is essential to potentially maximize service life.
- If the ceramic component(s) fracture, necessitating revision, take special care to remove all ceramic debris from the joint. Any remaining fragments could accelerate wear of the replacement components.
- Use caution when handling ceramic components during assembly because of the brittle nature of ceramic material.
- Intentional removal of an acetabular component can be accomplished by careful use of cutting burrs, thin and narrow osteotomes and cautious extraction forces. A threaded metal shell can be removed by carefully unscrewing the shell in a counterclockwise direction. If difficulty is encountered, the preceding techniques may be employed.
- Removal of an unloosened arc deposited or hydroxylapatite surface treated implant may require the use of special instruments to disrupt the interface at the implant surface.
- Care should be taken not to cut through surgical gloves when handling any sharp-edged orthopaedic device.

Utilization and Implantation

- The surgeon must be completely familiar with the implant system and surgical protocol, and complete preoperative planning should be carried out.
- The suggested surgical procedure should be strictly adhered to. Proper assembly of the ceramic inserts and the ceramic heads to their mating taper surfaces and proper assembly technique are critical to the success of ceramic hip systems.
- The recommended trial components should be used for size determination, trial reduction and range of motion evaluation, thus preserving the integrity of the actual implants and their sterile packaging.
- Radiographic templates are available to assist in the preoperative prediction of component size and style.
- The Surgical Protocol for the Howmedica Osteonics Trident[®] Acetabular Component System provides additional procedural information.

Adverse Effects

- While the expected life of total hip replacement components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential restoration of mobility or reduction of pain. However, due to the many biological, mechanical and physiochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone.
- Dislocation of the hip prosthesis can occur due to inappropriate patient activity, trauma or other biomechanical considerations.

- Loosening of total hip components can occur. Early mechanical loosening may result from inadequate initial fixation, latent infection, premature loading of the prosthesis or trauma. Late loosening may result from trauma, infection, biological complications, including osteolysis, or mechanical problems, with the subsequent possibility of bone erosion and/or pain.
- Fracture of ceramic components has been reported in a small percentage of cases.
- Intraoperative fissure, fracture, or perforation of the femur, acetabulum or trochanter can occur due to impaction of the component into the prepared femoral canal or acetabulum. Postoperative femoral or acetabular fracture can occur due to trauma, the presence of defects, or poor bone stock.
- If bone screws are used, appropriate selection of bone screw length and location is essential to avoid damage to underlying soft tissue structures. Perforation of the pelvic wall can result in internal bleeding and possible damage to vital organs.
- Peripheral neuropathies, nerve damage, circulatory compromise and heterotopic bone formation may occur.
- Serious complications may be associated with any total joint replacement surgery. These complications include, but are not limited to: genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; bronchopulmonary disorders, including emboli; myocardial infarction or death.
- Acetabular pain may occur due to loosening of the implant.
- Metal sensitivity reactions have been reported following joint replacement.
- Adverse effects may necessitate reoperation, revision, arthrodesis of the involved joint, Girdlestone and/or amputation of the limb. Surgeons should advise patients of these potential adverse effects.
- With all implant devices, asymptomatic, localized progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to the particulate matter of cement, metal, Ultra-High Molecular Weight Polyethylene (UHMWPE) and/or ceramic. Particulate is generated by interaction between components and bone, primarily through wear mechanisms of adhesion, abrasion and fatigue. Secondly, particulate can also be generated by third-body wear. Osteolysis can lead to future complications, including loosening, necessitating the removal and replacement of prosthetic components.
- Very small particles from metal and polyethylene components can be shed from the components during normal use and over time. Although most of this debris stays in the relevant joint (i.e. contained in the synovium) or is trapped by surrounding scar tissue, microscopic particles can be disseminated (migrate) throughout the body and on occasions have been described as accumulating in lymph nodes and other parts of the body. Although no significant medical complications have been reported as a result of these particles, their migration and/or accumulation in the body have been described in the literature. Given the insufficient time period during which patients with these devices have been followed and the fact that these devices are currently being used in younger patients and remain in the body for increasingly longer periods of time, it should be said that the long-term effects, if any, from these particles, is unknown. The long-term effects that have been theorized to include:
 - Cancer: There is presently no scientific evidence that links metallic or polyethylene debris with cancer. However, the possibility cannot be ruled out.
 - Lymphadenopathy and Accumulation in Other Tissues/Organs: There have been a few reports of the accumulation of wear debris in lymph nodes (proximate and distal). Although no medical complications or disease process has been reported as stemming from these accumulations, their existence should be recognized to facilitate diagnosis and avoid

confusion with suspicious lesions, cancerous or otherwise.

- **Systemic Disease:** There has been some speculation that there could be an association between migration of debris and as yet unidentified systemic effects. It is possible that some long-term effect may be demonstrated at some point in the future, but because there is very little scientific data suggesting association between migration of debris and systemic disease, it is believed that the benefits of these devices clearly outweigh the potential risks for any such theoretical long-term effect.

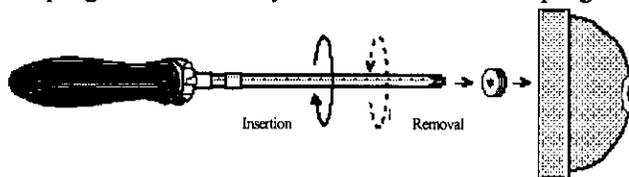
Sterilization

- These components have been sterilized by either gamma radiation or ethylene oxide. Refer to the package label for the sterilization method.
- **Do NOT resterilize.**
- Autoclaving ceramic components can compromise their mechanical and structural integrity.
- Inspect the packaging of ALL sterile products for flaws before opening. In the presence of any flaws, assume that the product is not sterile.
- Take care to prevent contamination of ANY components.
- Discard ALL nonsterile or contaminated product.

DOME HOLE PLUG ASSEMBLY INSTRUCTIONS

INSERTION:

- Once the acetabular shell is seated in the acetabulum, the Dome Hole Plug may be inserted. Place the Dome Hole Plug onto the captive twist head of the driver (secure by tapping on a hard surface). Insert the Dome Hole Plug into the threaded dome hole of the shell. Turn the driver clockwise until the plug is seated firmly. Extract driver from plug.



REMOVAL:

- Removal of the plug is the same as insertion, except the driver is turned counterclockwise.

Biolox® Delta is a registered trademark of CeramTec AG.

APPENDIX C: MECHANICAL TESTING AND ANALYSIS

- C-1 (b)(4)Trade Secret : Mechanical Tests for BioloX® Delta C Taper Femoral Heads
- C-2 (b)(4)Trade Secret Hip Simulator Wear Comparison of BioloX® Delta Ceramic Femoral Heads Against X3™ UHMWPE Acetabular Inserts

Appendix C-1: (b)(4)Trade : Mechanical Tests for Biolo[®] Delta C Taper Femoral Heads
S t

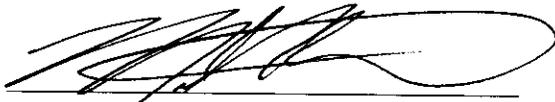
Appendix C-2: (b)(4)Trade Hip Simulator Wear Comparison of BioloX® Delta Ceramic
S t Femoral Heads Against X3™ UHMWPE Acetabular Inserts

APPENDIX D
DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY

All verification and validation activities were performed by the appropriately designated individual(s), and the results demonstrated that the predetermined acceptance criteria were met.

Howmedica Osteonics' 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.



Milton Torres
Manager, Hip Product Development

13 JUNE 05

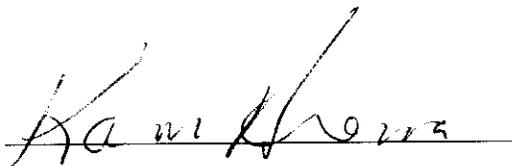
Date

APPENDIX E
STATEMENT OF SCIENTIFIC TECHNOLOGY AND INDICATIONS

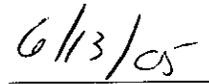
STATEMENT OF SCIENTIFIC TECHNOLOGY AND INDICATIONS

The indications for use of the subject BioloX[®] Delta Ceramic Femoral Heads as described in the labeling have not changed from the indications for use of the currently available BioloX[®] Delta Ceramic Femoral Heads cleared via 510(k) K041940.

In addition, the fundamental scientific technology of the subject BioloX[®] Delta Ceramic Femoral Heads as described in the labeling has not changed from that of the BioloX[®] Delta Ceramic Femoral Heads cleared via 510(k) K041940.



Karen Ariemma
Senior Regulatory Affairs Specialist



Date

APPENDIX F

(b)(4) Trade Secret Process

From: Reviewer(s) - Name(s) HORACE SAAS RHODES

Subject: 510(k) Number K051588

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 n.d.
- The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) 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: Additional Product Code(s) with panel (optional):

87-170 Class II

Review: [Signature] OR ORDB 7/8/05
 (Branch Chief) (Branch Code) (Date)

Final Review: [Signature] 7/11/05
 (Division Director) (Date)

Internal Administrative Form

| | YES | NO |
|---|-----|----|
| 1. Did the firm request expedited review? | | X |
| 2. Did we grant expedited review? | | X |
| 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? | X | |
| 6. Is the device exempt from 510(k) by regulation or policy? | | X |
| 7. Is the device subject to review by CDRH? | X | |
| 8. Are you aware that this device has been the subject of a previous NSE decision? | | X |
| 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? | | X |
| 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. | | — |

“SPECIAL” 510(k) MEMORANDUM

TO: K05-1588

FROM: Hollace Saas Rhodes, Biomedical Engineer
ODE/DGRND/Orthopedic Devices Branch

js 7/8/05

DATE: July 7, 2005

SUBJ: Line Extension to BioloX® Delta Ceramic Femoral Heads
Product Code: 87-LZO, Class II (21 CFR 888.3353, Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis)

Karen Ariemma, Stryker Howmedica Osteonics
201.831.5781

Recommendation:

This document was reviewed as a “Special 510(k)” using the BioloX® Delta Ceramic Femoral Heads (K04-1940) as the predicate device for the subject device. Differences between the subject device and predicate device do not affect the substantial equivalence of the Line Extension to the BioloX® Delta Ceramic Femoral Heads. Therefore, I recommend that the subject device be found substantially equivalent to legally marketed devices.

Review:

1. **Predicate Device:**

BioloX® Delta Ceramic Femoral Heads (K04-1940).

2. **Device description:**

Line Extension to BioloX® Delta Ceramic Femoral Heads

This 510(k) adds two femoral head designs to the available sizes of the BioloX® Delta Ceramic Femoral Heads:

- 36 mm diameter, – 5.0 mm offset
- 36 mm diameter, + 7.5 mm offset

This 510(k) also allows for use of the BioloX® Delta Ceramic Femoral Heads with the Trident® X3™ Acetabular inserts.

All ceramic heads mate with Howmedica Osteonics C-Taper femoral stems fabricated from titanium or CoCr alloys.

Differences from Predicate:

K04-1940 included the following femoral head designs:

- 28 mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm

- 32 mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm
- 36 mm diameter with neck lengths of -2.5mm, +0mm, +2.5mm, +5mm
- The predicate ceramic femoral heads were cleared for use with Howmedica Osteonics N₂Vac and Crossfire Acetabular Inserts. This 510(k) also allows for use of the BioloX[®] Delta Ceramic Femoral Heads with the Trident[®] X3[™] Acetabular inserts.

The sponsor states on page 60 (Appendix E) that the fundamental scientific technology of the modified device has not changed.

3. Intended Use:

The subject devices are single use devices. They are intended for mechanical fixation to their mating hip stems, and can be used in cemented or cementless hip arthroplasty procedures. They can be used with all Howmedica Osteonics C-Taper* hip stems made from Titanium or CoCr alloys. When used as a total hip replacement, they are intended for use only with Howmedica Osteonics polyethylene bearing surfaces.

Indications for Use as a Bipolar

- Femoral head/neck fractures or non-union
- Aseptic necrosis of the femoral head
- Osteo-, rheumatoid, and post-traumatic arthritis of the hip with minimal acetabular involvement or distortion
- Pathological conditions or age considerations which indicate a more conservative acetabular procedure and an avoidance of the use of bone cement in the acetabulum
- Salvage of failed total hip arthroplasty

Indications for use as a total hip:

- Painful, disabling joint disease resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage avascular necrosis,
- Revision of previous unsuccessful femoral head replacement, cup arthroplasty, or other procedure
- Clinical management problems where arthrodesis or other alternative reconstructive techniques are less likely to achieve satisfactory results.
- Where bone stock is of poor quality or is inadequate for other reconstructive techniques as indicated by deficiencies in the acetabulum.

* The term "C-Taper" includes both the original C-Taper design, and the modified C-Taper design first introduced on the hip stems found Substantially Equivalent via K982032.

Differences from Predicate:

- None.

The sponsor states on page 60 (Appendix E) that the intended use of the modified device has not changed.

4. Labeling:

Draft labels and package insert are provided in Appendix B.

Differences from Predicate:

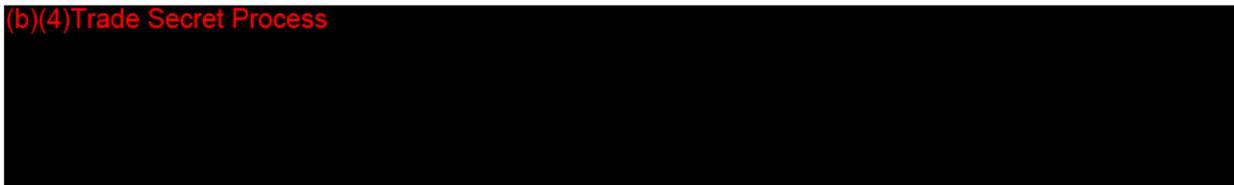
- None.

5. Design Control Activities:

The guidance document for “Special” 510(k)s states that the summary of design control activities should include several items:

- identification of the risk analysis method
- based on the risk analysis, an identification of the verification and/or validation activities required, included methods or tests used and the acceptance criteria applied.

(b)(4)Trade Secret Process



NOTE: A (b)(4)Trade Secret Process

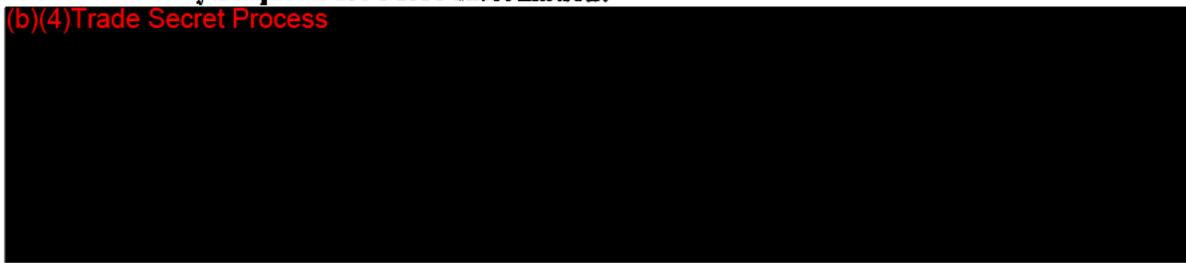


6. Declaration of Conformity with Design Controls:

- a. The sponsor provided a statement that all verification activities, as required by the risk analysis, were performed and the results demonstrated that the predetermined acceptance criteria were met. It was signed by Milton Torres.
- b. The sponsor provided a statement that the manufacturing facility is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review. It was signed by Milton Torres.

7. Contact History/Requests for More Information:

(b)(4)Trade Secret Process



8. Decision-Making Rationale:

This document was reviewed as a “Special 510(k)” using the BioloX[®] Delta Ceramic Femoral Heads (K04-1940) as the predicate device for the subject device. Differences between the subject device and predicate device do not affect the substantial equivalence of the Line Extension to the BioloX[®] Delta Ceramic Femoral Heads. Therefore, I recommend that the subject device be found substantially equivalent to legally marketed devices.

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| | | YES | NO | |
|-----|---|-----|----|--------------------------------------|
| 1. | Is Product A Device | Yes | | If NO = Stop |
| 2. | Is Device Subject To 510(k)? | Yes | | If NO = Stop |
| 3. | Same Indication Statement? | Yes | | 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? | Yes | | If YES = Go To 7 |
| 6. | Could The New Characteristics Affect Safety Or Effectiveness? | | | If YES = Go To 8 |
| 7. | Descriptive Characteristics Precise Enough? | Yes | | 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: SE |

Rhodes, Hollace

From: Ariemma, Karen [karen.ariemma@stryker.com]
Sent: Thursday, July 07, 2005 10:59 AM
To: HXS@CDRH.FDA.GOV
Subject: RE: (b)(4)Trade Secret Process

Holly,

(b)(4)Trade Secret Process

Karen Ariemma
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-----Original Message-----

From: HXS@CDRH.FDA.GOV [mailto:HXS@CDRH.FDA.GOV]
Sent: Thursday, July 07, 2005 7:43 AM
To: Ariemma, Karen
Subject: (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

Holly Rhodes

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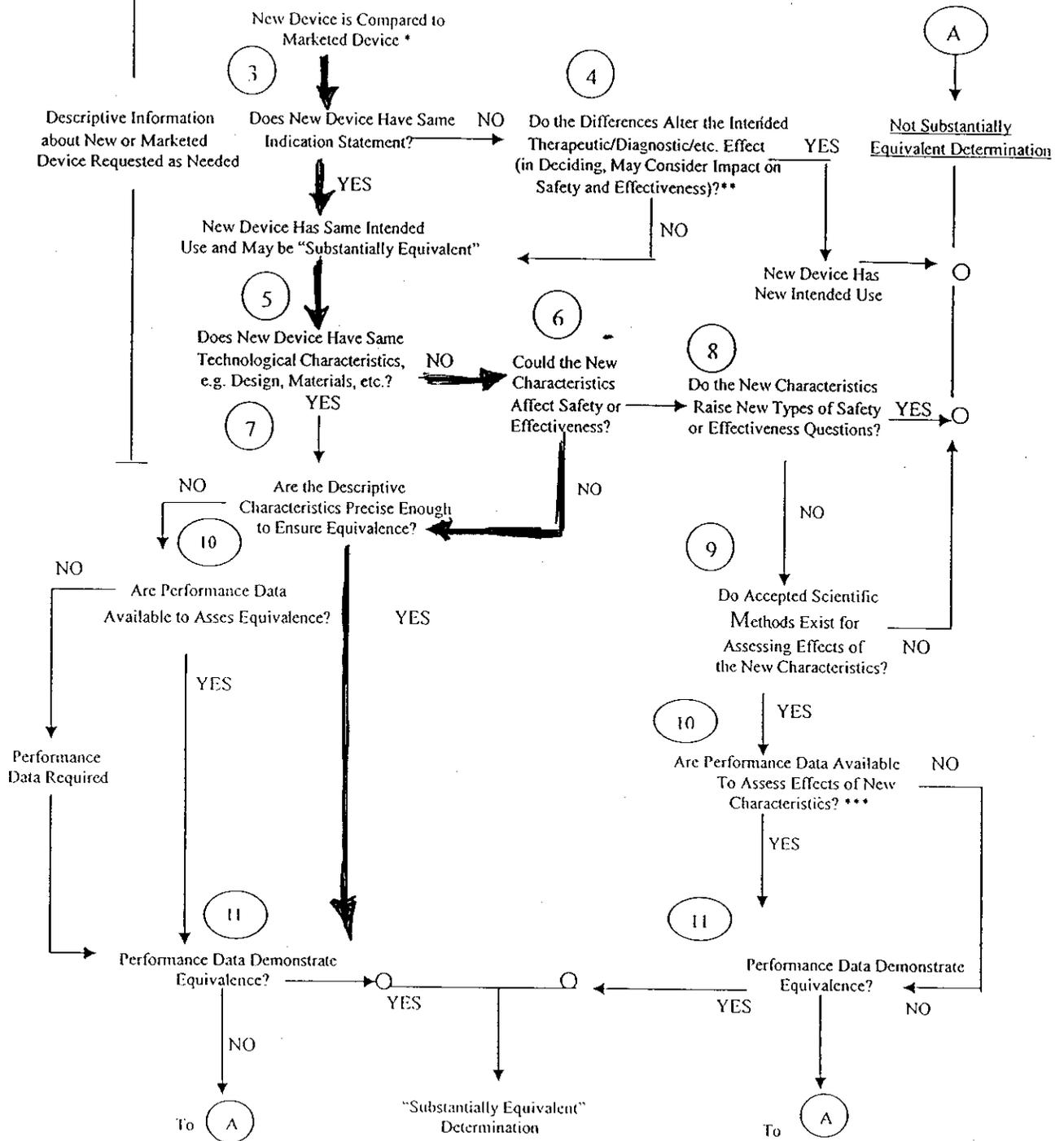
7/7/2005

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Table 1: Chart of Potential Risks

| Device Modification | Risk | Verification Activity | Acceptance Criteria | Results of Verification |
|-----------------------------|------|-----------------------|---------------------|-------------------------|
| (b)(4) Trade Secret Process | | | | |

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.