OCT 27 2005

510(k) Summary of Safety and Effectiveness

Line Extension to the Alumina V40™ Ceramic Femoral Heads

Proprietary Name:	V40™ 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:	September 28, 2005

Device Description

The subject V40™ Biolox® delta Ceramic Femoral Heads mate with Howmedica Osteonics' V40™ taper femoral stems fabricated from Titanium, CoCr or stainless steel alloys. The V40™ Biolox® delta Ceramic Femoral Heads are available in 28, 32 and 36 mm diameters and a variety of neck offsets.

Device Modification

This submission modifies the material of the Alumina V40™ Ceramic Femoral Heads from alumina to Zirconoia Toughened Alumina (ZTA) and adds additional offsets of 28 and 36mm diameter heads.

Indications for Use

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Asceptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations 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

Substantial Equivalence

The features of the new components are substantially equivalent to the predicate devices based on similarities in intended use 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, manufacturing methods, packaging, and sterilization of the predicate and new components are identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2005

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

Re: K052718
Trade/Device Name: V40™ Biolox® delta Ceramic Femoral Heads (Line Extension to the Alumina V40™ 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: September 28, 2005
Received: September 29, 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,

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

Enclosure

Indications for Use

510(k) Number (if known): K052718

Device Name: Biolox® delta V40™ Ceramic Femoral Heads

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
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- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Asceptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations 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

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)

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

510(k) Number K052718

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2005

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

Re: K052718
Trade/Device Name: V40™ Biolox® delta Ceramic Femoral Heads (Line Extension to the Alumina V40™ Ceramic Femoral Heads)
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Dear Ms. Ariemma:

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Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K052718

Device Name: Biolox® delta V40™ Ceramic Femoral Heads

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
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- Pathological considerations 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

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)

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

510(k) Number K052718

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 29, 2005

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

510(k) Number: K052718
Received: 29-SEP-2005
Product: V40 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. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/cdrh/oivd/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

17

K052718

stryker
Howmedica
OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

Via Federal Express

September 28, 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

Re: Special 510(k) Notification: Line Extension to the Alumina V40™ 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 line extension to the Alumina V40™ Ceramic Femoral Heads which was cleared via 510(k)s K003413 and K023901.

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.

18

K-10

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 line extension to the Alumina V40™ 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.

Karen Ariemma

Senior Regulatory Affairs Specialist

Indications for Use

510(k) Number (if known): _____

Device Name: Biolox® delta V40™ Ceramic Femoral Heads

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

For Use as a Total Hip Replacement:

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Other Considerations:

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- Salvage of failed total hip arthroplasty

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)

stryker
Howmedica
OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

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 that no material facts have been willfully omitted.

Karen Ariemma

Senior Regulatory Affairs Specialist

9/28/05

Date

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

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

PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Secret
Write the Payment Identification number on your check.

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

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

-->

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

HOWMEDICA OSTEONICS CORP
325 CORPORATE DR
MAHWAH NJ 07430
US

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/dc/mdufma

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

3.1 Select one of the types below
[X] Original Application
Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

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

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

[ ] YES [X] NO

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

Form FDA 8601 (08/2003)

Close Window

Print Cover sheet

SPECIAL 510(k) PREMARKET NOTIFICATION

LINE EXTENSION TO THE ALUMINA V40™ CERAMIC FEMORAL HEADS

Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, NJ 07430

September 28, 2005

TABLE OF CONTENTS

510(k) Summary of Safety and Effectiveness
Line Extension to the Alumina V40™ Ceramic Femoral Heads

Proprietary Name:	V40™ 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:	September 28, 2005

Device Description

The subject V40™ Biolox® delta Ceramic Femoral Heads mate with Howmedica Osteonics' V40™ taper femoral stems fabricated from Titanium, CoCr or stainless steel alloys. The V40™ Biolox® delta Ceramic Femoral Heads are available in 28, 32 and 36 mm diameters and a variety of neck offsets.

Device Modification

This submission modifies the material of the Alumina V40™ Ceramic Femoral Heads from alumina to Zirconoia Toughened Alumina (ZTA) and adds additional offsets of 28 and 36mm diameter heads.

Indications for Use

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

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Other Considerations:

- Pathological considerations 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

Substantial Equivalence

The features of the new components are substantially equivalent to the predicate devices based on similarities in intended use 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, 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:	V40™ 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 Alumina (Biolox® forte) V40™ Ceramic Femoral Heads. This submission modifies the material of the femoral heads from Alumina to Biolox® delta (Zirconia Toughened Alumina). The Alumina V40™ Ceramic Femoral Heads remain available.

Predicate Device History and Description

The Alumina V40™ Ceramic Femoral Heads were determined substantially equivalent via 510(k)s K003413 and K023901. The Alumina V40™ Ceramic Femoral Heads can be used with any Howmedica Osteonics' V40™ femoral stems fabricated from titanium or stainless steel alloy. The Alumina V40™ Ceramic Femoral Heads were cleared for use with Howmedica Osteonics' N_2Vac Acetabular Inserts, Crossfire® Acetabular Inserts and Trident® X3™ Acetabular Inserts. The Alumina V40™ Ceramic Femoral Heads are available in the following sizes:

- 28mm diameter with neck lengths of -2.7mm, +0mm, +4.0mm,
- 32mm diameter with neck lengths of –4.0mm, +0mm, +4.0mm,
- 36mm diameter with neck lengths of –5.0mm, +0mm, +5.0mm.

The C-Taper Biolox® delta Ceramic Femoral Heads were determined substantially equivalent via 510(k) K041940 and K051588. The Biolox® delta Ceramic Femoral Heads can be used with Howmedica Osteonics' C-Taper femoral stems fabricated from Titanium alloy or Cobalt Chromium Alloy. The Biolox® delta Ceramic Femoral Heads were cleared for use with Howmedica Osteonics' N_2Vac, Crossfire® Acetabular Inserts and Trident® X3™ Acetabular Inserts. The Biolox® delta Ceramic Femoral Heads are available in the following sizes:

- 28mm diameter with neck lengths of –2.5mm, +0mm, +2.5mm, +5.0mm
- 32mm diameter with neck lengths of –2.5mm, +0mm, +2.5mm, +5.0mm
- 36mm diameter with neck lengths of –5 mm, –2.5mm, +0mm, +2.5mm, +5mm, +7.5

Description of Device Modification

The line extension to the V40™ Alumina Ceramic Femoral Heads involves two changes. These changes are described below.

1. Change in material

The material of the V40™ Ceramic Femoral Heads will be changed from alumina to Zirconia-Toughened-Alumina (Biolox® Delta) material. This material is (b)(4)Trade Secret Process [redacted]1

2. 28mm and 36 mm diameter V40™ Biolox® Delta Ceramic Femoral Heads: Additional Offsets

The predicate 28 mm diameter Alumina Ceramic Femoral Heads are available in the following offsets: –2.7mm, +0mm, +4.0mm. The subject 28 mm diameter V40™ Biolox® delta Ceramic Femoral Heads are available in the following offsets –4.0mm, –2.7mm, +0mm, +4.0mm. The predicate 36 mm diameter Alumina Ceramic Femoral Heads are available in the following offsets: –5.0mm, +0mm, +5.0mm. The subject 36 mm diameter V40™ Biolox® delta Ceramic Femoral Heads are available in the following offsets –5 mm, –2.5mm, +0mm, +2.5mm, +5mm, +7.5. Refer to subject component list in Appendix A-1, page 20 and the engineering drawings in Appendix A-2, page 21

The V40™ Biolox® delta Ceramic Femoral Heads are available in the following sizes:

- 28mm diameter with neck lengths of –4.0mm, -2.7 mm, +0mm, +4.0mm,
- 32mm diameter with neck lengths of –4.0mm, +0mm, +4.0mm,
- 36mm diameter with neck lengths of –5 mm, –2.5mm, +0mm, +2.5mm, +5mm, +7.5.

The V40™ Biolox® delta Ceramic Femoral Heads can be used with Howmedica Osteonics' femoral V40™ stems fabricated from Titanium alloy, Cobalt Chromium Alloy or Stainless Steel

alloy. The V40™ Biolox® delta Ceramic Femoral Heads are compatible with the acetabular components listed in Appendix A-3, page 35.

Indications for Use

The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

For Use as a Total Hip Replacement:

- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
- Revision of previous cup arthroplasty or other procedures.
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement

- Femoral head/neck fractures or non-unions.
- Asceptic necrosis of the femoral head.
- Osteo-, rheumatoid, and post traumatic arthritis of the hip with minimal acetabular involvement or distortion.

Other Considerations:

- Pathological considerations 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.

Materials

The subject Biolox ® delta Ceramic Femoral Heads are fabricated from Zirconia Toughened Alumina (ZTA) which is composed of (b)(4)Trade Secret Process [redacted]

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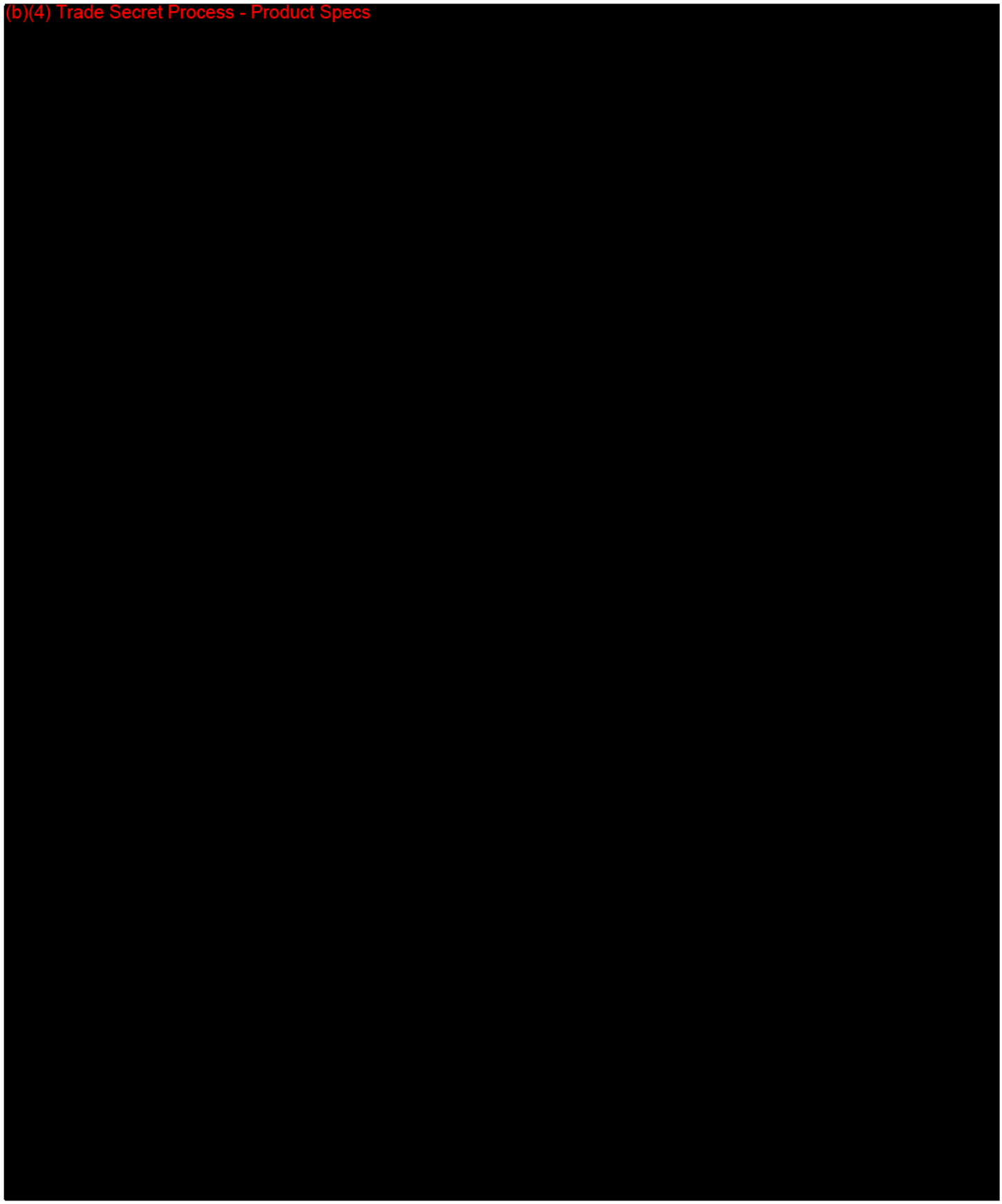
[redacted] (b)(4)Trade Secret Process [redacted]

Design Control

Analyses were performed to evaluate the potential risks associated with the changes made to the V40™ Alumina Ceramic Femoral Heads. Mechanical testing was used to assess whether the subject device falls within preestablished acceptance criteria. The overall risk analysis method used was FMEA. [redacted] (b)(4)Trade Secret Process [redacted] All test results exceed the minimum requirements from the FDA Guidance Document. [redacted] (b)(4) [redacted]

(b)(4) Trade Secret Process - Product Specs



(b)(4)Trade Secret Process

1. Mak et al: Analysis of contact mechanism in ceramic on ceramic hip joint replacements. Proc Instn. Mech Engrs Vol 216 Part H: J. Engineering in Medicine P231, 2002

Table 1: Chart of Potential Risks

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
[redacted]				

(b)(4)Trade Secret Process

Declaration of Conformity

A Declaration of Conformity stating each of the following may be found in Appendix D, page 69.

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 71.

Sterility Information

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

Sterilization Method:

Gamma Irradiation - Cobalt 60 Isotope

Dose 25kGy

Validated according to ANSI/AAMI/ISO 11137

SAL - 10^{-6}

Sterilization/Packaging Information

[redacted] (b)(4)Trade Secret [redacted]

(b)(4)Trade Secret Process

[redacted]

Labeling

Refer to Appendix B for product labeling and instructions for use for V40™ Biolox® delta Ceramic Femoral Heads. The instructions for use was updated to reflect the compatibility of the V40™ Biolox® delta Ceramic Femoral Heads with the appropriate Howmedica Osteonics' femoral stems.

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 Secret [redacted]

APPENDIX A: COMPONENT INFORMATION

A-1 Catalog Numbers for the Subject V40™ Biolox® delta Ceramic Femoral Heads

A-2 Engineering Drawings for the Subject V40™ Biolox® delta Ceramic Femoral Heads

A-3 Acetabular Insert Compatibility Chart

Appendix A-1

Catalog Numbers for the Subject V40™ Biolox® delta Ceramic Femoral Heads

Catalog Number	Head Diameter (mm)	Neck Offset (mm)
6570-0-028	28	-4.0
6570-0-328	28	-2.7
6570-0-128	28	+0
6570-0-228	28	+4.0
6570-0-032	32	-4.0
6570-0-132	32	+0
6570-0-232	32	+4.0
6570-0-036	36	-5
6570-0-436	36	-2.5
6570-0-136	36	+0
6570-0-536	36	+2.5
6570-0-236	36	+5
6570-0-736	36	+7.5

Appendix A-2

Engineering Drawings for the Subject V40™ Biolox® delta Ceramic Femoral Heads

- CONFIDENTIAL -

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

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(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

(b)(4)Trade Secret Process - Engineering Drawings

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

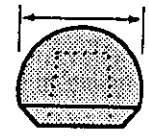
Appendix B-1

Draft Label for the Subject Components

Catalog No. 6570-0-028

BIOLOX® delta Ceramic
V40™ Head

28mm



-4

- Use only with V40™ Taper Stems
- 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

+H825657000280F

+$$8010910CASECASECAF2

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

2010-09

Al_2O_3

ZrO2

STERILE R

CE 0086

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

QIN 4350

Howmedica Osteonics® Trident® Acetabular Component System and Howmedica Osteonics® Alumina and BIOLOX® *delta* Ceramic Heads

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 but not limited to 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® Corp. 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.

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- 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.
- Howmedica Osteonics V40™ BIOLOX® *delta* Ceramic Heads can be used with Howmedica Osteonics V40™ titanium, CoCr or stainless steel 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 (Al_2O_3)	Alumina Ceramic Head
• Zirconia Toughened Aluminum Oxide	Delta Ceramic Head
• ASTM F-648 Ultra-High Molecular Weight Polyethylene (UHMWPE)	Acetabular Bearing Insert

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Indications

- 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.

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- 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.

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- 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. Secondarily, 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 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, hydrogen peroxide, or ethylene oxide. Refer to the package label for the sterilization method.
- Do NOT re-sterilize.
- 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 the product is not sterile.
- Take care to prevent contamination of ANY components.
- Discard ALL nonsterile or contaminated product.

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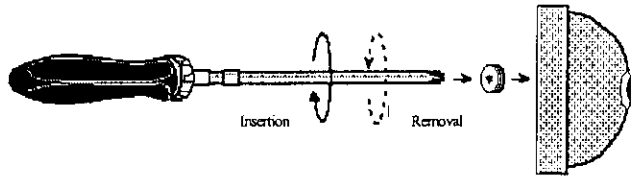
DOME HOLE PLUG ASSEMBLY INSTRUCTIONS

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 trademark of Cerasiv GmbH Innovatives Keramick-Engineering and CeramTec AG Innovative Ceramic Engineering.

CAUTION: **FEDERAL LAW (U.S.A) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.**

APPENDIX C: MECHANICAL TESTING AND ANALYSIS

(b)(4) Trade Secret Process - Product Specs

Appendix C-1: [redacted] (b)(4) Trad [redacted]

- CONFIDENTIAL -

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

1. Introduction

The Biolox Delta ceramic is a new improved alumina ceramic material or alumina composite developed by CeramTec. It demonstrated the increased fracture toughness while still maintaining the superior wear characteristics. The purpose of this study was to qualify the Biolox Delta V40 taper femoral head under standard lab test conditions.

2. Materials and Methods

2.1 Test Samples

(b)(4)

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(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

Appendix C-2: (b)(4) Trade Secret Process - Product Specs

- CONFIDENTIAL -

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

Appendix C-3: [redacted]

(b)(4) Trade Secret

[redacted]

Process - P d t

- CONFIDENTIAL -

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(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

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(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

(b)(4)Trade Secret Process - Testing Report

APPENDIX D

DECLARATION OF CONFORMITY

stryker
Howmedica
OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

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.

Marie Moindreau
Project Manager

27/08/2005
Date

APPENDIX E

STATEMENT OF SCIENTIFIC TECHNOLOGY AND INDICATIONS

stryker
Howmedica
OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

STATEMENT OF SCIENTIFIC TECHNOLOGY AND INDICATIONS

The indications for use of the subject V40™ Biolox® delta Ceramic Femoral Heads as described in the labeling have not changed from the indications for use of the currently available V40™ Alumina Ceramic Femoral Heads cleared via 510(k)s K003413 and K023901.

In addition, the fundamental scientific technology of the subject V40™ Biolox® delta Ceramic Femoral Heads as described in the labeling has not changed from that of the V40™ Alumina Ceramic Femoral Heads cleared via 510(k)s K003413 and K023901.

Karen Ariemma
Senior Regulatory Affairs Specialist

9/28/05
Date

APPENDIX F

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

(b)(4)Trade Secret Process

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Memorandum

From: Reviewer(s) - Name(s) Hollace Saas Rhodes

Subject: 510(k) Number K052718

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.a.

☒ 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-LZO, Class II

Review: [signature] ORDB 10/27/05
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] 10/27/05
(Division Director) (Date)

Revised:4/2/03

"SPECIAL" 510(k) MEMORANDUM

TO: **K05-2718**

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

10/27/05

DATE: October 27, 2005

SUBJ: V40™ 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, Howmedica Osteonics Corp.
201.831.5718

Recommendation:

This document was reviewed as a "Special 510(k)" using the Alumina V40™ Femoral Heads (K00-3413 and K02-3901) as the predicate device for the subject device. Differences between the subject device and predicate device do not affect the substantial equivalence of V40™ Biolox® delta Ceramic Femoral Heads. Therefore, I recommend that the subject device be found substantially equivalent to legally marketed devices.

Review:

1. **Predicate Devices:**
Alumina V40™ Femoral Heads (K00-3413 and K02-3901).

2. **Device description:**
V40™ Biolox® delta Ceramic Femoral Heads
   1. The V40™ Biolox® delta Ceramic Femoral Heads are made of a ceramic composite (i.e., [redacted] (b)(4) Trade
   2. The heads can be used with Howmedica Osteonics' femoral V40™ stems fabricated from titanium alloy, cobalt chromium alloy, or stainless steel alloy. See sponsor's October 27, email for a list of mating stems.
   3. These ceramic femoral heads can be used with Howmedica Osteonics N_2Vac, Crossfire, and Trident® X3™ Acetabular Inserts. See Appendix A-3 for a list of the acetabular components with their 510(k) number.

[redacted] (b)

Differences from Predicate:

- The material of the femoral heads is modified from Alumina to Biolox® delta (Zirconia Toughened Alumina). Note: Howmedica Osteonics femoral heads made of Biolox® delta were cleared in K04-1940 and K05-1588; these heads have a C-Taper instead of a V40™ taper.

- The predicate Alumina heads could be mated with V40™ tapers on stems made of titanium and stainless steel alloy; the subject Biolox® delta heads can be used with V40™ tapers on stems fabricated from titanium, cobalt chromium, and stainless steel alloy.
- Additional head offsets are to be made available relative to the sizes and number available with the Alumina V40™ heads. See Table 1 below.

Table 1 – Ceramic Head Neck Offset Availability

Femoral Head Diameter	V40™ Biolox® delta Ceramic Femoral Heads (Subject Device)	Alumina V40™ Femoral Heads (K00-3413 and K02-3901)
28mm	-4.0mm	
	-2.7mm	-2.7mm
	+0mm	+0mm
	+4.0mm	+4.0mm
32mm	-4.0mm	-4.0mm
	+0mm	+0mm
	+4.0mm	+4.0mm
36mm	-5.0mm	-5.0mm
	-2.5mm	
	+0mm	+0mm
	+2.5mm	
	+5.0mm	+5.0mm
	+7.5mm	

The sponsor states on page 72 that the fundamental scientific technology of the modified device has not changed.

3. **Intended Use:**
The indications for use of the subject device, in keeping with those of other legally marketed Howmedica Osteonics' ceramic femoral bearing heads are as follows:

For Use as a Total Hip Replacement:
- Painful disabling joint disease of the hip resulting from: degenerative arthritis, rheumatoid arthritis, post-traumatic arthritis or late stage vascular necrosis.
- Revision of previous cup arthroplasty or other procedures
- Clinical management problems where arthrodesis or alternative reconstructive techniques are less likely to achieve satisfactory results.

For Use as a Bipolar Hip Replacement:
- 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.

Other Considerations:
- Pathological considerations 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

Differences from Predicate:
- None. The indications list above are identical to the indications in K00-3413.

The sponsor states on page 72 that the intended use of the modified device has not changed.

4. **Labeling:**
Page 17 states that the instructions for use in the package insert were updated to reflect the compatibility of the V40™ Biolox® delta Ceramic Femoral Heads with stems fabricated from titanium alloy, cobalt chromium alloy, or stainless steel alloy.

Differences from Predicate:
- The predicate Alumina V40™ Femoral Heads are compatible with stems fabricated from titanium alloy or stainless steel alloy (not cobalt chromium alloy).

5. **Design Control Activities:**
[redacted] (b)(4) Trade

6. **Declaration of Conformity with Design Controls:**
   a. The sponsor provided a statement that all verification and validation activities were performed by the appropriately designated individual(s), and the results demonstrated that the predetermined acceptance criteria were met. It was signed by Marie Moindreau.
   b. The sponsor provided 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. It was signed by Marie Moindreau.

7. **Contact History/Requests for More Information:**
10-26-05 An email requesting the following was sent to Karen Ariemma:
1. [redacted] (b)(4) Trade Secret Process
2. In Appendix A-3 you provided the list of acetabular components and their 510(k) numbers with which the V40™ Biolox® delta Ceramic Femoral Heads can be used. Please provide a similar list for the femoral stems with which these femoral heads may be mated. In addition to the 510(k) number, please identify the stem material.

8. Decision-Making Rationale:

This document was reviewed as a "Special 510(k)" using the Alumina V40™ Femoral Heads (K00-3413 and K02-3901) as the predicate device for the subject device. Differences between the subject device and predicate device do not affect the substantial equivalence of V40™ Biolox® delta Ceramic Femoral Heads. Therefore, I recommend that the subject device be found substantially equivalent to legally marketed devices.

		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? *No, the material of the femoral heads is modified from Alumina to Biolox® delta (Zirconia Toughened Alumina).*		No	If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness? *Yes, the change in material may affect the burst strength of the modified femoral heads.*	Yes		If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?			If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions? *No, whether the femoral head has adequate strength is the same question as with the predicate head.*		No	If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist? *Yes, Howmedica Osteonics revised their DCAS to include the risk of "hydrothermic instability." See 10-26-05 Contact History in Section 7 of this memo and revised DCAS in their October 27, email.*	Yes		If **NO** = Stop **NE**
10.	Performance Data Available? *Yes, see revised DCAS in their October 27, email.*	Yes		If **NO** = Request Data
11.	Data Demonstrate Equivalence? *Yes, see revised DCAS.*	Yes		Final Decision: **SE**

Rhodes, Hollace

n: Ariemma, Karen [karen.ariemma@stryker.com]
Sent: Thursday, October 27, 2005 10:31 AM
To: Rhodes, Hollace
Subject: RE: K05-2718, V40 Biolox® delta Ceramic Femoral Heads, Request for Additional Information

Holly,

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

Karen Ariemma
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karen.ariemma@stryker.com

-----Original Message-----
From: Rhodes, Hollace [mailto:HXS@CDRH.FDA.GOV]
Sent: Wednesday, October 26, 2005 9:43 AM
To: Ariemma, Karen
Subject: K05-2718, V40 Biolox® delta Ceramic Femoral Heads, [redacted] (b)(4)Trade

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

(b)(4)Trade Secret Process

Holly

Hollace Rhodes

Biomedical Engineer

Food & Drug Administration

Orthopedic Devices Branch

301.594.2036, Ext. 165

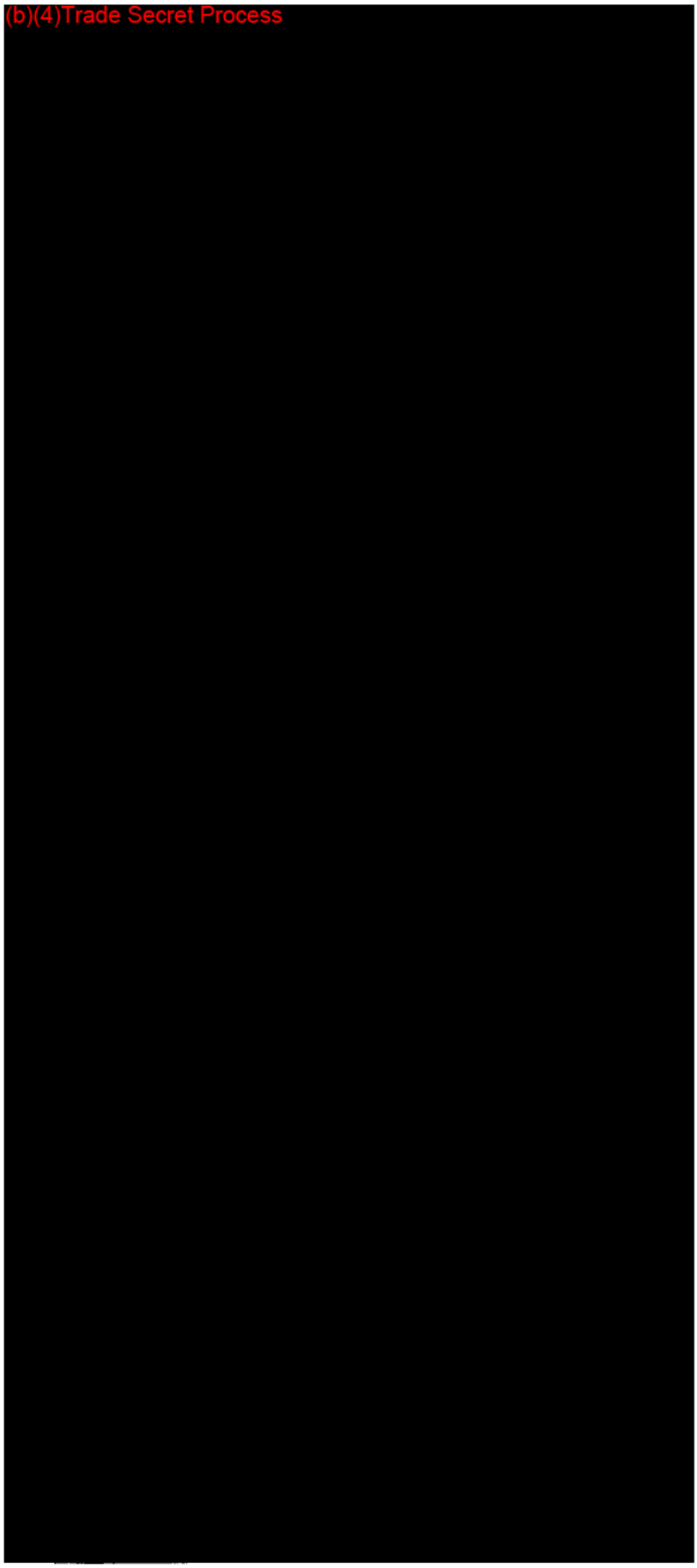
301.827.4349, Fax

hollace.rhodes@fda.hhs.gov

Table 1: Chart of Potential Risks

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
[redacted]				

(b)(4)Trade Secret Process


(b)(4)Trade Secret Process

Product Name	Material	510(k) Reference
Accolade HFx	ASTM F799 ASTM F1580	K051741
Accolade RPS	ASTM F1813 ASTM F1580 ASTM F1185	K052542
Accolade TMZF	ASTM F1813 ASTM F1580 ASTM F1185	K994366 K020572 K023102
Accolade C	ASTM F799	K002320 K022555
Citation AT	ASTM F799	K955871
Citation TMZF	ASTM F1813 ASTM F1185 ASTM F1580	K993768
Definition PM	ASTM F799	K936127
Exeter	ASTM F1586	K011623
Meridian TMZF	ASTM F1813 ASTM F1580	K940307 K972228
Meridian PA	ASTM F799 ASTM F1185	K971206
Meridian ST	ASTM F799	K940307
Reliance CM	ASTM F799	K936126 K940307
Reliance PF	ASTM F1537	K970200
Restoration HA	ASTM F620 ASTMF1580	K944836
Restoration Modular (MT3 Body)	ASTM F620	K040734
Restoration Modular (Cone, Broached, and Milled Bodies)	ASTM F620 ASTM F1580 ASTM F1185 ASTM F136 (bolt)	K013106 K022549 K040734
Restoration Modular (Calcar Body)	ASTM F620 ASTM F1580 ASTM F1185 ASTM F136 (bolt) ASTM F1573 (bushing) ASTM F90 (bushing)	K050137

Rhodes, Hollace

From: Rhodes, Hollace
Sent: Wednesday, October 26, 2005 9:43 AM
To: 'Ariemma, Karen'
Subject: K05-2718, V40 Biolox® delta Ceramic Femoral Heads, Request for Additional Information

(b)(4)Trade Secret Process

[redacted]

Holly

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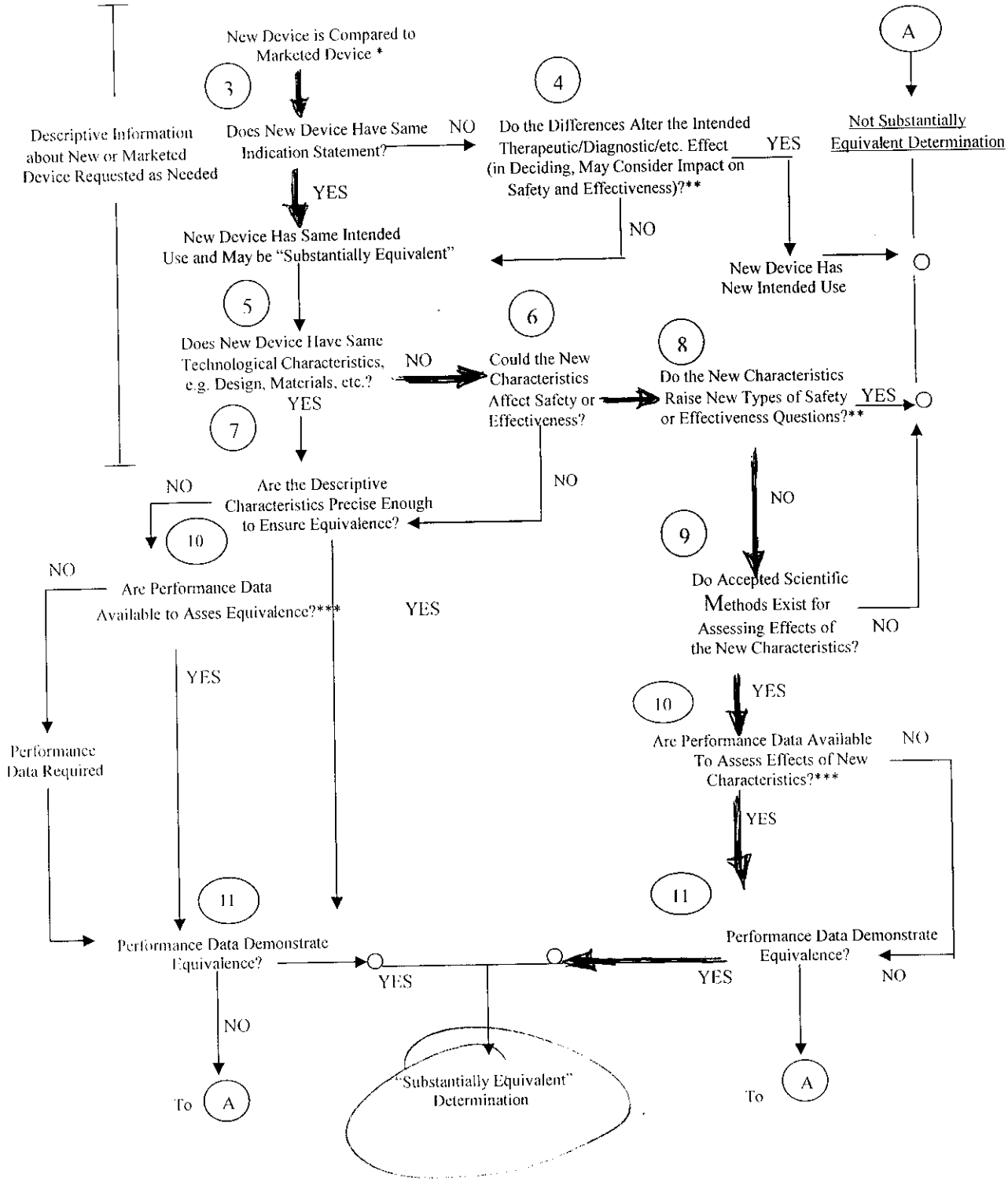
Internal Administrative Form

	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.	—	

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.