

Summary of Safety and Effectiveness for  
Smith & Nephew BioloX Delta Ceramic Femoral Heads

MAR 11 2009

**Contact Person and Address**

Mandy L. Coe  
Regulatory Affairs Specialist  
Smith & Nephew, Inc.  
Orthopaedic Division  
1450 E. Brooks Road  
Memphis, Tennessee 38116  
(901) 399-6277

Date of Summary: August 27, 2008

**Name of Device:** Smith & Nephew BioloX Delta Ceramic Femoral Heads**Common Name:** Femoral Head**Device Classification:** 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis – Class II**Device Product Code:** LZO**Device Description**

The BioloX Delta Ceramic femoral heads feature a 12/14 taper and are intended to be used with existing Smith & Nephew femoral hip stems. The ceramic femoral head mechanically locks with the femoral hip stem via a taper junction and articulates against a Smith & Nephew polyethylene acetabular liner. The subject devices are similar in design and function to the BioloX Forte Alumina Ceramic femoral heads cleared via 510(k) premarket notifications K981847, K991162, and K022958 respectively.

**Mechanical Testing**

A review of the mechanical data indicated that the Smith & Nephew BioloX Delta Ceramic femoral heads are equivalent to devices currently cleared for market and are capable of withstanding expected *in vivo* loading without failure.

**Intended Use**

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. The BioloX Delta Ceramic femoral heads are for single use only.

**Substantial Equivalence Information**

The Smith & Nephew BioloX Delta Ceramic femoral heads are similar in overall design, material and indications to the Smith & Nephew BioloX Forte Alumina Ceramic femoral heads cleared via 510(k) premarket notifications K981847, K991162, and K022958 as well as the Zimmer BioloX Delta Ceramic femoral heads cleared via K071535.



MAR 11 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Smith & Nephew, Inc.  
% Ms. Mandy Coe  
Regulatory Affairs Specialist  
1450 E. Brooks Road  
Memphis, Tennessee 38116

Re: K083762

Trade/Device Name: 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  
Regulation Class: Class II  
Product Code: LZO  
Dated: February 27, 2009  
Received: March 2, 2009

Dear Ms. Coe:

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.

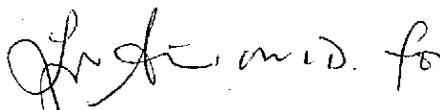
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure





MAR 11 2009

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Smith & Nephew, Inc.  
% Ms. Mandy Coe  
Regulatory Affairs Specialist  
1450 E. Brooks Road  
Memphis, Tennessee 38116

Re: K083762

Trade/Device Name: 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  
Regulation Class: Class II  
Product Code: LZO  
Dated: February 27, 2009  
Received: March 2, 2009

Dear Ms. Coe:

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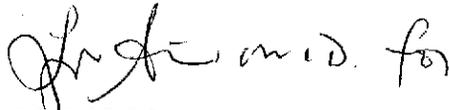
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Sincerely yours,



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

Enclosure





March 03, 2009

SMITH & NEPHEW, INC.  
1450 BROOKS RD.  
MEMPHIS, TENNESSEE 38116  
UNITED STATES  
ATTN: MANDY COE

510k Number: K083762

Product: BIOLOX DELTA CERAMIC FEMORAL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at [www.fda.gov/cdrh/ode/a02-01.html](http://www.fda.gov/cdrh/ode/a02-01.html). On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

February 27, 2009

Office of Device Evaluation  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

RECEIVED  
FEB 27 2009  
OFFICE OF DEVICE EVALUATION  
CENTERS FOR DEVICE AND RADIOLICAL HEALTH  
FOOD AND DRUG ADMINISTRATION  
9200 CORPORATE BLVD  
ROCKVILLE, MD 20850

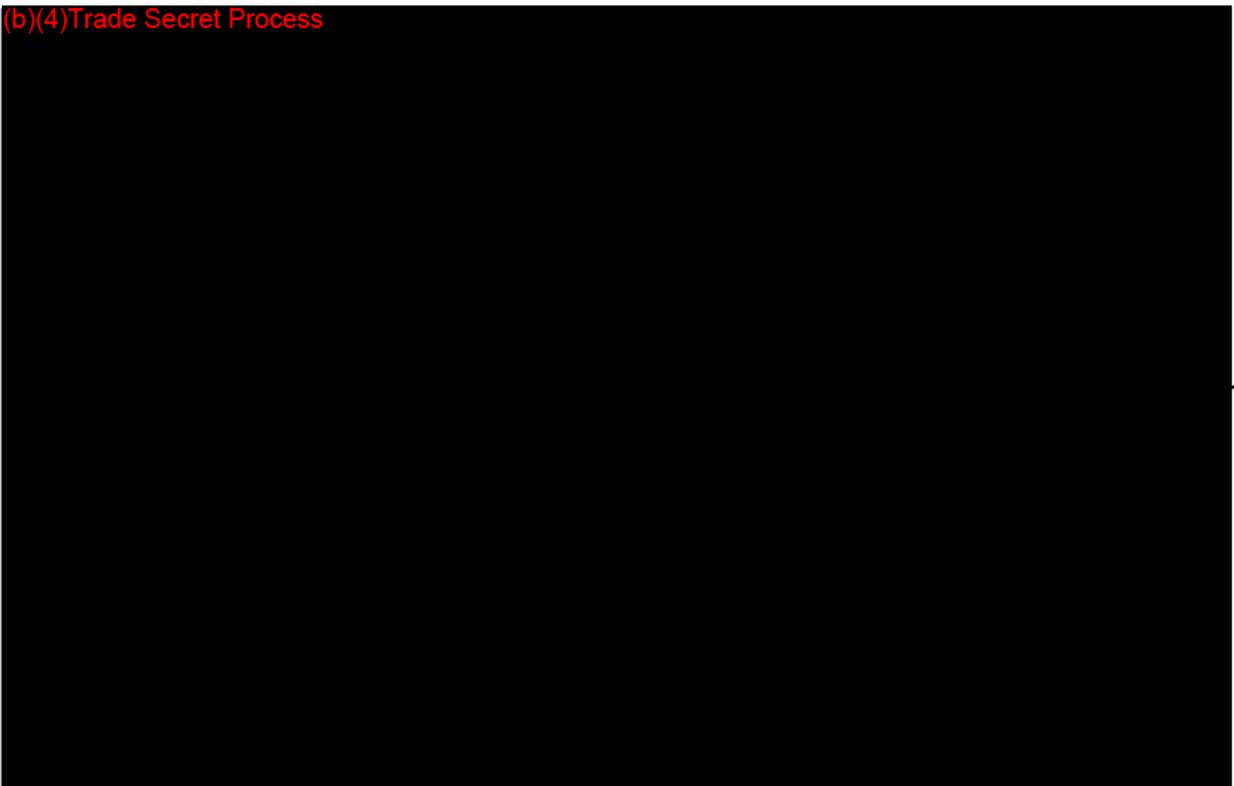
Attn: Mr. Ronald Jean

**RE: "Telephone Hold" K083762 – Smith & Nephew BioloX Delta Ceramic Femoral Heads**

Dear Mr. Jean:

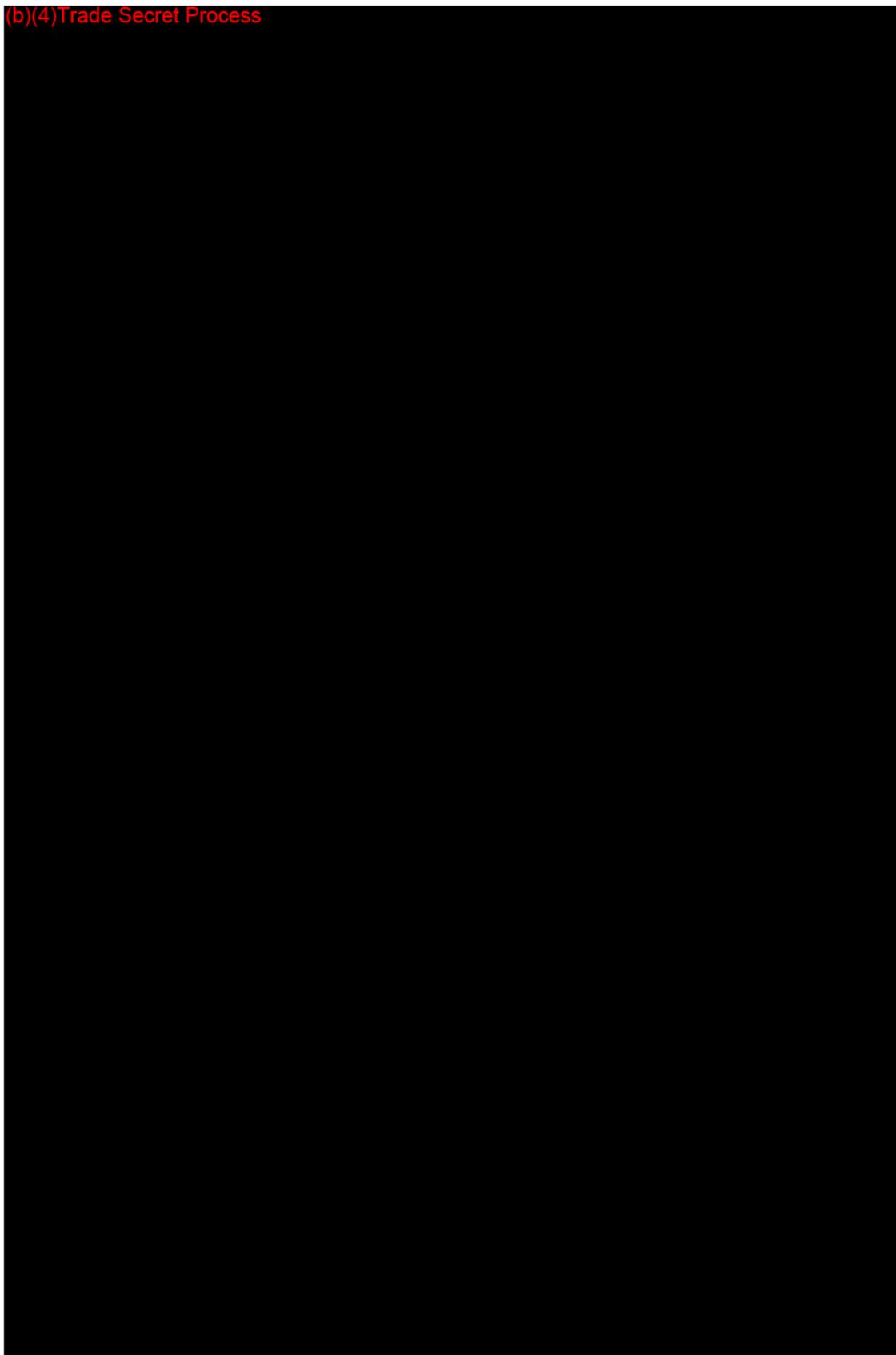
Pursuant to a "Telephone Hold" from the Food and Drug Administration dated January 12, 2009, during which FDA requested clarification and/or additional information relevant to 510(k) K083762, we are providing the following information and documentation via FedEx. Please refer to Exhibit 1 to review a copy of the FDA letter containing the inquiries we received regarding the Special 510(k) K083762.

(b)(4)Trade Secret Process

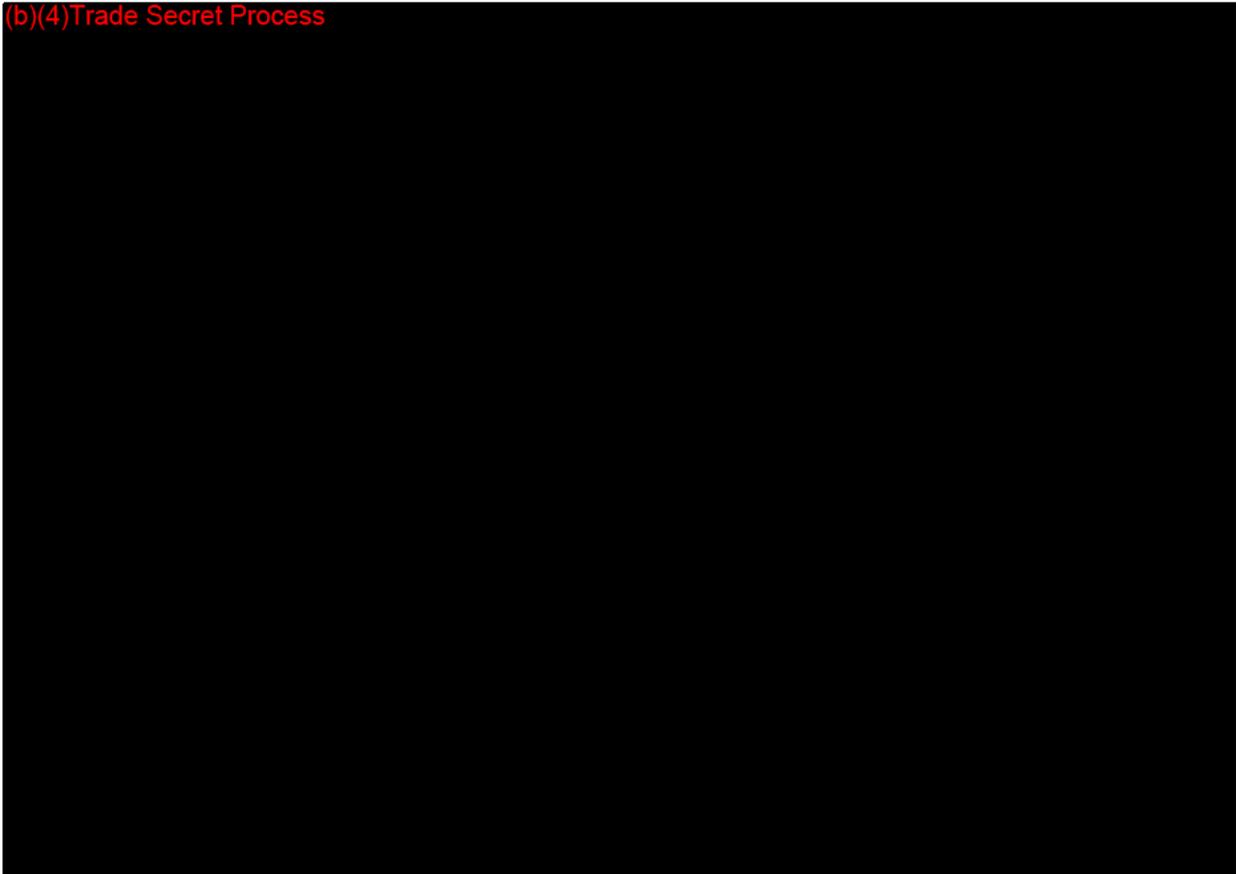


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(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



We believe the above clarification, as well as the attached documentation, is responsive to the questions. However, if you have further questions, or require additional information, please contact me directly at 901-399-6277 or via email at [mandy.coe@smithnephew.com](mailto:mandy.coe@smithnephew.com) as soon as possible.

We appreciate you working with us to resolve these issues quickly.

Sincerely,



Mandy Coe  
Regulatory Affairs Specialist



February 02, 2009

SMITH & NEPHEW, INC.  
ORTHOPAEDICS  
1450 BROOKS RD.  
MEMPHIS, TENNESSEE 38116  
UNITED STATES  
ATTN: MANDY COE

510k Number: K083762

Product: BIOLOX DELTA CERAMIC FEMORAL H

Extended Until: 03/16/2009

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

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

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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

Orthopaedic Reconstruction  
Orthopaedic Trauma & Clinical Therapies  
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F + 901 399 6174  
www.smith-nephew.com

 We are **smith&nephew**

K083762

January 29, 2009

**Mr. Ronald Jean**  
Office of Device Evaluation  
Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, MD 20850

FDA CDRH DMC

FEB 2 2009

Received

**Attn: Ronald Jean**

**Re: K083762 – Traditional 510(k): Smith & Nephew BioloX Delta Ceramic Femoral Heads**

Dear Mr. Jean:

Please allow this letter to serve as Smith & Nephew Inc.'s request to keep the BioloX Delta Ceramic Femoral Head Special Premarket Notification filing open for an additional 60 days. Should you have any additional questions or concerns related to the subject components, please do not hesitate to contact me directly at (901) 399-6277 or via email at [mandy.coe@smithnephew.com](mailto:mandy.coe@smithnephew.com).

Sincerely,



Mandy Coe  
Regulatory Affairs Specialist

K20



January 14, 2009

SMITH & NEPHEW, INC.  
ORTHOPAEDICS  
1450 BROOKS RD.  
MEMPHIS, TENNESSEE 38116  
UNITED STATES  
ATTN: MANDY COE

510k Number: K083762

Product: BIOLOX DELTA CERAMIC FEMORAL H

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

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

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

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (240)276-3150 or at their toll-free number (800) 638-2041, or contact the 510k staff at (240)276-4040.

Sincerely yours,

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



December 18, 2008

SMITH & NEPHEW, INC.  
ORTHOPAEDICS  
1450 BROOKS RD.  
MEMPHIS, TENNESSEE 38116  
UNITED STATES  
ATTN: MANDY COE

510k Number: K083762

Received: 12/18/2008

Product: BIOLOX DELTA CERAMIC FEMORAL H

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

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

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/cdrh/mdufma/index.html> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007” ([http://www.fda.gov/oc/initiatives/fdaaa/guidance\\_certifications.html](http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html)). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1655.pdf>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at [www.fda.gov/cdrh/ode/guidance/1567.html](http://www.fda.gov/cdrh/ode/guidance/1567.html). Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

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

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice [www.fda.gov/cdrh/devadvice/](http://www.fda.gov/cdrh/devadvice/)". If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have procedural questions, please contact the 510(k) Staff at (240)276-4040.

Sincerely yours,

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

KO 83762

We are smith&nephew

Orthopaedic  
Reconstruction  
Smith & Nephew, Inc.  
1450 Brooks Road  
Memphis, TN 38116  
USA

T 1-901-396-2121  
1-800-821-5700  
F 1 901-399 6174  
www.smith-nephew.com

ROA 0711 100

DEC 18 2008

Received

December 16, 2008

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

**RE: Special 510(k) Premarket Notification for Smith & Nephew BioloX Delta Ceramic Femoral Heads**

Dear Sir or Madam:

The purpose of this letter is to notify FDA of Smith & Nephew's intent to market BioloX Delta Ceramic Femoral Heads. Smith & Nephew is submitting this Special 510(k) in accordance with *The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, dated March 20, 1998. It is our belief that the devices subject of this submission are eligible for review under the Special 510(k) process given that they share the same fundamental scientific technology, intended use, and are manufactured from the same material as currently marketed devices.

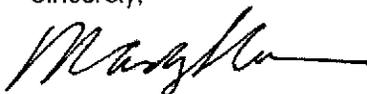
Per the requirements of a Special 510(k) filing, the following information is included:

- Items required under § 807.87, including a description of the modified device and a comparison to the cleared device, the intended use of the device, and the proposed labeling for the device;
- A concise summary of the design control activities;
- A Declaration of Conformity with Design Controls; and
- Indications for Use enclosure.

We consider our intent to market these devices to be confidential, commercial information and therefore exempt from public disclosure. We have taken precautions to protect confidentiality of the intent to market these devices.

We believe this information fulfills the present requirements for the Special 510(k) submission. Should additional clarification be needed or information be required, please contact me directly at 901-399-6277 or via email at [mandy.coe@smith-nephew.com](mailto:mandy.coe@smith-nephew.com).

Sincerely,



Mandy Coe  
Regulatory Affairs Specialist

R22

Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>MEDICAL DEVICE USER FEE COVER SHEET</b>		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. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>																					
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  SMITH AND NEPHEW INC 1450 BROOKS ROAD MEMPHIS TN 38116 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)		2. CONTACT NAME Mandy Coe 2.1 E-MAIL ADDRESS mandy.coe@smith-nephew.com 2.2 TELEPHONE NUMBER (include Area code) 901-3996277 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 901-3985146																			
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: <a href="http://www.fda.gov/dc/mdufma">http://www.fda.gov/dc/mdufma</a> )  Select an application type: <table border="0"> <tr> <td><input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party</td> <td>3.1 Select one of the types below</td> </tr> <tr> <td><input type="checkbox"/> 513(g) Request for Information</td> <td><input checked="" type="checkbox"/> Original Application</td> </tr> <tr> <td><input type="checkbox"/> Biologics License Application (BLA)</td> <td><u>Supplement Types:</u></td> </tr> <tr> <td><input type="checkbox"/> Premarket Approval Application (PMA)</td> <td><input type="checkbox"/> Efficacy (BLA)</td> </tr> <tr> <td><input type="checkbox"/> Modular PMA</td> <td><input type="checkbox"/> Panel Track (PMA, PMR, PDP)</td> </tr> <tr> <td><input type="checkbox"/> Product Development Protocol (PDP)</td> <td><input type="checkbox"/> Real-Time (PMA, PMR, PDP)</td> </tr> <tr> <td><input type="checkbox"/> Premarket Report (PMR)</td> <td><input type="checkbox"/> 180-day (PMA, PMR, PDP)</td> </tr> <tr> <td><input type="checkbox"/> Annual Fee for Periodic Reporting (APR)</td> <td></td> </tr> <tr> <td><input type="checkbox"/> 30-Day Notice</td> <td></td> </tr> </table>				<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party	3.1 Select one of the types below	<input type="checkbox"/> 513(g) Request for Information	<input checked="" type="checkbox"/> Original Application	<input type="checkbox"/> Biologics License Application (BLA)	<u>Supplement Types:</u>	<input type="checkbox"/> Premarket Approval Application (PMA)	<input type="checkbox"/> Efficacy (BLA)	<input type="checkbox"/> Modular PMA	<input type="checkbox"/> Panel Track (PMA, PMR, PDP)	<input type="checkbox"/> Product Development Protocol (PDP)	<input type="checkbox"/> Real-Time (PMA, PMR, PDP)	<input type="checkbox"/> Premarket Report (PMR)	<input type="checkbox"/> 180-day (PMA, PMR, PDP)	<input type="checkbox"/> Annual Fee for Periodic Reporting (APR)		<input type="checkbox"/> 30-Day Notice	
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<input type="checkbox"/> 30-Day Notice																					
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> 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. <table border="0"> <tr> <td><input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms</td> <td><input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population</td> </tr> <tr> <td><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</td> <td><input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially</td> </tr> </table>				<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"/> The sole purpose of the application is to support conditions of use for a pediatric population	<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 application is submitted by a state or federal government entity for a device that is not to be distributed commercially														
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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).)  <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO																					
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION		(b)(4)Trade Secret																			

25-Sep-2008

(b)(4)Trade Secret  
FDA 3601 (01/2007)

"Close Window" Print Cover sheet

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 11/10/2008	User Fee Payment ID Number <b>(b)(4)Trade</b>	FDA Submission Document Number (if known) Received
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**SECTION A TYPE OF SUBMISSION**

<b>PMA</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	<b>PMA &amp; HDE Supplement</b> <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA & HDE Supplement <input type="checkbox"/> Other	<b>PDP</b> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<b>510(k)</b> <input type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	<b>Meeting</b> <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify):
<b>IDE</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<b>Humanitarian Device Exemption (HDE)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<b>Class II Exemption Petition</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Evaluation of Automatic Class III Designation (De Novo)</b> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<b>Other Submission</b> <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):

Have you used or cited Standards in your submission?  Yes  No (If Yes, please complete Section I, Page 5)

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Smith & Nephew Inc.		Establishment Registration Number (if known) 1020279	
Division Name (if applicable) Orthopaedics		Phone Number (including area code) ( 901 ) 399-6277	
Street Address 1450 Brooks Road		FAX Number (including area code) ( 901 ) 398-5146	
City Memphis	State / Province TN	ZIP/Postal Code 38116	Country USA
Contact Name Mandy Coe			
Contact Title Regulatory Affairs Specialist		Contact E-mail Address mandy.coe@smith-nephew.com	

**SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)**

Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code) ( )	
Street Address		FAX Number (including area code) ( )	
City	State / Province	ZIP/Postal Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

**SECTION D1**

**REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other ( <i>specify below</i> )	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D2**

**REASON FOR APPLICATION - IDE**

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final		
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION D3**

**REASON FOR SUBMISSION - 510(k)**

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason ( <i>specify</i> ):		

**SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1 LZO	2	3	4	<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 510 (k) statement	
5	6	7	8		

Information on devices to which substantial equivalence is claimed (if known)					
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K981847	1	Bilox Alumina Ceramic Femoral Head	1	Smith & Nephew Inc.
2	K991162	2	Bilox Alumina Ceramic Femoral Head 28 mm long with CoCr stems	2	Smith & Nephew Inc.
3	K022958	3	Bilox Alumina Ceramic Femoral Head	3	Smith & Nephew Inc.
4	K071535	4	Bilox Delta Ceramic Femoral Heads	4	Zimmer Inc.
5		5		5	
6		6		6	

**SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification

	Trade or Proprietary or Model Name for This Device		Model Number
1	Bilox Delta Ceramic Femoral Heads	1	N/A
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

Laboratory Testing     
  Animal Trials     
  Human Trials

**SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code LZO	C.F.R. Section (if applicable) 21 CFR888.3353	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopaedics/87		

Indications (from labeling)

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; lipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

**Note:** Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

**SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION**

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	Facility Establishment Identifier (FEI) Number <b>(b)(4)Trade Secret</b>	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Smith & Nephew Inc.		Establishment Registration Number 1020279	
Division Name (if applicable) Orthopaedics		Phone Number (including area code) ( 901 ) 399-6277	
Street Address 1450 Brooks Road		FAX Number (including area code) ( 901 ) 398-5146	
City Memphis		State / Province TN	ZIP/Postal Code 38116
		Country USA	
Contact Name Mandy Coe	Contact Title Regulatory Affairs Specialist	Contact E-mail Address mandy.coe@smith-nephew.com	

**(b)(4)Trade Secret Process**

**(b)(4)Trade Secret Process**

**SECTION I**

**UTILIZATION OF STANDARDS**

**Note:** Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	(b)	(b)	(b)(4) Trade Secret Process		
2	6474	ISO	Ceramic materials based on high purity alumina	94	02/03/1994
3	F603	ASTM	High-purity dense aluminum oxide for medical application	0	01/10/2000
4	(b)(4) Trade Secret Process	(b)(4) Trade Secret Process	(b)(4) Trade Secret Process		
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration  
 CDRH (HFZ-342)  
 9200 Corporate Blvd.  
 Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control

Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
*(To be filled in by applicant)*

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 6474-00 "Ceramic materials based on high purity alumina

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 017

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

Does this standard include acceptance criteria? .....       
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....       
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....       
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....       
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: .....

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)

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Department of Health and Human Services  
Food and Drug Administration  
**STANDARDS DATA REPORT FOR 510(k)s**  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 7206-5 "Determination of resistance to static load of head and neck region of stemmed femoral components"

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # .....

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....    

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If no, include the results of testing in the 510(k).

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If yes, was the guidance document followed in preparation of this 510k? .....    

Title of guidance: .....

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Department of Health and Human Services  
Food and Drug Administration  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ASTM F603 "High-purity dense aluminum oxide for medical application

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....    

FDA Recognition number <sup>3</sup> ..... # 017

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)? .....       
If no, complete a summary report table.

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Title of guidance: \_\_\_\_\_

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Department of Health and Human Services  
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**STANDARDS DATA REPORT FOR 510(k)s**  
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ASTM F2009 "Standard test method for determining the axial disassembly force of taper connections of modular prosthesis"

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA<sup>2</sup>? .....    

FDA Recognition number<sup>3</sup> ..... # .....

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....    

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If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? .....    

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....    

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)<sup>5</sup>? .....    

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....    

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....    

If yes, report these exclusions in the summary report table.

Is there an FDA guidance<sup>6</sup> that is associated with this standard? .....    

If yes, was the guidance document followed in preparation of this 510(k)? .....    

Title of guidance: .....

<sup>1</sup> The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

<sup>2</sup> Authority [21 U.S.C. 360d], [www.fda.gov/cdrh/stdsprog.html](http://www.fda.gov/cdrh/stdsprog.html)

<sup>3</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>4</sup> The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

<sup>5</sup> The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

<sup>6</sup> The online search for CDRH Guidance Documents can be found at [www.fda.gov/cdrh/guidance.html](http://www.fda.gov/cdrh/guidance.html)



DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with  
Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

**SPONSOR / APPLICANT / SUBMITTER INFORMATION**

1. NAME OF SPONSOR/APPLICANT/SUBMITTER SMITH & NEPHEW, INC.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 11/10/2008
3. ADDRESS (Number, Street, State, and ZIP Code) 1450 Brooks Road Memphis, TN 38116	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 901-399-6277 (Fax) 901-398-5146

**PRODUCT INFORMATION**

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)  
**FOR DEVICES:** Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)  
(Attach extra pages as necessary)

Smith & Nephew Biolox Delta Ceramic Femoral Heads

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**APPLICATION / SUBMISSION INFORMATION**

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND     NDA     ANDA     BLA     PMA     HDE     510(k)     PDP     Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

**CERTIFICATION STATEMENT / INFORMATION**

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s): \_\_\_\_\_

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act. **Warning:** A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11 (Name) Mandy Coe (Title) Regulatory Affairs Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 1450 Brooks Road Memphis, TN 38116	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 901-399-6277 (Fax) 901-398-5146
	15. DATE OF CERTIFICATION 12/17/08

### Instructions for Completion of Form FDA 3674

**Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))**  
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.
9. **Certification** - This section contains three different check-off boxes.  
**Box A** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.  
**Box B** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.  
**Box C** should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11.** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

#### Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration  
Center for Drug Evaluation and Research  
Central Document Room  
Form No. FDA 3674  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Food and Drug Administration  
Center for Biologics Evaluation and Research  
1401 Rockville Pike  
Rockville, MD 20852-1448

Food and Drug Administration  
Center for Devices and Radiological Health  
Program Operations Staff (HFZ-403)  
9200 Corporate Blvd.  
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number.

## Smith & Nephew BioloX Delta Ceramic Femoral Heads

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**Executive Summary**  
**Smith & Nephew BioloX Delta Ceramic Femoral Heads**

**Device Description**

Subject of this special premarket notification are Smith & Nephew BioloX Delta Ceramic femoral heads. The Delta Ceramic heads will be offered in sizes 28, 32, and 36mm with a 12/14 taper and are intended to be used with existing Smith & Nephew femoral hip stems. The ceramic femoral head mechanically locks with the femoral hip stem via a taper junction and articulates against a Smith & Nephew polyethylene acetabular liner. The subject devices are similar in design and function to the BioloX Forte Alumina Ceramic femoral heads cleared via 510(k) premarket notifications K981847, K991162, and K022958 respectively.

**Indications for Use**

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew BioloX Delta Ceramic femoral heads are for single use only.

**Device Comparison**

The overall design and the indications for use for the Smith & Nephew BioloX Delta Ceramic femoral heads are substantially equivalent to the Smith & Nephew BioloX Alumina Ceramic femoral heads cleared via 510(k) premarket notifications K981847, K991162, and K022958 respectively.

The material used in the manufacture of the subject devices has been used in the manufacture of femoral head components cleared in the premarket notification listed in Table 1 below.

**Table 1:** Predicate femoral heads fabricated from BioloX Delta Ceramic material

Description	Company	510(k)	Clearance Date
BioloX Delta Ceramic Femoral Head	Zimmer Inc.	K071535	11/19/2007

**Testing**

According to the Guidance Document, *The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, appropriate Design Control Activities have been completed for the subject devices. The risk analysis used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA).

**Executive Summary**  
**Smith & Nephew BioloX Delta Ceramic Femoral Heads**

The design verification tests that were performed as a result of the risk analysis assessment are listed in **Exhibit 12**. These Design Verification Tests are based on requirements outlined in the following FDA guidance documents:

- *Draft Guidance Document for Testing Acetabular Cup Prostheses*, dated May 1, 1995.
- *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components*, dated May 1, 1995.
- *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

As required in the guidance document, the concise summary of the design activities includes the following information:

- An identification of the Risk Analysis method(s) used to assess the impact of the modification on the device and its components as well as the results of the analysis; and
- Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied.

**I. ADMINISTRATIVE INFORMATION**

**A. Truthful and Accurate Statement**

The required Truthful and Accurate Statement is provided as **Exhibit 1**.

**B. 510(k) Summary and Indications Enclosure**

The required 510(k) Summary and Indications Enclosure is provided as **Exhibit 2**.

**C. Declaration of Conformity**

A Declaration of Conformity with Design Controls is provided as **Exhibit 3**. The Declaration of Conformity includes the following information:

- 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; and
- 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.

The above two statements have been signed by the designated individual(s) responsible for those particular activities.

**D. Manufacturer Identification**

Manufacturer's Name: Smith & Nephew, Inc.  
Orthopaedic Division  
1450 E. Brooks Road  
Memphis, Tennessee 38116

Establishment Registration Number: 1020279

Primary Contact: Mandy Coe  
Regulatory Affairs Specialist  
T (901) 399-6277  
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mandy.coe@smithnephew.com

Secondary Contact: Gino Rouss  
Manager, Regulatory Affairs  
T (901) 399-6707  
F (901) 398-5146  
gino.rouss@smithnephew.com

## **E. Device Identification**

### **Proprietary Name of Subject Device:**

Smith & Nephew BioloX Delta Ceramic Femoral Heads

### **Common Name of Subject Device:**

Femoral Head

### **Classification Name and Reference of Subject Device:**

21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis - Class II

### **Proprietary Name of Predicate Device:**

Smith & Nephew BioloX Forte Alumina Ceramic Femoral Heads

### **Common Name of Predicate Device:**

Femoral Head

### **Classification Name and Reference for the Predicate Device:**

21 CFR 888.3353 - Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis - Class II

### **Device Product Code and Panel Code:**

Orthopedics/87 LZO

## **II. DEVICE INFORMATION**

### **A. Intended Use**

The Smith & Nephew BioloX Delta Ceramic Femoral Heads are intended to be used as part of a total hip replacement system. Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of

deformity. Smith & Nephew BioloX Delta Ceramic femoral heads are for single use only.

The indications for the subject device are identical to the indications for use cleared in the premarket notifications listed below.

**Table I: Predicate Devices with Identical Indications for Use**

Description	510(k)	Clearance Date
BioloX Forte Alumina Ceramic Femoral Heads (28mm & 32mm)	K981847	07/17/1998
BioloX Forte Alumina Ceramic Femoral Head (28mm long for use with CoCr stems)	K991162	01/28/2000
(BioloX) Forte Alumina Ceramic Femoral Heads (36mm)	K022958	10/02/2002

**B. Device Description**

Subject of this special premarket notification are BioloX Delta Ceramic femoral heads that are manufactured and supplied by (b) (4) Trade Secret Process (Medical Products Division). The femoral heads are fabricated from (b) (4) Trade Secret Process and offered in sizes ranging from 28-36mm. The components feature a 12/14 Morse-type taper for attachment to the trunnion of commercially-available Smith & nephew femoral stems. The BioloX Delta Ceramic femoral heads will be offered with neck length offset adjustments of +0, +4, and +8mm to accommodate various patient anatomies. The subject devices are similar in design and function to the BioloX Forte Alumina Ceramic femoral heads cleared via 510(k) premarket notifications K981847, K991162, and K022958.

The following modification has been made in developing the BioloX Delta Ceramic femoral heads:

- (b) (4) Trade Secret Process

This modification is described in greater detail below and on the following page.

**Material Change - BioloX Forte Alumina Ceramic to BioloX Delta Ceramic**

The subject devices will be supplied by (b) (4) Trade Secret Process and are manufactured from a delta ceramic material composed of (b) (4) Trade Secret Process. The predicate devices that have been cleared via premarket notifications K981847, K991162, and K022958 are manufactured from (b) (4) Trade Secret Process. The delta ceramic material exhibits greater strength and wear properties than the alumina ceramic material of the predicate devices, and, as such, the subject devices will be marketed as an alternative option to

surgeons that currently use ceramic femoral heads that are intended to articulate against a polyethylene acetabular liner.

BioloX Delta Ceramic femoral heads will initially be offered in diameters ranging from 28 to 36 mm with head offsets consisting of +0, +4 and +8 mm. In keeping with the design philosophy of the predicate Smith & Nephew BioloX Forte Alumina Ceramic femoral heads, the subject devices will feature a 12/14 Morse-type taper and are intended to be used with existing Smith & Nephew femoral hip stems with a corresponding taper junction. The ceramic femoral head mechanically locks with the femoral hip stem via a taper junction and is intended to articulate against a polyethylene acetabular liner. The subject devices are designed to be used with existing Smith & Nephew femoral stems listed below.

**Table 2:** Previously cleared Smith & Nephew Hip Stems with a 12/14 Taper

Description	510(k)	Clearance Date
Echelon (Revision) Hip Stems – Porous and Non-porous	K963486	11/27/96
Echelon Primary Hip Stems	K983834	2/24/99
Echelon Hip Stems – HA Coated	K023302	10/25/02
Synergy (Tapered) Hip Stems – Porous and Non-porous	K963509	1/27/97
Synergy (Tapered) Hip Stems – HA Press-fit	K970337	2/28/97
Synergy Cemented Hip Stems	K990369	3/12/99
Synergy Porous Size 8 Hip Stem	K991485	7/12/99
Synergy HA Coated Porous Hip Stems	K002996	12/11/00
Spectron Hip Stems	K970351	2/28/97
Smith & Nephew Modular Hip (Emperion)	K042127	11/19/04
Smith & Nephew Modular Hip (Emperion) – Line Additions	K052426	12/07/05
Platform Hip Stem	K052275	12/07/05
Anthology Hip Stems	K052792	10/07/05
Smith & Nephew Patient Matched Hip Stem (PMHS)	K053246	7/12/06

A table has been provided in **Exhibit 4** that provides additional information about the head sizes (diameters) and offsets previously cleared for use with each femoral stem listed in Table 2. The subject BioloX Delta Ceramic femoral heads included in this 510(k) are offered in 28, 32, and 36mm head diameters. Each femoral head size includes three different femoral head offset options: +0, +4, and +8mm. The subject femoral heads are offered in the same diameters and head offsets as existing femoral heads previously cleared by FDA.

These head diameters and offsets are also within the range of existing femoral heads previously cleared for market with the femoral hip stems identified in Exhibit 4. As such, a new worst-case femoral head option has not been introduced in this premarket notification. Each diameter and offset option offered in the BioloX Delta Ceramic design has been cleared previously in predicate designs as noted in the following table.

**Table 3: Predicate Femoral Heads and Offsets**

Head Size (Diameter)	Head Offset (mm)	Predicate 510(k)
28mm	+8 with CoCr Stems	K991162
	+0	K981847
	+4	
	+8	
32mm	+0	K981847
	+4	
	+8	
36mm	+0	K022958
	+4	
	+8	

The subject devices are designed to articulate against polyethylene liners and acetabular shells listed below.

**Table 4:** Previously cleared Smith & Nephew Acetabular Liners and Shells

Description	510(k)	Clearance Date
Reflection Acetabular Cup System (formerly the Modular Acetabular Cup System) (cemented use)	K920430	7/21/92
Reflection Acetabular Components (uncemented use)	K932755	5/6/94
Reflection Dual Dimension Shell (Interfit Shells)	K960094	3/27/96
Hydroxyapatite Reflection Acetabular Shells (Interfit HA coated shell)	K990666	8/6/99
Reflection Cross-linked UHMWPE Acetabular Liners: 5 Mrad Irradiation Dosage	K991026	10/28/99
Reflection Cross-linked UHMWPE Acetabular Liners: 10 Mrad Irradiation Dosage	K002747	12/15/00
Reflection Cross-linked UHMWPE Acetabular Liners: 10 Mrad Irradiation Dosage for use with zirconia ceramic femoral heads	K013658	12/5/01
Smith & Nephew Hip System – Reflection 36 mm XLPE Liners	K022902	10/2/02
Reflection 3 Acetabular System	K061253	5/31/06
Reflection 3-Hole Shell with Asymmetric Porous Coating	K060630	6/14/06
Reflection 3 Acetabular System	K070756	6/6/07

Please refer to **Exhibit 5** for additional information pertaining to the acetabular liners and shells intended for use with the subject BioloX Delta Ceramic femoral heads. Specified in this table are the materials used in the manufacture of the acetabular devices.

Engineering drawings for the subject BioloX Delta Ceramic femoral heads and existing BioloX Forte Alumina Ceramic femoral heads are provided in **Exhibit 6**. The previously cleared BioloX Forte Alumina Ceramic femoral heads have been included to illustrate that the design dimensions for the subject device will remain the same as the predicate Smith & Nephew devices listed in Table 1. Component descriptions are provided in **Exhibit 7**. A Device Comparison Table has been provided in **Exhibit 8** to summarize the device features of the subject Smith & Nephew BioloX Delta Ceramic femoral heads compared to predicate devices previously cleared for market.

### C. Material Information

The subject Smith & Nephew BioloX Delta Ceramic femoral heads will be manufactured by (b)(4)Trade Secret Process [REDACTED], which conforms to the internal Smith & Nephew standard listed below.

**Table 5: Material Standard**

Material	Standard
(b)(4)Trade Secret Process	[REDACTED]

The BioloX Delta Ceramic material, (b)(4)Trade Secret Process [REDACTED] has been used in the manufacture of femoral head components cleared in the premarket notification listed below.

**Table 6: Predicate premarket notifications for Delta Ceramic femoral heads**

Description	Company	510(k)	Clearance Date
BioloX Delta Ceramic Femoral Head	Zimmer Inc.	K071535	11/19/2007

### D. Sterilization Information

The Smith & Nephew BioloX Delta Ceramic Heads are sold sterile, and are intended for single-use only. The subject femoral heads will be sterilized via gamma radiation. This is the same sterilization process used for the predicate

K991162, and K022958. Additional sterilization information is provided in **Exhibit 9**.

#### **E. Labeling**

Representative carton labels for the BioloX Delta Ceramic femoral heads are provided in **Exhibit 10**. All product will be labeled with a ten year expiration date.

Smith & Nephew has conducted both package integrity and sterility testing to support a ten year expiration date label. Sterility testing data was based on real-time testing of recovered product that had been returned after being in the field ten or more years. Smith & Nephew has the test data in a report filed in Regulatory Affairs to satisfy FDA inspections.

A package insert for Smith & Nephew, Inc. Hip Systems is provided in **Exhibit 11**.

#### **F. Design Control Activities Summary**

According to the Guidance Document, *The New 510(k) Paradigm: Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications*, appropriate Design Control Activities have been completed for the subject BioloX Delta Ceramic femoral heads. The risk analysis used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). The design verification tests that were performed as a result of this risk analysis assessment are listed in **Exhibit 12**.

These Design Verification Tests are based on requirements outlined in the following FDA guidance documents:

- *Draft Guidance Document for Testing Acetabular Cup Prostheses*, dated May 1, 1995.
- *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components*, dated May 1, 1995.
- *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

As required in the guidance document, the concise summary of the design activities includes the following information:

- An identification of the Risk Analysis method(s) used to assess the impact of the modification on the device and its components as well as the results of the analysis; and

- Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and the acceptance criteria applied.

**G. Substantial Equivalence Information**

The overall design and indications for use of the Smith & Nephew BioloX Delta Ceramic femoral heads are substantially equivalent to the previously cleared devices listed below.

**Table 6:** Predicate femoral heads

Manufacturer	Description	510(k)	Clearance Date
Smith & Nephew, Inc.	BioloX Alumina Ceramic Femoral Heads (28 & 32mm)	K981847	07/17/1998
Smith & Nephew, Inc.	BioloX Alumina Ceramic Femoral head (28mm long)	K991162	01/28/2000
Smith & Nephew, Inc.	(BioloX) Alumina Ceramic Femoral Heads (36mm)	K022958	10/02/2002

The subject Smith & Nephew BioloX Delta Ceramic femoral heads will be manufactured by (b)(4)Trade Secret Process. This material has been used to manufacture femoral head components which have been cleared in the premarket notification listed below.

**Table 7:** Predicate femoral heads fabricated from Delta Ceramic material

Description	Company	510(k)	Clearance Date
BioloX Delta Ceramic Femoral Head	Zimmer Inc.	K071535	11/19/2007

Premarket notification information for the predicate devices is included in **Exhibit 13**.

In summary, the Smith & Nephew BioloX Delta Ceramic femoral heads are similar in design, function, intended use, and material composition to currently marketed predicate devices. Although the Delta Ceramic femoral heads are not identical in all aspects to the predicate devices, any differences that exist have been shown to not significantly affect the safety and effectiveness of the device. As such, the Delta Ceramic femoral heads are considered substantially equivalent to commercially available femoral head prostheses.

## Smith & Nephew BioloX Delta Ceramic Femoral Heads

### List of Exhibits

- |            |  |
|------------|--|
| Exhibit 1  | Truthful and Accurate Certification                                |
| Exhibit 2  | 510(k) Summary of Safety and Effectiveness & Indications Statement |
| Exhibit 3  | Declaration of Conformity with Design Controls                     |
| Exhibit 4  | Femoral Heads/Stems cleared for use                                |
| Exhibit 5  | Acetabular Liners/Shells Cleared for Use                           |
| Exhibit 6  | Engineering Drawings   |
| Exhibit 7  | Components List and Description                                    |
| Exhibit 8  | Device Comparison Tables   |
| Exhibit 9  | Sterilization Information  |
| Exhibit 10 | Representative Labels  |
| Exhibit 11 | Package Insert   |
| Exhibit 12 | Design Verification Table  |
| Exhibit 13 | Predicate Information  |

- Exhibit 14 (b)(4)Trade Secret Process [REDACTED]
- Exhibit 15 (b)(4)Trade Secret Process [REDACTED]
- Exhibit 16 Orthopaedic Research Report OR-07-178, (b)(4)Trade Secret Process [REDACTED]
- Exhibit 17 Technical Memo TM-08-19, (b)(4)Trade Secret Process [REDACTED]
- Exhibit 18 Technical Memo, (b)(4)Trade Secret Process [REDACTED]
- Exhibit 19 Technical Memorandum, (b)(4)Trade Secret Process [REDACTED]

Special Premarket Notification  
Smith & Nephew BioloX Delta Ceramic Femoral Heads

Truthful and Accurate Certification

I certify that, in my capacity as a Regulatory Affairs Specialist for Smith & Nephew, Inc., Orthopaedic Division, I believe to the best of my knowledge that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

  
Mandy Coe  
Regulatory Affairs Specialist

12/17/08  
Date

## Summary of Safety and Effectiveness for Smith & Nephew BioloX Delta Ceramic Femoral Heads

### Contact Person and Address

Mandy L. Coe  
Regulatory Affairs Specialist  
Smith & Nephew, Inc.  
Orthopaedic Division  
1450 E. Brooks Road  
Memphis, Tennessee 38116  
(901) 399-6277

Date of Summary: August 27, 2008

**Name of Device:** Smith & Nephew BioloX Delta Ceramic Femoral Heads

**Common Name:** Femoral Head

**Device Classification:** 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis – Class II

**Device Product Code:** LZO

### Device Description

The BioloX Delta Ceramic femoral heads feature a 12/14 taper and are intended to be used with existing Smith & Nephew femoral hip stems. The ceramic femoral head mechanically locks with the femoral hip stem via a taper junction and articulates against a Smith & Nephew polyethylene acetabular liner. The subject devices are similar in design and function to the BioloX Forte Alumina Ceramic femoral heads cleared via 510(k) premarket notifications K981847, K991162, and K022958 respectively.

### Mechanical Testing

A review of the mechanical data indicated that the Smith & Nephew BioloX Delta Ceramic femoral heads are equivalent to devices currently cleared for market and are capable of withstanding expected *in vivo* loading without failure.

### Intended Use

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. The BioloX Delta Ceramic femoral heads are for single use only.

### Substantial Equivalence Information

The Smith & Nephew BioloX Delta Ceramic femoral heads are similar in overall design, material and indications to the Smith & Nephew BioloX Forte Alumina Ceramic femoral heads cleared via 510(k) premarket notifications K981847, K991162, and K022958 as well as the Zimmer BioloX Delta Ceramic femoral heads cleared via K071535.

## Indications for Use

**510(k) Number (if known):**

**Device Name:** Biolox Delta Ceramic Femoral Heads

### Indications for Use:

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew Delta Ceramic femoral heads are for single use only.

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)

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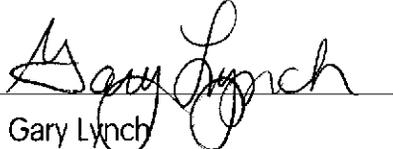
Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of \_\_\_\_\_

Special Premarket Notification Declaration of Conformity  
Smith & Nephew BioloX Delta Ceramic Femoral Heads

Declaration of Conformity with Design Controls

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

  
\_\_\_\_\_  
Gary Lynch  
Group Director of Quality  
Smith & Nephew, Inc.

  
\_\_\_\_\_  
Date

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

  
\_\_\_\_\_  
Gary Lynch  
Group Director of Quality  
Smith & Nephew, Inc.

  
\_\_\_\_\_  
Date

Smith & Nephew Femoral Hip Stems Used with Biolox Delta Ceramic Femoral Heads

Previously cleared Smith & Nephew Hip Stems with a 12/14 Taper

Description	510(k)	Clearance Date	Femoral Head Sizes	
			Head Diameters (mm)	Head Offsets (mm)
Echelon (Revision) Hip Stems – Porous and Non-porous	K963486	11/27/96	22, 26, 28, 32	22mm: +0, +4, +8, +12 26mm: +0, +4, +8, +12 28mm: -3, +0, +4, +8, +12, +16 32mm: -3, +0, +4, +8, +12, +16
	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K022958	10/2/02	36	-3, +0, +4, +8
	K983834	2/24/99	Existing heads cleared via K963486	Existing heads cleared via K963486
Echelon Primary Hip Stems	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K022958	10/2/02	36	-3, +0, +4, +8
Echelon Hip Stems – HA Coated	K023302	10/25/02	Used with existing heads cleared via K983486 and K021673	Used with existing heads cleared via K983486 and K021673
Synergy (Tapered) Hip Stems – Porous and Non-porous	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K963509	1/27/97	22, 26, 28, 32	22mm: +0, +4, +8, +12 26mm: +0, +4, +8, +12 28mm: -3, +0, +4, +8, +12, +16 32mm: -3, +0, +4, +8, +12, +16
Synergy (Tapered) Hip Stems – HA Press-fit	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K022958	10/2/02	36	-3, +0, +4, +8
	K970337	2/28/97	Existing heads cleared via K963509	Existing heads cleared via K963509
	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
Synergy Cemented Hip Stems	K022958	10/2/02	36	-3, +0, +4, +8
	K990369	3/12/99	Existing heads cleared via K963486	Existing heads cleared via K963486
	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K022958	10/2/02	36	-3, +0, +4, +8
Synergy Porous Size 8 Hip Stem	K991485	7/12/99	Existing heads cleared via K963486	Existing heads cleared via K963486
	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
Synergy HA Coated Porous Hip Stems	K022958	10/2/02	36	-3, +0, +4, +8
	K002996	12/11/00	Existing heads cleared via K963486	Existing heads cleared via K963486
	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K022958	10/2/02	36	-3, +0, +4, +8

Description	510(k)	Clearance Date	Femoral Head Sizes	
			Head Diameters (mm)	Head Offsets (mm)
Spectron Hip Stems	K970351	2/28/97	Existing heads cleared via K963509	Existing heads cleared via K963509
	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K022958	10/2/02	36	-3, +0, +4, +8
Smith & Nephew Modular Hip (Emperion)	K042127	11/19/04	22, 26, 28, 32, 36	22mm: +0, +4, +8, +12
				26mm: +0, +4, +8, +12
				28mm: -3, +0, +4, +8, +12, +16
				32mm: -3, +0, +4, +8, +12, +16
				36mm: -3, +0, +4, +8
Smith & Nephew Modular Hip (Emperion) – Line Additions	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K052426	12/07/05	Utilizes same femoral heads as stems cleared via K042127	Utilizes same femoral heads as stems cleared via K042127
	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
Platform Hip Stem	K052275	12/07/05	Existing heads cleared via K021673 and K963509	Existing heads cleared via K021673 and K963509
	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K052792	10/07/05	Existing heads cleared via K021673 and K963509	Existing heads cleared via K021673 and K963509
Anthology Hip Stems	K062408	9/12/06	38-58 (in 2mm increments)	-4, +0, +4, +8 for all head diameters
	K053246	7/12/06	Existing heads cleared via K021673 and K963509	Existing heads cleared via K021673 and K963509
Smith & Nephew Patient Matched Hip Stem (PMHS)	K072417	1/10/08	Utilizes same femoral heads as stems cleared via K042127	Utilizes same femoral heads as stems cleared via K042127
	K080625	5/8/08	Utilizes same femoral heads as stems cleared via K042127	Utilizes same femoral heads as stems cleared via K042127
SL-PLUS Standard and Lateral Hip Stems	K072852	6/9/08	22-60	-3mm to +15mm

Smith & Nephew Acetabular Liners and Shells Used with Biolox Delta Ceramic Femoral Heads

Previously cleared Smith & Nephew Acetabular Liners and Shells

Description	510(k)	Clearance Date	Acetabular Component Material Information	
			Acetabular Liners	Acetabular Shells
Reflection Acetabular Cup System (formerly the Modular Acetabular Cup System) (cemented use)	K920430	7/21/92	UHMWPE (ASTM F648)	Shells: Ti-6Al-4V (ASTM F1472) Porous Coating: CPTI (ASTM F67)
Reflection Acetabular Components (uncemented use)	K932755	5/6/94	Existing liners cleared in K920430	Existing shells cleared in K920430
Reflection Dual Dimension Shell (Interfit Shells)	K960094	3/27/96	Same as K932755	Shells: Ti-6Al-4V (ASTM F1472) Porous Coating: CPTI (ASTM F67)
Hydroxyapatite Reflection Acetabular Shells (Interfit HA coated shell)	K990666	8/6/99	Same as K932755	Shells: Ti-6Al-4V (ASTM F1472) Porous Coating: CPTI (ASTM F67) HA coating applied to porous coated shells <sup>1</sup>
Reflection Cross-linked UHMWPE Acetabular Liners: 5 Mrad Irradiation Dosage	K991026	10/28/99	Includes an all-polyethylene acetabular cups and UHMWPE acetabular liners for use with a metal shell (ASTM F648)	Existing shells cleared via K920430, K932755, and K960094 (shells not used with all-poly design)
Reflection Cross-linked UHMWPE Acetabular Liners: 10 Mrad Irradiation Dosage	K002747	12/15/00	Includes an all-polyethylene acetabular cups and UHMWPE acetabular liners for use with a metal shell (ASTM F648)	Existing shells cleared via K920430, K932755, and K960094 (shells not used with all-poly design)
Smith & Nephew Hip System – Reflection 36 mm XLPE Liners	K022902	10/2/02	UHMWPE (ASTM F648)	Existing shells cleared via K920430 and K932755
Reflection 3 Acetabular System	K061253	5/31/06	UHMWPE (ASTM F648)	Shells: Ti-6Al-4V (ASTM F1472) Porous Coating: CPTI (ASTM F67) Available with or without HA coating (same HA coating as used on shells cleared via K990666)
Reflection 3-Hole Shell with Asymmetric Porous Coating	K060630	6/14/06	Existing liners cleared via K920430, K932755, K991026, K002747, and K022902	Shells: Ti-6Al-4V (ASTM F1472) Porous Coating: CPTI (ASTM F67)
Reflection 3 Acetabular System	K070756	6/6/07	Existing liners cleared via K061253	Shells: Ti-6Al-4V (ASTM F1472) Porous Coating: CPTI (ASTM F67)

<sup>1</sup> Additional information related to the HA coating applied to the shells cleared via K990666 is available in HA Master Device File MAF-339.

Subject Device Drawings  
Biolox Delta Ceramic

























Predicate Device Drawings  
BioloX Forte Alumina Ceramic













**Component Descriptions**  
**Smith & Nephew Delta Ceramic Femoral Heads**

Catalog #	Size	Offset	Description
71346001	28 mm	+0	Bilox Delta Head 28mm 12/14 Short +0
71346002		+4	Bilox Delta Head 28mm 12/14 Medium +4
71346003		+8	Bilox Delta Head 28mm 12/14 Long +8
76539160	32 mm	+0	Bilox Delta Head 32MM 12/14 Short +0
76539161		+4	Bilox Delta Head 32MM 12/14 Medium +4
76539162		+8	Bilox Delta Head 32MM 12/14 Long +8
76539165	36 mm	+0	Bilox Delta Head 36MM 12/14 Short +0
76539166		+4	Bilox Delta Head 36MM 12/14 Medium +4
76539167		+8	Bilox Delta Head 36MM 12/14 Long +8

## Device Comparison Table – Indications for Use Smith & Nephew Biolox Delta Ceramic Femoral Heads

Comparison	Subject Device Smith & Nephew Biolox Delta Ceramic Femoral Heads	Predicate Device Smith & Nephew Biolox Forte Alumina Ceramic Femoral Heads (K981847, K991162, and K022958)
<b>Indications for Use</b>	<p>Total hip components are indicated for individuals who are undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of:</p> <ul style="list-style-type: none"> <li>• trauma</li> <li>• inflammatory joint disease such as rheumatoid arthritis</li> <li>• Noninflammatory degenerative joint disease (NIDJD)</li> <li>• Osteoarthritis</li> <li>• Avascular necrosis</li> <li>• Traumatic arthritis</li> <li>• Slipped capital epiphysis</li> <li>• Fused hip</li> <li>• Fracture of the pelvis</li> <li>• Diastrophic variant</li> <li>• Old, remote osteomyelitis with an extended drainage-free period</li> <li>• Nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques</li> <li>• Femoral osteotomy, or Girdlestone resection</li> <li>• Fracture dislocation of the hip and correction of deformity.</li> </ul> <p>Smith &amp; Nephew Delta Ceramic femoral heads are for single use only.</p>	<p>Total hip components are indicated for individuals who are undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of:</p> <ul style="list-style-type: none"> <li>• trauma</li> <li>• inflammatory joint disease such as rheumatoid arthritis</li> <li>• Noninflammatory degenerative joint disease (NIDJD)</li> <li>• Osteoarthritis</li> <li>• Avascular necrosis</li> <li>• Traumatic arthritis</li> <li>• Slipped capital epiphysis</li> <li>• Fused hip</li> <li>• Fracture of the pelvis</li> <li>• Diastrophic variant</li> <li>• Old, remote osteomyelitis with an extended drainage-free period</li> <li>• Nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques</li> <li>• Femoral osteotomy, or Girdlestone resection</li> <li>• Fracture dislocation of the hip and correction of deformity.</li> </ul> <p>Smith &amp; Nephew Biolox Alumina Ceramic femoral heads are for single use only.</p>

**Device Comparison Table  
Smith & Nephew BioloX Delta Ceramic Femoral Heads**

Comparison	<i>Subject Device</i> BioloX Delta Ceramic Femoral Heads	BioloX Forte Alumina Ceramic Femoral Heads (K981847, K991162, and K022958)	BioloX Delta Ceramic Femoral Heads (K071535)
Manufacturer	Smith & Nephew	Smith & Nephew	Zimmer Inc.
Material	BioloX Delta Ceramic	BioloX Forte Alumina Ceramic	BioloX Delta Ceramic
Material Manufacturer	(b) (4) Trade Secret Process		
Sizes	28, 32, 36	28, 32, 36	28, 32, 36, 40
Offsets	+4, +8	+4, +8	Range of Offsets Unknown

### Radiation Sterilization Process

<b>Source/Type of Sterilization:</b>	Cobalt 60/Gamma radiation
<b>Sterility Assurance Level:</b>	(b) (4)Trade Secret
<b>Type of Cycle:</b>	Overkill
<b>Dosage:</b>	25 Kilo grays minimum
<b>Validation:</b>	Validation is accomplished by following the procedures set forth by the Association for the Advancement of Medical Instrumentation (AAMI) Guideline for Gamma Radiation Sterilization, ANSI/AAMI/ISO 11137-1-1994.
<b>Description of Packaging:</b>	The packaging is a PETG thermoformed tray with Tyvek lid heat sealed to the tray and placed inside a second PETG tray with Tyvek lid. The trays are inserted into a paperboard carton that is shrink wrapped.
<b>Pyrogen Statement:</b>	These products are not labeled as "non-pyrogenic." Applications of orthopaedic implants are such that routine pyrogen testing is not required.
<b>Contract Sterilizer:</b>	(b)(4)Trade Secret Process

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Title: LABEL SPECIFICATION / Etikettenspezifikation

OUTER LABEL / Außenetikett	INNER LABEL / Innenetikett	CHART-STIK® LABEL / CHART-STIK® Etikett
<p>REF 76539160 QTY: (1)</p> <p><b>BIOLOX DELTA</b></p> <p><b>ALUMINA CERAMIC</b></p> <p><b>12/14 TAPER</b></p> <p>FEMORAL HEAD</p> <p>FETE FEMORALE / HIIFKOPF</p> <p>CABEZA FEMORAL / TESTA FEMORALE</p> <p><b>32 MM O.D., S</b></p> <p><b>(S&amp;N +0 = CERAMTEC -4)</b></p> <p>smith&amp;nephew LOT NO. SAMPLE</p> <p>FEMORAL HEAD</p> <p>ALUMINA CERAMIC</p> <p>LOT SAMPLE</p> <p>CE</p> <p>STERILE R</p> <p>2018-12</p> <p>2</p> <p>▲</p> <p>Made in GERMANY</p> <p>Smith &amp; Nephew, Inc. Morrisville, NC 27554 USA</p> <p>EC REP: Smith &amp; Nephew Grieshauser GmbH, Tuttlingen, Germany</p> <p>TS-0457C</p>	<p>REF 76539160 QTY: (1)</p> <p>BIOLOX DELTA</p> <p>32 MM O.D., S</p> <p>(S&amp;N +0 = CERAMTEC -4)</p> <p>12/14 TAPER FEMORAL HEAD</p> <p>ALUMINA CERAMIC</p> <p>LOT SAMPLE</p> <p>smith&amp;nephew</p> <p>STERILE R</p> <p>2018-12</p> <p>TS-0457A</p> <p>CE</p>	<p>ATTACH TO PATIENT'S RECORD</p> <p>CHART-STIK® LABEL</p> <p>REF 76539160</p> <p>LOT SAMPLE</p> <p>BIOLOX DELTA</p> <p>32 MM O.D., S</p> <p>(S&amp;N +0 = CERAMTEC -4)</p> <p>12/14 TAPER FEMORAL HEAD</p> <p>ALUMINA CERAMIC</p> <p>STERILE R</p> <p>2018-12</p> <p>smith&amp;nephew</p> <p>TS-0457K</p> <p>OTHER LABEL / sonstige Etiketten</p>

Note: The attached label is representative of the actual label. Reference Packaging Data Sheet for CE Mark information on actual label.

KEY:

CE Mark: N = Label will not contain CE mark, CE Mark: Y = Label will contain CE mark, CE Mark: Y & Notify Body: 1 = Label will contain CE0086

Labels that show CE0120 on the actual label should match the label printed above.

Form 00113 - Label Specification

Form Date 5/2007

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Title: LABEL SPECIFICATION / Etikettenspezifikation

OUTER LABEL / Außenetikett	INNER LABEL / Innenetikett	CHART-STIK® LABEL / CHART-STIK® Etikett
<p>REF: 76539162 QTY: (1)</p> <p><b>12/14</b></p> <p><b>BIOLOX DELTA</b></p> <p><b>ALUMINA CERAMIC</b></p> <p><b>FEMORAL HEAD</b></p> <p><b>TAPER</b></p> <p><b>32 MM O.D., L</b></p> <p><b>(S&amp;N +8 = CERAMTEC +4)</b></p> <p>smith&amp;nephew LOT NO. SAMPLE</p> <p>FEMORAL HEAD</p> <p>ALUMINA CERAMIC</p> <p>LOT: SAMPLE</p> <p>CE</p> <p>STERILE R</p> <p>2018-12</p> <p>EG REP: Smith &amp; Nephew Orthopaedics GmbH, Tuttlingen, Germany</p> <p>745151C</p>	<p>REF: 76539162 QTY: (1)</p> <p><b>BIOLOX DELTA</b></p> <p><b>32 MM O.D., L</b></p> <p><b>(S&amp;N +8 = CERAMTEC +4)</b></p> <p><b>12/14 TAPER FEMORAL HEAD</b></p> <p><b>ALUMINA CERAMIC</b></p> <p><b>LOT: SAMPLE</b></p> <p>smith&amp;nephew</p> <p>CE</p> <p>STERILE R</p> <p>2018-12</p> <p>729837A</p>	<p>CHART-STIK® LABEL</p> <p>REF: 76539162 QTY: (1)</p> <p><b>BIOLOX DELTA</b></p> <p><b>32 MM O.D., L</b></p> <p><b>(S&amp;N +8 = CERAMTEC +4)</b></p> <p><b>12/14 TAPER FEMORAL HEAD</b></p> <p><b>ALUMINA CERAMIC</b></p> <p><b>LOT: SAMPLE</b></p> <p>smith&amp;nephew</p> <p>STERILE R</p> <p>2018-12</p> <p>ATTACH TO PATENT'S RECORD</p> <p>TH4857A</p>
OTHER LABEL / sonstige Etiketten		

Note: The attached label is representative of the actual label. Reference Packaging Data Sheet for CE Mark information on actual label.

KEY:

CE Mark: N = Label will not contain CE mark, CE Mark: Y = Label will contain CE mark, CE Mark: Y & Notify Body: 1 = Label will contain CE0086

Labels that show CE0120 on the actual label should match the label printed above.

Form 00113 - Label Specification

Form Date 5/2007

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We are smith&nephew

Title: LABEL SPECIFICATION / Etikettenspezifikation

OUTER LABEL / Außenetikett	INNER LABEL / Innenetikett	CHART-STIK® LABEL / CHART-STIK® Etikett
<p>QTY: (1)</p>  <p><b>76539165</b>  <b>BIOLOX DELTA</b>  <b>ALUMINA CERAMIC</b>  <b>12/14 TAPER</b>  <b>FEMORAL HEAD</b>  <b>FETE FEMORALE / HUFTKOPF</b>  <b>CABEZA FEMORAL / TESTA FEMORALE</b>  <b>36 MM O.D., S</b>  <b>(S&amp;N +0 = CERAMTEC -4)</b>  <b>LOT NO. SAMPLE</b>  <b>FEMORAL HEAD</b></p> <p>ALUMINA CERAMIC</p> <p>LOT SAMPLE    <b>STERILE R</b>  2018-12  </p> <p>Made in GERMANY  Smith &amp; Nephew, Inc.  Memphis, TN 38118 USA  EC REP: Smith &amp; Nephew  Compañías GmbH, Tübingen,  Germany</p> <p>*H728765391651W*  **SSAMPLEWH*</p>	<p>QTY: (1)</p> <p><b>76539165</b>  <b>BIOLOX DELTA</b>  <b>36 MM O.D., S</b>  <b>(S&amp;N +0 = CERAMTEC -4)</b>  <b>12/14 TAPER FEMORAL HEAD</b>  <b>ALUMINA CERAMIC</b>  <b>LOT SAMPLE</b>  </p> <p>  <b>STERILE R</b>  2018-12  TAM-STIK</p>	<p>ATTACH TO PATENTS RECORD</p> <p><b>CHART-STIK® LABEL</b>  <b>76539165</b>  <b>LOT SAMPLE</b>  <b>BIOLOX DELTA</b>  <b>36 MM O.D., S</b>  <b>(S&amp;N +0 = CERAMTEC -4)</b>  <b>12/14 TAPER FEMORAL HEAD</b>  <b>ALUMINA CERAMIC</b></p> <p>*H728765391650V*  **SSAMPLELVQ*</p> <p></p> <p><b>OTHER LABEL / sonstige Etiketten</b></p>

Note: The attached label is representative of the actual label. Reference Packaging Data Sheet for CE Mark information on actual label.

KEY:

CE Mark: N = Label will not contain CE mark, Y = Label will contain CE mark, Y & Notify Body: 1 = Label will contain CE0086

Labels that show CE0120 on the actual label should match the label printed above.

Form 00113 - Label Specification

Form Date 5/2007

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## Total Hip System

### Important Medical Information

#### Important Note

Total hip replacement (THR) arthroplasty has become a successful procedure for relieving pain and restoring motion in patients who are disabled from hip arthropathy. The goals of total hip replacement are to decrease pain, increase function, and increase mobility.

#### Materials

Femoral components are cobalt chromium alloy, titanium 6Al-4V alloy or stainless steel. Femoral heads are cobalt chromium alloy, alumina ceramic, OXINIUM® oxidized zirconium or stainless steel. Acetabular liners are ultra-high molecular weight polyethylene (UHMWPE), cobalt chromium (CoCr) alloy, alumina ceramic, or delta ceramic. All poly acetabular components are UHMWPE. Acetabular shells are titanium 6Al-4V alloy or cobalt chromium (CoCr). The component material is provided on the outside carton label. Note: R3 metal acetabular liners and delta ceramic heads are not available in the US.

Some of the alloys needed to produce orthopedic implants contain some metallic components that may be carcinogenic in tissue cultures or intact organism under very unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified conclusive evidence of such phenomenon, in spite of the millions of implants in use.

#### Description of System

The Total Hip System consists of femoral components, modular necks, proximal sleeves, taper sleeves, acetabular components, fixation screws and pegs, hole covers, centralizers, and femoral heads. Components may be grit blasted, porous coated, hydroxylapatite (HA) coated, or HA porous coated. All implantable devices are designed for single use only.

#### Femoral Components

Femoral components are available in a variety of sizes. Porous coated components are coated for biological ingrowth and are intended to be used without cement. Modular femoral components are available with an oval taper to accept Smith & Nephew, Inc. CoCr modular necks and/or a Morse type taper to accept proximal sleeves. Non-porous femoral components can feature PMMA centralizers that help produce a uniform thickness of cement.

Femoral components are available with a Small (10/12), Large (14/16), or 12/14 taper.

Small taper femoral components mate and lock directly with a 22 mm metal or oxidized zirconium or ceramic heads. The Small taper also mates with a taper sleeve which, in turn, mates with either metal or ceramic heads (26, 28, or 32 mm), bipolar or unipolar components.

Large taper femoral components mate and lock with either metal heads (26, 28, or 32 mm), ceramic heads (28 or 32 mm), oxidized zirconium (28, 32, or 36mm), bipolars or unipolar components.

Femoral components or modular necks with a 12/14 taper mate and lock with either metal heads, oxidized zirconium heads, ceramic heads, bipolar or unipolar components.

Small, Large, and 12/14 taper femoral component tapers are machined to mate and lock with ceramic heads, thus preventing rotation of the ceramic head on the stem, which would cause wear of the stem taper.

### Taper Sleeves

A taper sleeve is required to be impacted on the Small taper femoral component prior to impacting a Large (14/16) taper femoral head size 26, 28, or 32 mm. A taper sleeve is required to attach a unipolar head. Unipolar taper sleeves are available in Small, Large, and 12/14 tapers. Never place more than one taper sleeve on a femoral component.

### Modular Necks

Modular necks are available in a variety of configurations. The modular neck mates and locks with the oval taper of a modular femoral component on one end and the taper of a 12/14 femoral head on the other end.

### Femoral Heads

Cobalt chromium, stainless steel, oxidized zirconium, and ceramic heads are available in multiple neck lengths for proper anatomic and musculature fit. Heads are highly polished for reduced friction and wear.

The following alumina ceramic and delta ceramic heads are available for use only with 12/14 taper femoral components:

Alumina Ceramic	Head Diameter	Neck Length	
71332800	28mm	+0mm	
71332804	28mm	+4mm	
71332808	28mm	+8mm	
71333200	32mm	+0mm	
71333204	32mm	+4mm	
71333208	32mm	+8mm	
71333600	36mm	+0mm	
71333604	36mm	+4mm	
71333608	36mm	+8mm	
76539150	36mm	-4mm	
76539151	36mm	+0mm	
76539152	36mm	+4mm	
71331047	36mm	+0mm	
71331048	36mm	+4mm	
71331049	36mm	+8mm	
Delta Ceramic	Head Diameter	Smith & Nephew Offset	CeramTec Offset
71336080	28mm	+0mm	-4mm
71336084	28mm	+4mm	+0mm
71336088	28mm	+8mm	+4mm
71337080	32mm	+0mm	-4mm
71337084	32mm	+4mm	+0mm
71337088	32mm	+8mm	+4mm
71338080	36mm	+0mm	-4mm

71338084	36mm	+4mm	+0mm
71338088	36mm	+8mm	+4mm
76539153	36mm	+8mm	+4mm

The following CoCr BIRMINGHAM HIP® (BH) modular heads should be used only with BHR\* acetabular cups and R3\*\* metal acetabular liners:

74121238	Modular Head 38mm -8mm
74121338	Modular Head 38mm -4mm
74121438	Modular Head 38mm +0mm
74121538	Modular Head 38mm +4mm
74121242	Modular Head 42mm -8mm
74121342	Modular Head 42mm -4mm
74121442	Modular Head 42mm +0mm
74121542	Modular Head 42mm +4mm
74121246	Modular Head 46mm -8mm
74121346	Modular Head 46mm -4mm
74121446	Modular Head 46mm +0mm
74121546	Modular Head 46mm +4mm
74121250	Modular Head 50mm -8mm
74121350	Modular Head 50mm -4mm
74121450	Modular Head 50mm +0mm
74121550	Modular Head 50mm +4mm
74121254	Modular Head 54mm -8mm
74121354	Modular Head 54mm -4mm
74121454	Modular Head 54mm +0mm
74121554	Modular Head 54mm +4mm
74121258	Modular Head 58mm -8mm
74121358	Modular Head 58mm -4mm
74121458	Modular Head 58mm +0mm
74121558	Modular Head 58mm +4mm
74222138	Modular Head 38mm
74222140	Modular Head 40mm
74222142	Modular Head 42mm
74222144	Modular Head 44mm
74222146	Modular Head 46mm
74222148	Modular Head 48mm
74222150	Modular Head 50mm
74222152	Modular Head 52mm
74222154	Modular Head 54mm
74222156	Modular Head 56mm
74222158	Modular Head 58mm

\*BH Modular Heads are not available in the US.

\*\*R3 metal acetabular liners are not available in the US.

### Acetabular Components

Acetabular components can be one-piece all polyethylene, or two-piece, consisting of a titanium shell and either a UHMWPE liner, alumina ceramic liner, delta ceramic liner or CoCr metal liner. For alumina ceramic liners available for use with the REFLECTION® Ceramic Acetabular System in the US, refer to the separate package insert provided with these components. See Warnings and Precautions for specific information on screws, pegs and hole covers use. Acetabular reinforcement and reconstruction rings are used with an all polyethylene acetabular component. Note: R3 metal acetabular liners and delta ceramic liners are not available in the US.

The BIRMINGHAM HIP Resurfacing (BHR) prosthesis is a metal-on-metal bearing component consisting of a stemmed femoral head resurfacing component designed for cemented insertion and a hemispherical acetabular cup designed for cementless interference fit into the acetabulum. For BHR components available in the US, refer to the separate package insert provided with these components. The acetabular cup has hydroxylapatite coating applied to the external surface and porous coating. Cement should not be used with this type of implant.

Note: 10 Mrad cross-linked UHMWPE acetabular liners may be used with metal (CoCr), oxidized zirconium, or alumina ceramic femoral heads.

Femoral components and femoral heads are designed for use with any Smith & Nephew polyethylene acetabular component or polyethylene-lined, metal-backed acetabular component having an appropriately-sized inside diameter. Acetabular liners are designed for use only with acetabular shells from the same product family (i.e. REFLECTION liners can only be used with REFLECTION shells; R3 liners can only be used with R3 shells).

#### **INDICATIONS, CONTRAINDICATIONS, AND ADVERSE EFFECTS**

Hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses of osteoarthritis, avascular necrosis, traumatic arthritis, slipped capital epiphysis, fused hip, fracture of the pelvis, and diastrophic variant.

Hip components are also indicated for inflammatory degenerative joint disease including rheumatoid arthritis, arthritis secondary to a variety of diseases and anomalies, and congenital dysplasia; old, remote osteomyelitis with an extended drainage-free period, in which case, the patient should be warned of an above normal danger of infection postoperatively; treatments of nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; endoprosthesis, femoral osteotomy, or Girdlestone resection; fracture-dislocation of the hip; and correction of deformity.

The BIRMINGHAM HIP Resurfacing (BHR) arthroplasty system is indicated for use for reduction or relief of pain and/or improved hip function in patients who are candidates for a total hip replacement but who have evidence of good femoral bone stock. These patients should also be skeletally mature with one or more of the following conditions: noninflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia; inflammatory degenerative joint disease such as rheumatoid arthritis; correction of functional deformity; and are of an age such that total hip revision is likely at some future point. For BHR components available in the US, refer to the separate package insert provided with these components.

Acetabular reinforcement and reconstruction rings are intended to be used in primary and revision surgeries where the acetabulum has the deficiencies of the acetabular roof, anterior or posterior pillar, medial wall deficiency, and / or protrusion as a result of the indications listed previously.

Some of the diagnoses listed above and below may also increase the chance of complications and reduce the chance of a satisfactory result.

## Contraindications

1. Conditions that would eliminate or tend to eliminate adequate implant support or prevent the use of an appropriately- sized implant, e.g.:
  - a. blood supply limitations;
  - b. insufficient quantity or quality of bone support, e.g., osteoporosis, or metabolic disorders which may impair bone formation, and osteomalacia; and
  - c. infections or other conditions which lead to increased bone resorption.
2. Mental or neurological conditions which tend to impair the patient's ability or willingness to restrict activities.
3. Physical conditions or activities which tend to place extreme loads on implants, e.g., Charcot joints, muscle deficiencies, multiple joint disabilities, etc.
4. Skeletal immaturity.
5. The alumina ceramic liner is contraindicated for use with any product other than the metal shell with the correlating inner taper geometry and the appropriate sized alumina ceramic head. The alumina ceramic liner should only be used with the alumina ceramic head.

Contraindications may be relative or absolute and must be carefully weighed against the patient's entire evaluation and the prognosis for possible alternative procedures such as non-operative treatment, arthrodesis, femoral osteotomy, pelvic osteotomy, resection arthroplasty, hemiarthroplasty and others.

Conditions presenting increased risk of failure include: osteoporosis, metabolic disorders which may impair bone formation, and osteomalacia.

## Possible Adverse Effects

1. Wear of the polyethylene and ceramic articulating surfaces of acetabular components may occur. Higher rates of wear may be initiated by the presence of particles of cement, metal, or other debris which can develop during or as a result of the surgical procedure and cause abrasion of the articulating surfaces. Higher rates of wear may shorten the useful life of the prosthesis and lead to early revision surgery to replace the worn prosthetic components.
2. With all joint replacements, asymptomatic, localized, progressive bone resorption (osteolysis) may occur around the prosthetic components as a consequence of foreign-body reaction to particulate wear debris. Particles are generated by interaction between components, as well as between the components and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Secondarily, particles may also be generated by third-body particles lodged in the polyethylene or ceramic articular surfaces. Osteolysis can lead to future complications necessitating the removal or replacement of prosthetic components.
3. Loosening, bending, cracking, or fracture of implant components may result from failure to observe the Warnings and Precautions below. Fracture of the implant can occur as a result of trauma, strenuous activity, improper alignment, or duration of service.
4. Dislocations, subluxation, decreased range of motion, or lengthening or shortening of the femur caused by improper neck selection, positioning, looseness of acetabular or femoral components, extraneous bone, penetration of the femoral prosthesis through the shaft of the femur, fracture of the acetabulum, intrapelvic protrusion of acetabular component, femoral impingement, periarticular calcification, and/or excessive reaming.
5. Fracture of the pelvis or femur: post-operative pelvic fractures are usually stress fractures. Femoral fractures are often caused by defects in the femoral cortex due to misdirected reaming, etc. Intraoperative fractures are usually associated with old congenital deformity, improper stem selection, improper broaching, and/or severe osteoporosis.
6. Infection, both acute post-operative wound infection and late deep wound sepsis.
7. Neuropathies; femoral, sciatic, peroneal nerve, and lateral femoral cutaneous neuropathies have been reported. Temporary or permanent nerve damage resulting in pain or numbness of the affected limb.
8. Wound hematoma, thromboembolic disease including venous thrombosis, pulmonary embolus, or myocardial infarction.

9. Myositis ossificans, especially in males with hypertrophic arthritis, limited pre-operative range of motion and/or previous myositis. Also, periarticular calcification with or without impediment to joint mobility can cause decreased range of motion.
10. Trochanteric nonunion usually associated with early weight bearing and/or improper fixation of the trochanter, when a transtrochanteric surgical approach is used.
11. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients following joint replacement.
12. Damage to blood vessels.
13. Traumatic arthrosis of the knee from intraoperative positioning of the extremity.
14. Delayed wound healing.
15. Aggravated problems of the affected limb or contralateral extremity caused by leg length discrepancy, excess femoral medialization, or muscle deficiency.
16. Failure of the porous coating/ substrate interface or hydroxylapatite coating/ porous coating bonding may result in bead separation delamination.
17. Stem migration or subsidence has occurred in conjunction with compaction grafting procedures usually resulting from insufficient graft material or improper cement techniques. Varus stem alignment may also be responsible.
18. Stem loosening or fracture, particularly of smaller sized stems, is most likely to occur in patients who are young, physically active, and/or heavy.

### **Warnings and Precautions**

The patient should be warned of surgical risks, and made aware of possible adverse effects. The patient should be warned that the device does not replace normal healthy bone, that the implant can break or become damaged as a result of activity or trauma, and that it has a finite expected service life and may need to be replaced in the future. Do not mix components from different manufacturers unless specially approved by the manufacturer of the components. For purposes of product inter-compatibility, products manufactured and labeled by entities formerly known as Plus Endoprothetik, Intraplant, Precision Implants and Plus Orthopedics (now Smith & Nephew Orthopaedics AG) may be considered as the same manufacturer, Smith & Nephew. Additional Warnings and Precautions may be included in component literature.

### **Preoperative**

1. Use extreme care in handling and storage of implant components. Cutting, bending, or scratching the surface of components can significantly reduce the strength, fatigue resistance, and/or wear characteristics of the implant system. These, in turn, may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected from corrosive environments such as salt air during storage. Do not allow the porous surfaces to come in contact with cloth or other fiber-releasing materials.
2. Allergies and other reactions to device materials, although infrequent, should be considered, tested for (if appropriate), and ruled out preoperatively.
3. Fixation and expected longevity of components expected to be left in place at revision surgery should be thoroughly assessed.
4. Surgical technique information is available upon request. The surgeon should be familiar with the technique. Refer to medical or manufacturer literature for specific product information.
5. Intraoperative fracture or breaking of instruments can occur. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Instruments should be examined for wear, or damage, prior to surgery.
6. Do not cold water quench ceramic components and never sterilize ceramic heads while fixed on the stem taper. (See sterilization section, below.)
7. Select components such that oxidized zirconium heads always articulate with a UHMWPE cup or a metal backed UHMWPE cup; alumina heads articulate with UHMWPE liners, alumina ceramic liners, or delta ceramic liners; and BHR resurfacing heads and BH modular heads articulate with BHR acetabular cups or R3 metal liners. Oxidized

zirconium and alumina ceramic heads should never articulate against metal because severe wear of the metal will occur. Note: Delta ceramic liners, BH modular heads and R3 metal liners are not available in the US.

8. Select only Smith & Nephew femoral components that indicate their use with ceramic heads. This is important because the taper on the stem is machined to tightly mate and lock with the ceramic head thus preventing rotation of the ceramic head on the stem. Also, an improperly dimensioned taper could result in fracture of the ceramic head.
9. Alumina ceramic should never articulate against metal because severe wear could occur.
10. The SL-PLUS<sup>®</sup> Standard Hip Stems and SL-PLUS Lateralized Hip Stems are compatible with Smith & Nephew femoral heads, including Unipolar and Bipolar, with the exception of the following heads: Smith & Nephew 36mm -3 heads or any of the +16 heads. In addition, PLUS 12/14 taper femoral heads are compatible with Smith & Nephew femoral stems.
11. If a computer assisted surgery system is used, consult the applicable software and hardware reference manuals provided by the manufacturer to ensure proper operation of this equipment.

### **Intraoperative**

1. The general principles of patient selection and sound surgical judgment apply. The correct selection of the implant is extremely important. The appropriate type and size should be selected for patients with consideration of anatomical and biomechanical factors such as patient age and activity levels, weight, bone and muscle conditions, any prior surgery and anticipated future surgeries, etc. Generally, the largest cross-section component which will allow adequate bone support to be maintained is preferred. Failure to use the optimum-sized component may result in loosening, bending, cracking, or fracture of the component and/or bone.
2. Correct selection of the neck length and cup, and stem positioning, are important. Muscle looseness and/or malpositioning of components may result in loosening, subluxation, dislocation, and/or fracture of components. Increased neck length and varus positioning will increase stresses which must be borne by the stem. The component should be firmly seated with the component insertion instruments.
3. Care should be taken not to scratch, bend (with the exception of the Reconstruction Rings) or cut implant components during surgery for the reasons stated in Number One of the "Pre-Operative" section of "Warnings and Precautions."
4. A +12 mm or +16 mm femoral head should not be used with any Small taper stems.
5. MATRIX<sup>®</sup> Small taper stem sizes 8S - 10L must have a minimum neck length of +8 mm when used with a bipolar component; and Small taper stem sizes 12S - 16L must have a minimum neck length of +4 mm when used with a bipolar component.
6. Modular heads, modular necks, modular sleeves and femoral components should be from the same manufacturer unless specially approved by the manufacturer of the components to prevent mismatch.
7. Stainless steel heads and stainless steel stems should only be used together. Neither should be used with other metal components.
8. Use only REFLECTION Liners with REFLECTION Shells. Use only R3 Liners with R3 Shells.
9. Clean and dry all taper connections prior to impacting for assembly. The modular femoral head, neck and/or sleeve components must be firmly seated on the femoral component to prevent disassociation.
10. Take care, when positioning and drilling screw and peg holes, to avoid penetration of the inner cortex of the pelvis, penetration of the sciatic notch, or damage to vital neurovascular structures. Perforation of the pelvis with screws that are too long can rupture blood vessels causing the patient to hemorrhage. Do not place a screw in the center hole of the acetabular prosthesis. Placement of drills and screws in the anterior or medial portions of the prosthesis is associated with a high risk of potentially fatal vascular injury. Bone screws must be completely seated in the holes of the shell to allow proper locking for the acetabular component liner. If the tapered pegs need to be removed from the shell after impaction of the pegs, do not reuse the pegs or the peg shell holes. Use new pegs and different shell holes, or a new shell if necessary.
11. REFLECTION Three Hole, FSO, INTERFIT<sup>®</sup> and R3 Shells accept both REFLECTION spherical head screws and Universal cancellous bone screws. REFLECTION FSO and INTERFIT Shells accept the Modified REFLECTION screw

hole covers. The REFLECTION V Shell only accepts Universal Cancellous, REFLECTION screws, tapered screw-hole covers and tapered, pegs. REFLECTION Peripheral Hole Screws should only be used with REFLECTION Peripheral Hole Shells. Locking Head Pegs and REFLECTION Locking Head Screw Hole Covers are only for use with REFLECTION Three Hole Shells. The threaded center hole in REFLECTION Shells only accepts threaded hole covers, not screws or pegs. The INTERFIT threaded hole cover is only for use with REFLECTION INTERFIT, Spiked and No Hole Shells. The REFLECTION threaded hole cover can be used with all REFLECTION and R3 shells. The R3 screw hole cover can be used with R3 and REFLECTION Three Hole shells. Refer to product literature for proper adjunctive fixation and hole cover usage.

12. Prior to seating modular components, surgical debris including tissue must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component locking mechanism. If the shell is to be cemented in place, remove extraneous cement with a plastic sculps tool to ensure proper locking of the liner. During liner insertion, make sure soft tissue does not interfere with the shell/liner interface. Chilling the liner reduces the impaction force required to seat the liner. Modular components must be assembled securely to prevent disassociation. Debris inhibits the proper fit and locking of modular components which may lead to early failure of the procedure. Failure to properly seat the acetabular liner into the shell can lead to disassociation of the liner from the shell.
13. Avoid repeated assembly and disassembly of the modular components which could compromise the critical locking action of the locking mechanism.
14. Care is to be taken to assure complete support of all parts of the device embedded in bone cement to prevent stress concentration which may lead to failure of the procedure. During curing of the cement, care should be taken to prevent movement of the implant components.
15. If the head is removed from a femoral component that will be left in place at revision surgery, it is recommended that a metal head be used. A ceramic head may fracture from irregularities on the femoral component taper.
16. If components are to be left in place at revision surgery, they should first be thoroughly checked for signs of looseness, etc. and replaced if necessary. The head/neck component should be changed only when clinically necessary.
17. Once removed from the patient, implants previously implanted should never be reused, since internal stresses which are not visible may lead to early bending or fracture of these components.
18. With the congenitally dislocated hip, special care should be taken to prevent sciatic nerve palsy. Also, note that the femoral canal is often very small and straight and may require an extra-small straight femoral prosthesis; however, a regular-sized prosthesis should be used when possible. Note that the true acetabulum is rudimentary and shallow. A false acetabulum should not ordinarily be utilized as a cup placement site for anatomical and biomechanical reasons.
19. With rheumatoid arthritis, especially for those patients on steroids, bone may be extremely osteoporotic. Care should be taken to prevent excessive penetration of the acetabular floor or fracture of the medial acetabular wall, femur, or greater trochanter.
20. Revision procedures for previous arthroplasty, Girdlestone, etc., are technically demanding and difficult to exercise. Common errors include misplacement of the incision, inadequate exposure or mobilization of the femur, inadequate removal of ectopic bone, or improper positioning of components. Postoperative instability as well as excessive blood loss can result. In summary, increased operative time, blood loss, increased incidence of pulmonary embolus and wound hematoma can be expected with revision procedures.
21. Prior to closure, the surgical site should be thoroughly cleaned of cement, bone chips, ectopic bone, etc. Ectopic bone and/or bone spurs may lead to dislocation or painful or restricted motion. Range of motion should be thoroughly checked for early contact or instability.
22. Proper positioning of the components is important to minimize impingement which could lead to early failure, premature wear, and/or dislocation.
23. In order to minimize the risks of dislocation and loosening of the shell-acetabular bone or shell-bone cement interface that may occur when using a metallic shell intended for biological fixation or cemented use only, surgeons should consider providing immediate resistance to tensile forces between the metallic shell and the

acetabular bone or bone cement interface through the use of orthopedic bone fixation devices such as bone screws, spikes, screw threads, pegs, fins, or other bone fixation devices.

24. Physicians should consider component malposition, component placement, and the effect on range of motion when using modular heads (with sleeves or skirts) and extended liners.
25. For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g. bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and malpositioned implants.

### Postoperative

1. Postoperative directions and warnings to patients by physicians, and patient care, are extremely important. Gradual weight bearing is begun after surgery in ordinary total hip arthroplasty. However, with trochanter osteotomy or certain complex cases, weight-bearing status should be individualized with the non or partial weight-bearing period extended.
2. Patients should be warned against unassisted activity, particularly use of toilet facilities and other activities requiring excessive motion of the hip.
3. Use extreme care in patient handling. Support should be provided to the operative leg when moving the patient. While placing the patient on bedpans, changing dressings, and clothing, and similar activities, precautions should be taken to avoid placing excessive load on the operative part of the body.
4. Postoperative therapy should be structured to regain muscle strength around the hip and a gradual increase of activities.
5. Periodic x-rays are recommended for close comparison with immediate postoperative conditions to detect long-term evidence of changes in position, loosening, bending and/or cracking of components or bone loss. With evidence of these conditions, patients should be closely observed, the possibilities of further deterioration evaluated, and the benefits of early revision considered.
6. Prophylactic antibiotics should be recommended to the patient similar to those suggested by the American Heart Association for conditions or situations that may result in bacteremia.

### Packaging and Labeling

Implants should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

### Sterilization

Implant components are supplied sterile to a Sterility Assurance Level (SAL) of (b) (4) Trade Secret. Implant components are supplied in protective packaging. Inspect packages for punctures or other damage prior to surgery. The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation.

DO NOT REUSE OR RESTERILIZE hip implant components or disposable instruments. Contact your local Smith & Nephew, Inc. Sales Representative regarding procedures to return components. If not specifically labeled sterile, instruments are supplied non-sterile and must be sterilized prior to surgery using one of the following validated, recommended methods:

### Cycle Parameters

- Dynamic Air Removal (Prevacuum) Steam Cycle: (b) (4) Trade Secret Process
- United Kingdom Steam Cycle (sterilization should be carried out in accordance with HTM 2010): (b) (4) Trade Secret

- World Health Organization Steam Cycle: 4 pulses at 134°C for 18 minutes and a minimum vacuum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C to 135°C (270°F to 275°F) with a minimum exposure time of 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle: Exposure temperature: 132°C to 135°C (270°F to 275°F). Exposure time for a Gravity Displacement Cycle of 15 minutes or Dynamic Air Removal (Prevacuum) Cycle of 3 to 4 minutes.

Please see also the document, "Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices:", which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

## INFORMATION

For further information, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Manufacturing facilities and EC representative:

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78532 Tuttlingen, Germany  
Tel.: 07462/208-0  
Fax: 07462/208-135

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

H<sub>2</sub>O<sub>2</sub> – hydrogen peroxide sterilization

®Trademark of Smith & Nephew, Certain Marks Reg. U.S. Pat. & TM Off.

81061128 Rev. 0 08/08



## Design Verification Tests – Biolox Delta Ceramic Femoral Heads

Evaluation conducted per the requirements of the *Draft Guidance Document for Testing Acetabular Cup Prostheses* dated May 1, 1995; the *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components* dated May 1, 1995; *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

Design Aspect Reviewed	Change	Risk	Verification Activity/ Acceptance Criteria	Results of Verification/Design Aspect Information
Material	Material change from Alumina Ceramic to Delta Ceramic	Material may not be biocompatible	<p><b>Verification Activity:</b> Verify that the delta ceramic material will not introduce any biocompatibility issues.</p> <p><b>Acceptance Criteria:</b> The subject device material must be equivalent to that used in the manufacture of devices previously cleared for market.</p> <p>N/A</p>	<p>The Biolox Delta Ceramic femoral heads subject of this premarket notification will be manufactured from (b) (4) Trade Secret Process. This material has been used in the manufacture of femoral head components cleared in premarket notification K071535 by Zimmer Inc.</p>
Identification of the Stem	No Change	N/A	N/A	<p>The Biolox Delta Ceramic femoral heads will feature a 12/14 taper and are intended to be used with existing Smith &amp; Nephew femoral hip stems with a corresponding taper junction; cleared as described in <b>Table 2</b> of the submission. The femoral head mechanically locks with the femoral hip stem via a taper junction and articulates against polyethylene acetabular liners which have been cleared for use as described in <b>Table 4</b> of the submission.</p>

### Design Verification Tests – BioloX Delta Ceramic Femoral Heads

Evaluation conducted per the requirements of the *Draft Guidance Document for Testing Acetabular Cup Prostheses* dated May 1, 1995; the *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components* dated May 1, 1995; *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

Design Aspect Reviewed	Change	Risk	Verification Activity/ Acceptance Criteria	Results of Verification/Design Aspect Information
Cone Design	No Change	N/A	N/A	There has been no change to the cone design of the 12/14 taper femoral hip stems that will be used with the BioloX Delta Ceramic femoral heads.
Identification of the Ball	Material change from Alumina Ceramic to Delta Ceramic	Biocompatibility	<p><b>Verification Activity:</b> Verify that the delta ceramic material composition will not introduce any biocompatibility issues.</p> <p><b>Acceptance Criteria:</b> The identification of the ball shall conform to the applicable parameters set forth in the Guidance document for Ceramic Femoral Heads<sup>1</sup> and be substantially equivalent to existing femoral heads already cleared for market.</p>	(b)(4) Trade Secret Process

<sup>1</sup> FDA Draft Guidance, "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip System," January 1995.

### Design Verification Tests – BioloX Delta Ceramic Femoral Heads

Evaluation conducted per the requirements of the *Draft Guidance Document for Testing Acetabular Cup Prostheses* dated May 1, 1995; the *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components* dated May 1, 1995; *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

Design Aspect Reviewed	Change	Risk	Verification Activity/ Acceptance Criteria	Results of Verification/Design Aspect Information
Identification of the Ball	Material change from Alumina Ceramic to Delta Ceramic	Increased Risk of Stress Fracture during Engraving	<p><b>Verification Activity:</b> Verify that the surface engraving of the delta ceramic material will not introduce an increased risk of stress fracture.</p> <p><b>Acceptance Criteria:</b> The identification of the ball shall conform to the applicable parameters set forth in the Guidance document for Ceramic Femoral Heads' and be substantially equivalent to existing femoral heads already cleared for market.</p>	(b)(4) Trade Secret Process

### Design Verification Tests – BioloX Delta Ceramic Femoral Heads

Evaluation conducted per the requirements of the *Draft Guidance Document for Testing Acetabular Cup Prostheses* dated May 1, 1995; the *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components* dated May 1, 1995; *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

Design Aspect Reviewed	Change	Risk	Verification Activity/ Acceptance Criteria	Results of Verification/Design Aspect Information
Ball Design	Material change from Alumina Ceramic to Delta Ceramic	Biocompatibility of the material in vivo	<p><b>Verification Activity:</b> Verify that the delta ceramic material will not introduce any biocompatibility issues.</p> <p><b>Acceptance Criteria:</b> The ball design shall conform to the applicable parameters set forth in the Guidance document for Ceramic Femoral Heads<sup>1</sup> and be substantially equivalent to existing femoral heads already cleared for market.</p>	<p>The mechanical ball design of the BioloX Delta Ceramic femoral heads is identical to the Smith &amp; Nephew BioloX Forte Alumina ceramic heads already cleared for market cleared via 510(k) premarket notifications K981847, K991162, and K022958 (Engineering drawings located in Exhibit 6). The material properties of the BioloX Delta Ceramic femoral heads are the same as Zimmer Inc. femoral head components cleared in premarket notification K071535. Additional information can be found (b)(4) Trade Secret Process</p>





### Design Verification Tests – Biolox Delta Ceramic Femoral Heads

Evaluation conducted per the requirements of the *Draft Guidance Document for Testing Acetabular Cup Prostheses* dated May 1, 1995; the *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components* dated May 1, 1995; *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

Design Aspect Reviewed	Change	Risk	Verification Activity/ Acceptance Criteria	Results of Verification/Design Aspect Information
<b>Fatigue Properties</b>	Material change from Alumina Ceramic to Delta Ceramic	Catastrophic burst of the femoral head	<p><b>Verification Activity:</b> Evaluate the fatigue performance of rationalizing the performance of the Biolox Delta Ceramic femoral heads.</p> <p><b>Acceptance Criteria:</b> The evaluation shall conclude that the fatigue performance of subject devices is equivalent to devices previously cleared for market.</p>	<p>Burst testing was performed on the 12/14 taper, 28mm long (+8) Biolox Delta ceramic femoral heads on CoCr trunnions, which represents worst case<sup>2</sup>. The femoral heads had an average burst strength of 57.5 kN. This burst strength exceeds the FDA requirement of 46 kN and is greater than the predicate Biolox Forte Alumina ceramic burst strength of 40.2 kN. Because of the increased strength of the subject delta ceramic heads over the predicate alumina ceramic heads, it can be expected that the fatigue performance of the Biolox Delta Ceramic femoral heads would be equivalent to, if not better than, the Biolox Forte Alumina ceramic heads already cleared for market and should be able to withstand <i>in vivo</i> loads without failure.<sup>5</sup> Please see <b>Exhibit 18</b> for a Technical Memorandum supporting this justification.</p>

<sup>5</sup> Technical Memo, "Justification for the Ceramtec Delta Alumina Femoral Heads," Tsai, S., Smith&Nephew, Inc., January 2008.



### Design Verification Tests – Biolox Delta Ceramic Femoral Heads

Evaluation conducted per the requirements of the *Draft Guidance Document for Testing Acetabular Cup Prostheses* dated May 1, 1995; the *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components* dated May 1, 1995; *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

Design Aspect Reviewed	Change	Risk	Verification Activity/ Acceptance Criteria	Results of Verification/Design Aspect Information																													
Stress Analysis	No Change	N/A	N/A	<p>The Biolox Delta Ceramic femoral heads are offered in the same diameters, head offsets, and material as existing femoral heads previously cleared by FDA as noted in the table below.</p> <table border="1"> <thead> <tr> <th>Size</th> <th>Offset (mm)</th> <th>Predicate 510(k)</th> </tr> </thead> <tbody> <tr> <td rowspan="3">28mm</td> <td>+0</td> <td></td> </tr> <tr> <td>+4</td> <td>K981847</td> </tr> <tr> <td>+8</td> <td></td> </tr> <tr> <td rowspan="3">32mm</td> <td>+8 (with CoCr Stem)</td> <td>K991162</td> </tr> <tr> <td>+0</td> <td></td> </tr> <tr> <td>+4</td> <td>K981847</td> </tr> <tr> <td rowspan="3">36 mm</td> <td>+8</td> <td></td> </tr> <tr> <td>+0</td> <td></td> </tr> <tr> <td>+4</td> <td>K022958</td> </tr> <tr> <td rowspan="2">28-40 mm</td> <td>+8</td> <td></td> </tr> <tr> <td>Unknown</td> <td>K071535</td> </tr> </tbody> </table> <p>In view of the fact that the Biolox Delta Ceramic femoral heads are offered in sizes and material equivalent to those of existing, FDA-cleared femoral heads, the stresses seen by the subject devices are expected to be equivalent to those of the predicate femoral heads identified in the table above.</p>	Size	Offset (mm)	Predicate 510(k)	28mm	+0		+4	K981847	+8		32mm	+8 (with CoCr Stem)	K991162	+0		+4	K981847	36 mm	+8		+0		+4	K022958	28-40 mm	+8		Unknown	K071535
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### Design Verification Tests – Biolox Delta Ceramic Femoral Heads

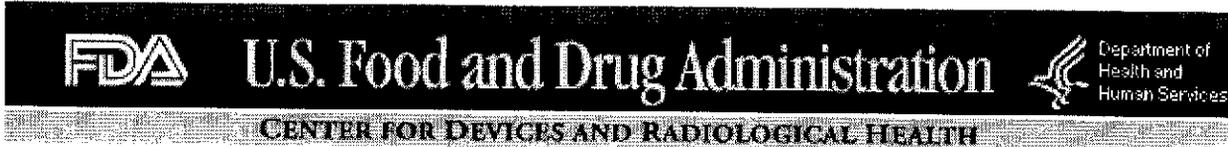
Evaluation conducted per the requirements of the *Draft Guidance Document for Testing Acetabular Cup Prostheses* dated May 1, 1995; the *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components* dated May 1, 1995; *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

Design Aspect Reviewed	Change	Risk	Verification Activity/Acceptance Criteria	Results of Verification/Design Aspect Information																								
Kinematics – Range of Motion	No change	N/A	N/A	<p>The Biolox Delta Ceramic femoral heads are offered in the same diameters and head offsets as existing femoral heads previously cleared by FDA as noted in the table below.</p> <table border="1" data-bbox="613 192 1084 825"> <thead> <tr> <th>Size</th> <th>Offset (mm)</th> <th>Predicate 510(k)</th> </tr> </thead> <tbody> <tr> <td rowspan="3">28mm</td> <td>+0</td> <td></td> </tr> <tr> <td>+4</td> <td>K981847</td> </tr> <tr> <td>+8</td> <td></td> </tr> <tr> <td rowspan="3">32mm</td> <td>+8 (with CoCr Stem)</td> <td>K991162</td> </tr> <tr> <td>+0</td> <td></td> </tr> <tr> <td>+4</td> <td>K981847</td> </tr> <tr> <td rowspan="3">36 mm</td> <td>+8</td> <td></td> </tr> <tr> <td>+0</td> <td></td> </tr> <tr> <td>+4</td> <td>K022958</td> </tr> </tbody> </table>	Size	Offset (mm)	Predicate 510(k)	28mm	+0		+4	K981847	+8		32mm	+8 (with CoCr Stem)	K991162	+0		+4	K981847	36 mm	+8		+0		+4	K022958
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36 mm	+8																											
	+0																											
	+4	K022958																										
<p>Given that the Biolox Delta Ceramic femoral heads are offered in identical sizes and offsets to those of existing, FDA-cleared femoral heads, the range of motion of the subject devices is expected to be equivalent to that of the predicate femoral heads identified in the table above.</p>																												

### Design Verification Tests – BioloX Delta Ceramic Femoral Heads

Evaluation conducted per the requirements of the *Draft Guidance Document for Testing Acetabular Cup Prostheses* dated May 1, 1995; the *Draft Guidance Document for Testing Non-Articulating, "Mechanically Locked," Modular Implant Components* dated May 1, 1995; *Draft Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, dated January 10, 1995.

Design Aspect Reviewed	Change	Risk	Verification Activity/ Acceptance Criteria	Results of Verification/Design Aspect Information
Biocompatibility	Material change from Alumina Ceramic to Delta Ceramic	Material not Biocompatible	<p><b>Verification Activity:</b> Verify that the delta ceramic material will not introduce any biocompatibility issues.</p> <p><b>Acceptance Criteria:</b> The subject device material must be equivalent to that used in the manufacture of devices previously cleared for market.</p>	(b)(4) Trade Secret Process - Testing Report
Clinical Data	No change	N/A	N/A	



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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<u>Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</u>
<b>510(K) Number</b>	K981847
<b>Device Name</b>	BIOLOX ALUMINA CERAMIC FEMORAL HEAD
<b>Applicant</b>	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis, TN 38116
<b>Contact</b>	Joann Kuhne
<b>Regulation Number</b>	888.3353
<b>Classification Product Code</b>	<u>LZO</u>
<b>Date Received</b>	05/26/1998
<b>Decision Date</b>	07/17/1998
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	Orthopedic
<b>Statement/Summary/Purged Status</b>	Summary Only
<b>Summary Type</b>	<u>Summary</u> Abbreviated
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 08/06/2008

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JUL 17 1998

K981847

510(k) Summary of Safety and Effectiveness  
BioloX Alumina Ceramic Femoral Head

**Submitter's name:** Smith & Nephew, Inc  
**Submitter's address:** 1450 Brooks Road, Memphis, TN 38116  
**Submitter's telephone number:** 901/396-2121  
**Contact person:** JoAnn Kuhne  
**Date summary prepared:** June 11, 1998

**Trade or proprietary device name:** BioloX Alumina Ceramic Femoral Head  
**Common or unusual name:** Ceramic Femoral Head  
**Classification name:** 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II

**Legally marketed predicate device:** BioloX Alumina Ceramic Femoral Head

**Subject device description:**

The BioloX Alumina Ceramic Femoral Head is (b)(4)Trade Secret Process

The 28 long size will not be marketed in the USA for use with a Co-Cr-Mo taper.

**Subject device intended use:**

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The BioloX Alumina Ceramic Femoral Head is designed for single use only.

**Technological characteristics:**

The BioloX Alumina Ceramic Femoral Head with a 12/14 taper is similar to the devices listed below.

- BioloX Alumina Ceramic Femoral Head - Smith & Nephew
- Zirconia Ceramic Femoral Head - Smith & Nephew
- Alumina C-Taper Ceramic Femoral Head - Osteonics

All of the devices listed above are indicated for total hip replacement and are similar in design to the BioloX Alumina Ceramic Femoral Head. The new device has the same technological characteristics as the predicate device.

**Performance characteristics:**

Mechanical testing was performed according to the requirements in the ceramic femoral head draft guidance document. All of the test results indicate that the BioloX Alumina Ceramic Femoral Head is equivalent to devices currently on the market and capable of withstanding *in vivo* loading without failure.



JUL 17 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. JoAnn M. Kuhne  
Manager, Regulatory Affairs  
Smith & Nephew, Inc.  
Orthopaedic Division  
1450 East Brooks Road  
Memphis, Tennessee 38116

Re: K981847  
Biolox Alumina Ceramic Femoral Heads  
Regulatory Class: II  
Product Code: LZ0  
Dated: May 22, 1998  
Received: May 26, 1998

Dear Ms. Kuhne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitation that the package insert must reflect that the Biolox Alumina Ceramic Femoral Heads are to be used only with cobalt-chrome and Ti6Al4V alloy Smith & Nephew hip stems with the 12/14 taper trunnions, and that the 28 mm long sized femoral head is not for use with cobalt-chrome tapers.

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.

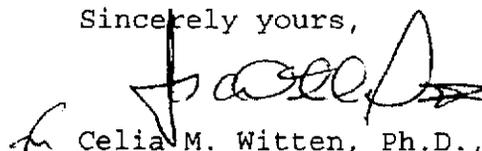
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that,

through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

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

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

Sincerely yours,

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

Enclosure

**Indications Statement**  
**BioloX Alumina Ceramic Femoral Head**

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

Prescription Use           X            
(Per 21 CFR 801.109)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices

510(k) Number           K981847          

CONFIDENTIAL



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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<a href="#">Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</a>
<b>510(K) Number</b>	K991162
<b>Device Name</b>	BIOLOX ALUMINA CERAMIC FEMORAL HEAD
<b>Applicant</b>	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis, TN 38116
<b>Contact</b>	David Henley
<b>Regulation Number</b>	<a href="#">888.3353</a>
<b>Classification Product Code</b>	LZO
<b>Date Received</b>	04/07/1999
<b>Decision Date</b>	01/28/2000
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	Orthopedic
<b>Statement/Summary/Purged Status</b>	<a href="#">Summary/Purged 510(K)</a>
<b>Summary Type</b>	<a href="#">Summary</a> Abbreviated
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 08/06/2008

JAN 28 2000

510(k) Summary of Safety and Effectiveness

K991162

28 mm. Long Biolox Alumina Ceramic Femoral Head

**Submitter's name:** Smith & Nephew, Inc  
**Submitter's address:** 1450 Brooks Road, Memphis, TN 38116  
**Submitter's telephone number:** 901-399-5363  
**Contact person:** David Henley  
**Date summary prepared:** April 01, 1999

**Trade or proprietary device name:** Biolox Alumina Ceramic Femoral Head  
**Common or unusual name:** Ceramic Femoral Head  
**Classification name:** 21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis Class II

**Product code and panel code:** 87LZO/Orthopaedics  
**Legally marketed predicate device:** Biolox Alumina Ceramic Femoral Head

**Subject device description:**

The 28 mm. long Biolox Alumina Ceramic Femoral Head is manufactured from [REDACTED], [REDACTED], and it is designed for use with both titanium and cobalt chromium alloy femoral components with a 12/14 taper.

**Subject device intended use:**

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

The 28 mm. long Biolox Alumina Ceramic Femoral Head is designed for single use only.

**Technological characteristics:**

The 28 mm. long Biolox Alumina Ceramic Femoral Head with a 12/14 taper is similar to the devices listed below.

- Biolox Alumina Ceramic Femoral Head - Smith & Nephew
- Zirconia Ceramic Femoral Head - Smith & Nephew
- Alumina C-Taper Ceramic Femoral Head - Osteonics

All of the devices listed above are indicated for total hip replacement and are similar in design to the 28 mm. long Biolox Alumina Ceramic Femoral Head. The new device has the same technological characteristics as the predicate device.

**Performance characteristics:**

Mechanical testing was performed according to the requirements in the ceramic femoral head draft guidance document. All of the test results indicate that the 28 mm. long Biolox Alumina Ceramic Femoral Head is equivalent to devices currently on the market and capable of withstanding *in vivo* loading without failure.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 28 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. David Henley  
Clinical/Regulatory Affairs Specialist  
Smith & Nephew, Inc.  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K991162

Trade Name: BioloX Alumina Ceramic Femoral Head, 28 mm Long, 12/14 Taper  
Regulatory Class: II  
Product Code: LZ0  
Dated: November 3, 1999  
Received: November 4, 1999

Dear Mr. Henley:

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

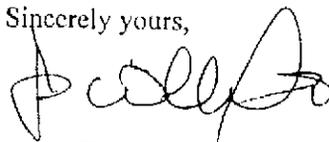
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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

Page 2 - Mr. David Henley

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

Sincerely yours,



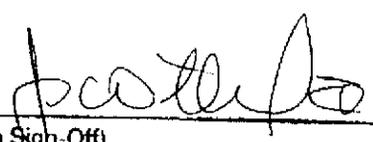
James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

K991162

**Indications Statement**  
**28 mm. Long BioloX Alumina Ceramic Femoral Head**

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.



(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991162

Prescription Use X  
(Per 21 CFR 801.109)



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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<a href="#">Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented</a>
<b>510(K) Number</b>	K022958
<b>Device Name</b>	TOTAL HIP FEMORAL HEADS AND LINERS
<b>Applicant</b>	SMITH & NEPHEW, INC. 1450 Brooks Rd. Memphis, TN 38116
<b>Contact</b>	Kim Kelly
<b>Regulation Number</b>	888.3350
<b>Classification Product Code</b>	JDI
<b>Subsequent Product Codes</b>	<a href="#">LPH LZO</a>
<b>Date Received</b>	09/06/2002
<b>Decision Date</b>	10/02/2002
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	Orthopedic
<b>Statement/Summary/Purged Status</b>	Summary Only
<b>Summary</b>	<a href="#">Summary</a>
<b>Type</b>	Special
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 08/06/2008

OCT 02 2002

K022958

Page 1 of 1

Smith & Nephew, Inc.  
Summary of Safety and Effectiveness :Total Hip Femoral Heads & Liners

**Contact Person and Address**

Kim Kelly  
Project Manager, Clinical and Regulatory Affairs  
Smith & Nephew, Inc., Orthopaedics Division  
1450 East Brooks Road  
Memphis, TN 38116  
(901) 399-6566

**Date of Summary:** September 5, 2002

**Name of Device:** Total Hip Femoral Heads & Liners

**Common Name:** Femoral heads and acetabular liners

**Device Classification Name**

21 CFR 888.3350 Hip joint metal/polymer semi-constrained cemented prosthesis: Class II  
21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis: Class II  
21 CFR 888.3358 Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis: Class II

**Substantial Equivalence Information**

The **Total Hip Femoral Heads** are substantially equivalent to Sulzer Inter-Op CoCr heads (K993259), Osteonics Alumina C-Taper Heads (K003391), and currently marketed heads distributed by Smith & Nephew. The **Total Hip Liners** are substantially equivalent to Sulzer Inter-Op Durasul Acetabular Inserts (K993259 & K002575), DePuy Duraloc Acetabular Cup System (K010171), and Smith & Nephew crosslinked polyethylene liners.

**Device Description**

The **Total Hip Femoral Heads** are zirconium alloy or alumina ceramic devices designed for use with both titanium and cobalt chromium alloy femoral components with a 12/14 taper. These heads are to be used with the appropriate sized crosslinked polyethylene **Total Hip Liners**. **Total Hip Liners** are to be used with corresponding titanium acetabular shells.

**Indications for Use**

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. The **Total Hip Femoral Heads & Liners** are designed for single use only and may be used as part of cemented or uncemented total hip arthroplasty.

**Technological & Performance Characteristics:**

The **Total Hip Femoral Heads and Liners** are similar to currently marketed femoral heads and liners. These components share the same intended use, material, and design features of one or more of the above mentioned predicates. A review of the mechanical and wear test data indicated that the **Total Hip Femoral Heads and Liners** are equivalent to devices currently on the market and are capable of withstanding expected *in vivo* loading without failure.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Kim P. Kelly  
Project Manager, Regulatory & Clinical Affairs  
Smith and Nephew, Inc.  
1450 Brooks Road  
Memphis, Tennessee 38116

OCT 02 2002

Re: K022958

Trade/Device Name: Total Hip Femoral Heads and Liners  
Regulation Number: 21 CFR 888.3350, 888.3353, 888.3358  
Regulation Name: Hip joint metal/polymer semi-constrained cemented prosthesis;  
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous  
uncemented prosthesis; Hip joint metal/polymer/metal semi-constrained  
porous-coated uncemented prosthesis  
Regulatory Class: Class II  
Product Code: JDI, LZO, LPH  
Dated: September 5, 2002  
Received: September 6, 2002

Dear Mr. Kelly:

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.

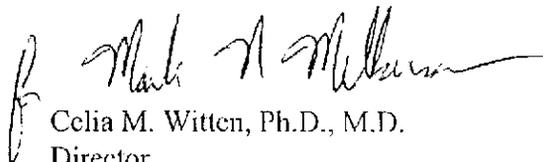
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 – Mr. Kim P. Kelly

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html>

Sincerely yours,



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

Enclosure

**Total Hip Femoral Heads & Liners  
Indications Statement**

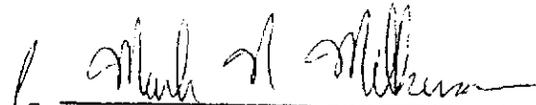
Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion; femoral neck fracture and trochanteric fractures of the proximal femur with heads involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity.

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

Prescription Use \_\_\_\_\_

OR  
(Per 21 CFR 801.109)

Over-The Counter Use \_\_\_\_\_

  
\_\_\_\_\_  
(Division Sign-Off)

Division of General, Restorative  
and Neurological Devices

510(k) Number K022958



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 CFR Title 21 | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

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**510(k) Premarket Notification Database**

<b>Device Classification Name</b>	<u>Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</u>
<b>510(K) Number</b>	K071535
<b>Device Name</b>	BIOLOX DELTA CERAMIC FEMORAL HEAD
<b>Applicant</b>	ZIMMER, INC. P.O. Box 708 Warsaw, IN 46581 0708
<b>Contact</b>	Patricia Jenks
<b>Regulation Number</b>	<u>888.3353</u>
<b>Classification Product Code</b>	<u>LZO</u>
<b>Date Received</b>	06/05/2007
<b>Decision Date</b>	11/19/2007
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	Orthopedic
<b>Statement/Summary/Purged Status</b>	Summary Only
<b>Summary Type</b>	<u>Summary</u> Traditional
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

Database Updated 08/06/2008

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K071535

Summary of Safety and Effectiveness

NOV 19 2007

**Submitter:** Zimmer, Inc.  
P.O. Box 708  
Warsaw, IN 46581-0708

**Contact Person:** Patricia Jenks  
Specialist, Corporate Regulatory Affairs  
Telephone: (574) 371-8354  
Fax: (574) 372-4605

**Date:** June 4, 2007

**Trade Name:** BIOLOX<sup>®</sup> *delta*\* Ceramic Femoral Head

**Common Name:** Ceramic Femoral Head Prosthesis

**Classification Name and Reference:** Hip joint metal/ceramic/polymer semiconstrained cemented or nonporous uncemented prosthesis  
21 CFR § 888.3353

**Predicate Device(s):** 36mm Biolox *delta* Ceramic Heads, manufactured by Biomet, K061312, cleared June 6, 2006  
  
DePuy Delta Ceramic Femoral Head, manufactured by DePuy, K062748, cleared November 30, 2006  
  
V40<sup>™</sup> Biolox *delta* Ceramic Femoral Heads, manufactured by Howmedica Osteonics, K052718, cleared October 27, 2005

**Device Description:** The BIOLOX *delta* Ceramic Femoral Heads are fabricated from an alumina matrix composite and are available in diameters of 28, 32, 36, and 40 mm with a range of offsets to accommodate various patient anatomies. They serve as an alternative to both metal and alumina ceramic femoral heads for use in total hip arthroplasty.

\* Trademark of CeramTec AG

**Intended Use:**

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprostheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

**Comparison to Predicate Device(s):**

The BIOLOX *delta* Ceramic Femoral Heads are substantially equivalent to the femoral heads listed above as predicate devices. Both the proposed and predicate designs are intended to function as a modular femoral head component in total hip arthroplasty and are manufactured from the same materials.

**Performance Data (Nonclinical and/or Clinical):**

**Non-Clinical Performance and Conclusions:**

Mechanical testing was performed and results indicate that the BIOLOX *delta* Ceramic Femoral Heads are equivalent to devices currently on the market and capable of withstanding *in vivo* loading.

**Clinical Performance and Conclusions:**

Clinical data and conclusions were not needed for this device.



NOV 19 2007

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Zimmer, Inc.  
c/o Ms. Patricia Jenks  
Specialist, Corporate Regulatory Affairs  
P.O. Box 708  
Warsaw, Indiana 46581-0708

Re: K071535  
Trade/Device Name: BioloX® *delta* Ceramic Femoral Head  
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: October 25, 2007  
Received: October 26, 2007

Dear Ms. Jenks:

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.

Page 2 -

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

K071535

Indications for Use

510(k) Number (if known):

Device Name:

BIOLOX<sup>®</sup> *delta*\* Ceramic Femoral Head

Indications for Use:

The BIOLOX *delta* Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:

Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head, and nonunion of previous fractures of the femur; patients with congenital hip dysplasia, protrusio acetabuli, or slipped capital femoral epiphysis; patients suffering from disability due to previous fusion; patients with previously failed endoprotheses and/or total hip components in the operative extremity; and patients with acute neck fractures.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(Please do not write below this line—Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Puchup  
(Division Sign-off)

Division of General, Restorative,  
and Neurological Devices

\*Trademark of CeramTec AG

Page 1 of 1

510(k) Number K071535

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

Smith & Nephew Inc.  
Mrs. Mandy Coe

1450 Brooks Road  
Memphis, TN 38116  
USA

(b)(4)Trade Secret Process

Your ref.

Your letter from

**Right Of Reference device masterfile MAF #197**

Dear Mrs. Coe,

By this letter (b)(4)Trade Secret Process

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

(b)(4)Trade Secret Process





































**COVER SHEET MEMORANDUM**

From: Reviewer Name Ronald P. Jean  
Subject: 510(k) Number K083762/S  
To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
  - Hold (Additional Information or Telephone Hold).
  - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		✓	
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)			✓
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)		✓	✓
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age ≤ 21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days - < 2 years old)			✓
Child (2 years - < 12 years old)			✓
Adolescent (12 years - < 18 years old)			✓
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)			✓
Nanotechnology			✓



**SPECIAL 510(k): Device Modification**  
**ODE Review Memorandum (Decision Making Document is Attached)**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K083762/S001

---

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

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

**K981847, K991162, K022958      Smith & Nephew BioloX forte Ceramic Femoral Heads**  
**K071535                              Zimmer BioloX delta Ceramic Femoral Head**

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew BioloX Delta Ceramic femoral heads are for single use only.

*The Indications for Use Statement is identical to that of the sponsor's unmodified predicate device (BioloX forte Ceramic Femoral Heads) cleared under K022958.*

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

The purpose of this 510(k) submission is for the following modifications to the Smith & Nephew Ceramic Femoral Heads (articulating against polyethylene):

- Material change from BioloX forte to BioloX delta (CeramTec)

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device.

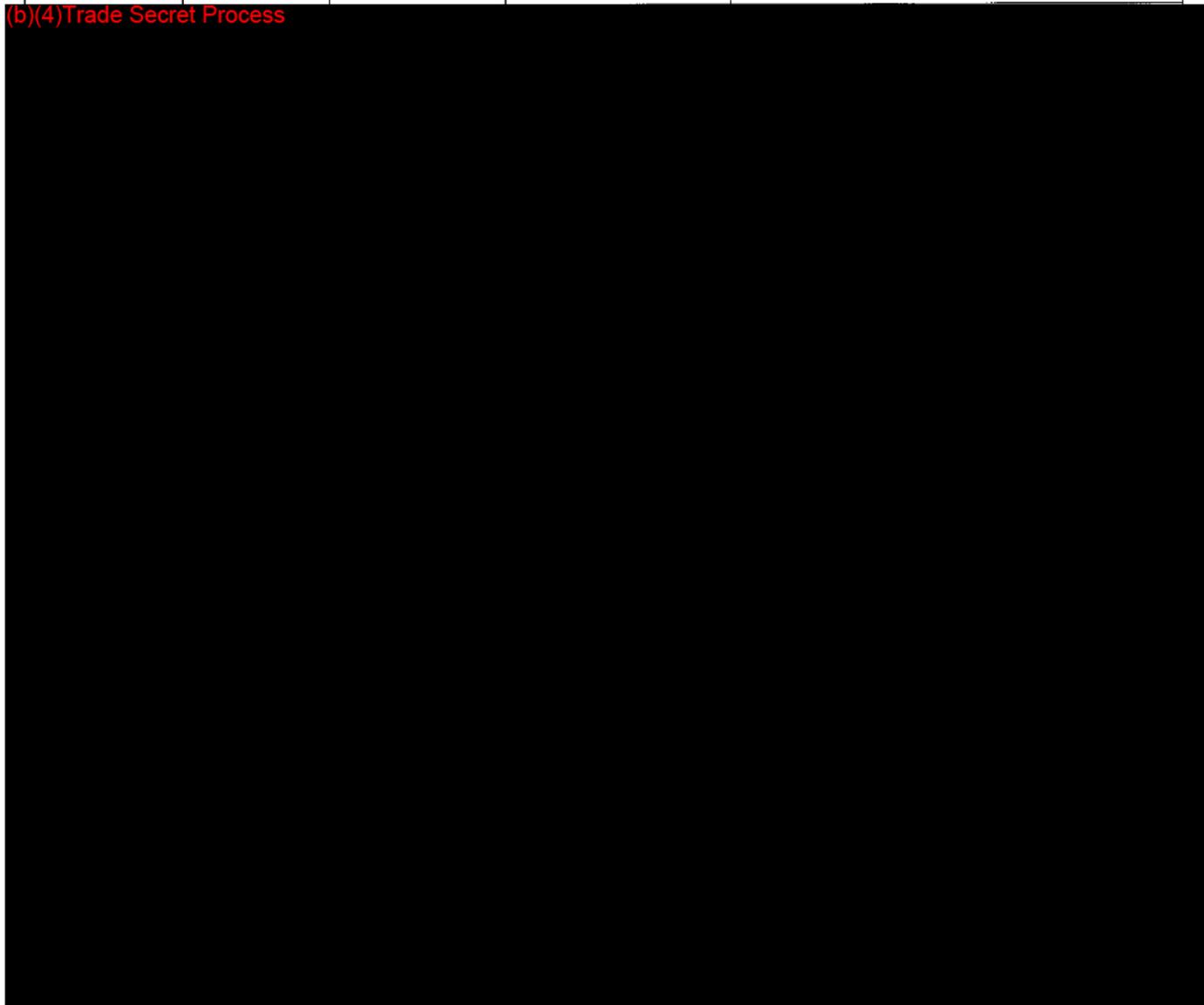
The subject device is similar in indications and design to the unmodified predicate ceramic femoral heads; the only difference is the ceramic material. Both femoral heads are offered in 28 mm, 32 mm, and 36 mm diameters with +4 mm and +8 mm offsets, and both are intended for articulation against a polyethylene acetabular surface. The manufacturer for both the predicate BioloX forte and subject BioloX delta materials is the same (CeramTec).

5. A **Design Control Activities Summary** which includes:
- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
  - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
  - c) A declaration of conformity with design controls. The declaration of conformity should include:
    - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
    - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

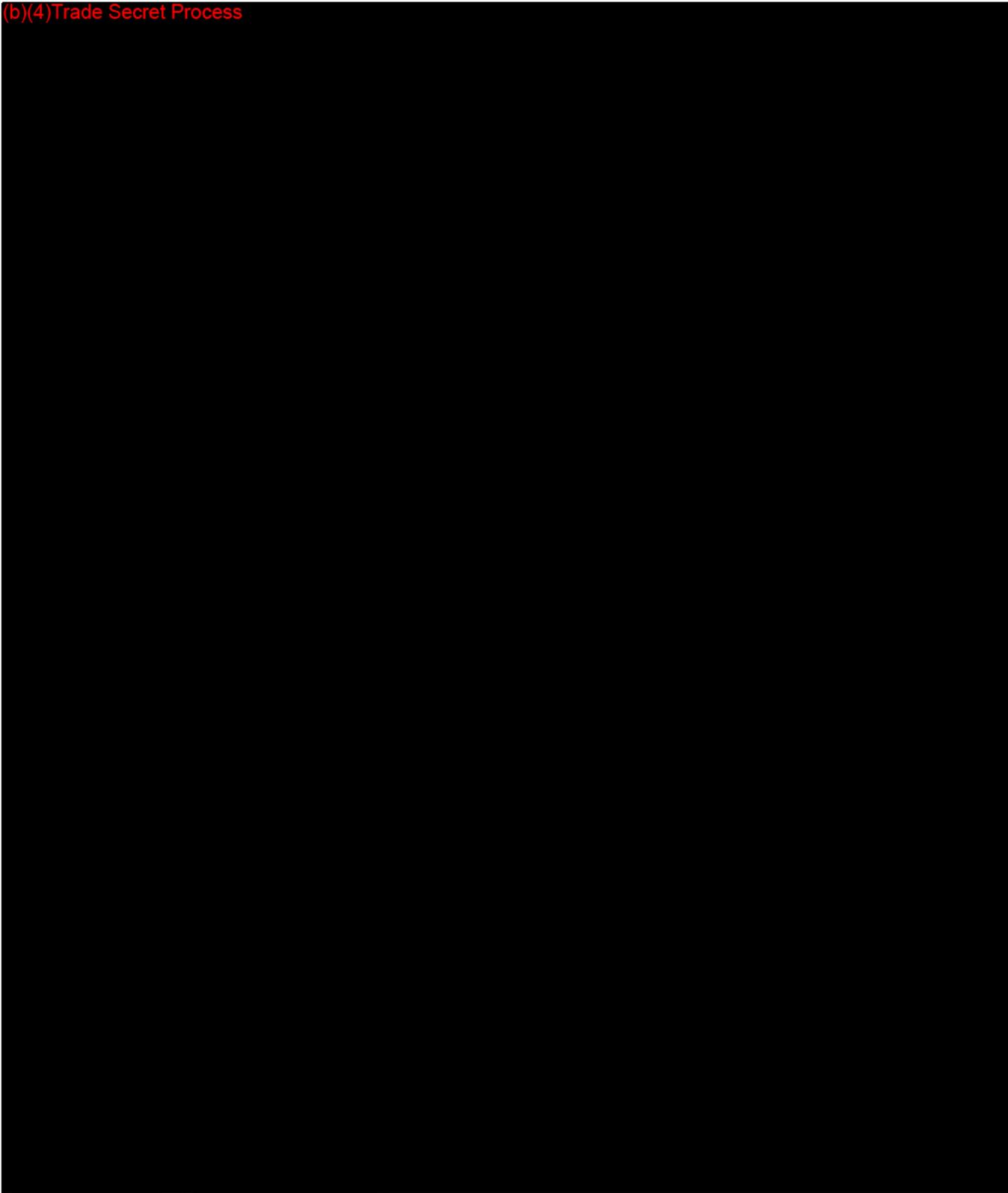
The sponsor provided the required declaration of conformity with design controls pertaining to the risk analysis and manufacturing facility in Exhibit 3 for the following Design Control Activities Summary Table (Supplement 001):

Change	Risk	Verification Activity	Acceptance Criteria	Results
--------	------	-----------------------	---------------------	---------

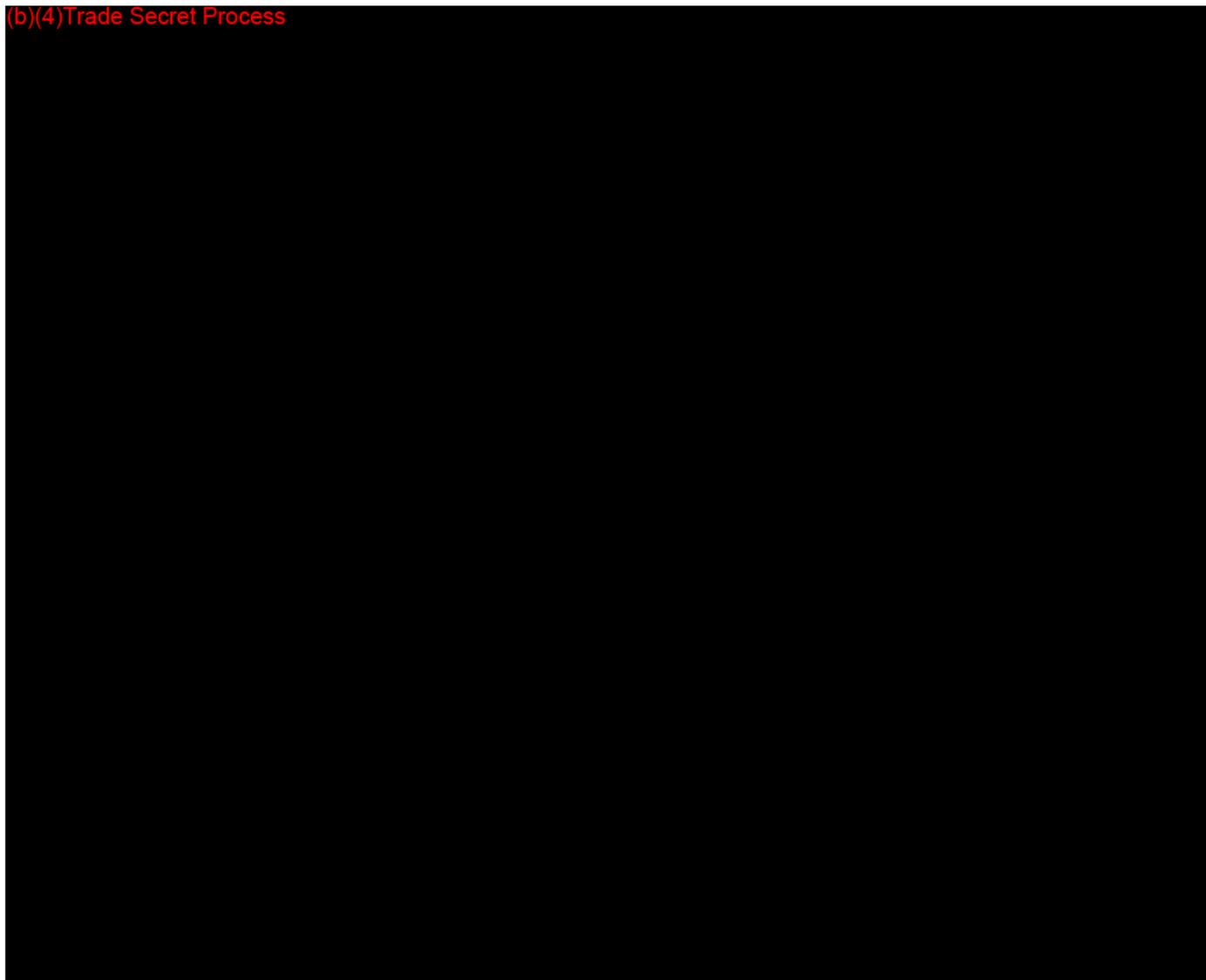
(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



**6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

In accordance with 21 CFR 807.87(k), the sponsor provided a truthful and accurate statement in Exhibit 1.

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

\_\_\_\_\_  
(Reviewer's Signature)

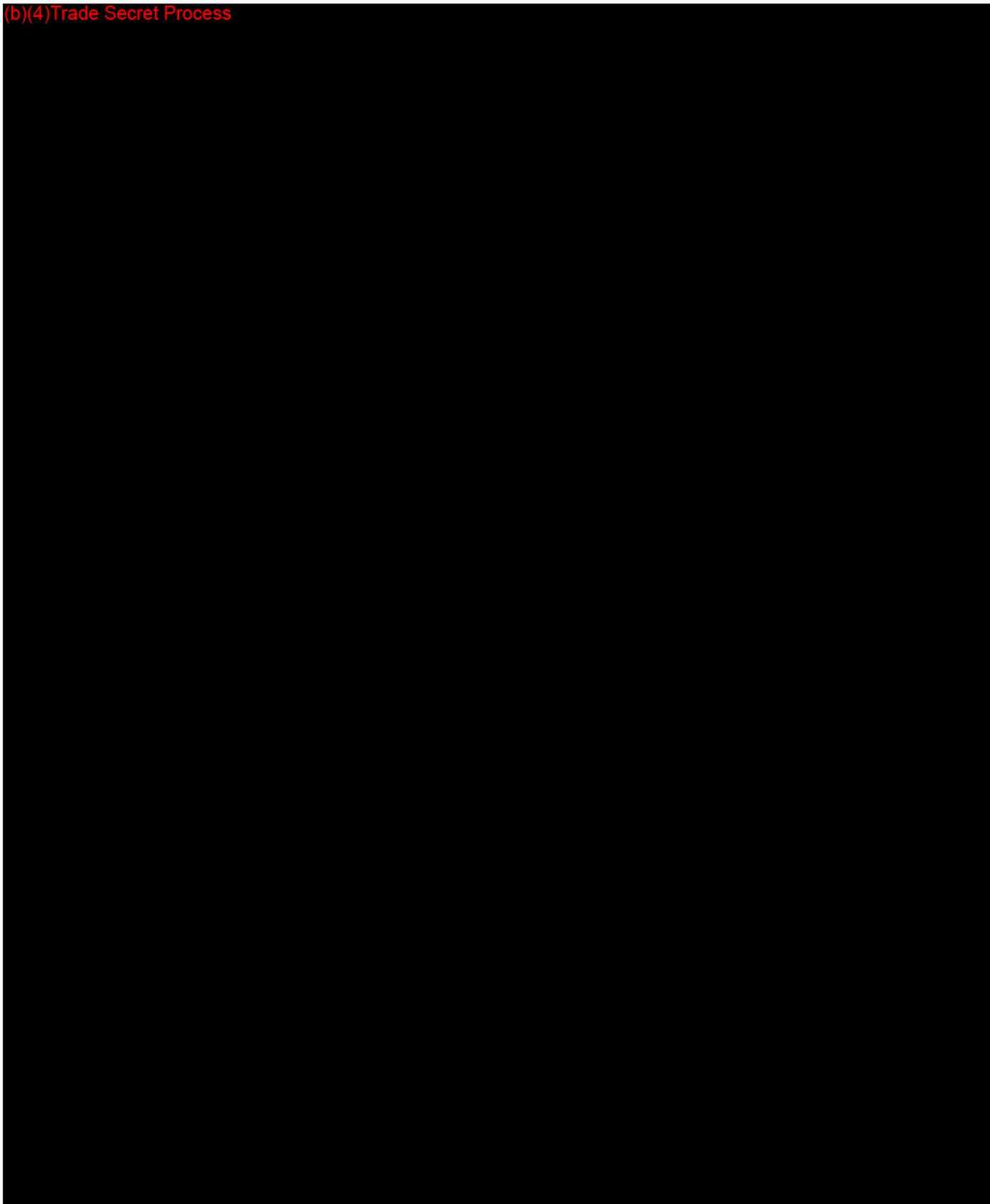
03/10/2009  
(Date)

*Jonathan J* 3/10/09

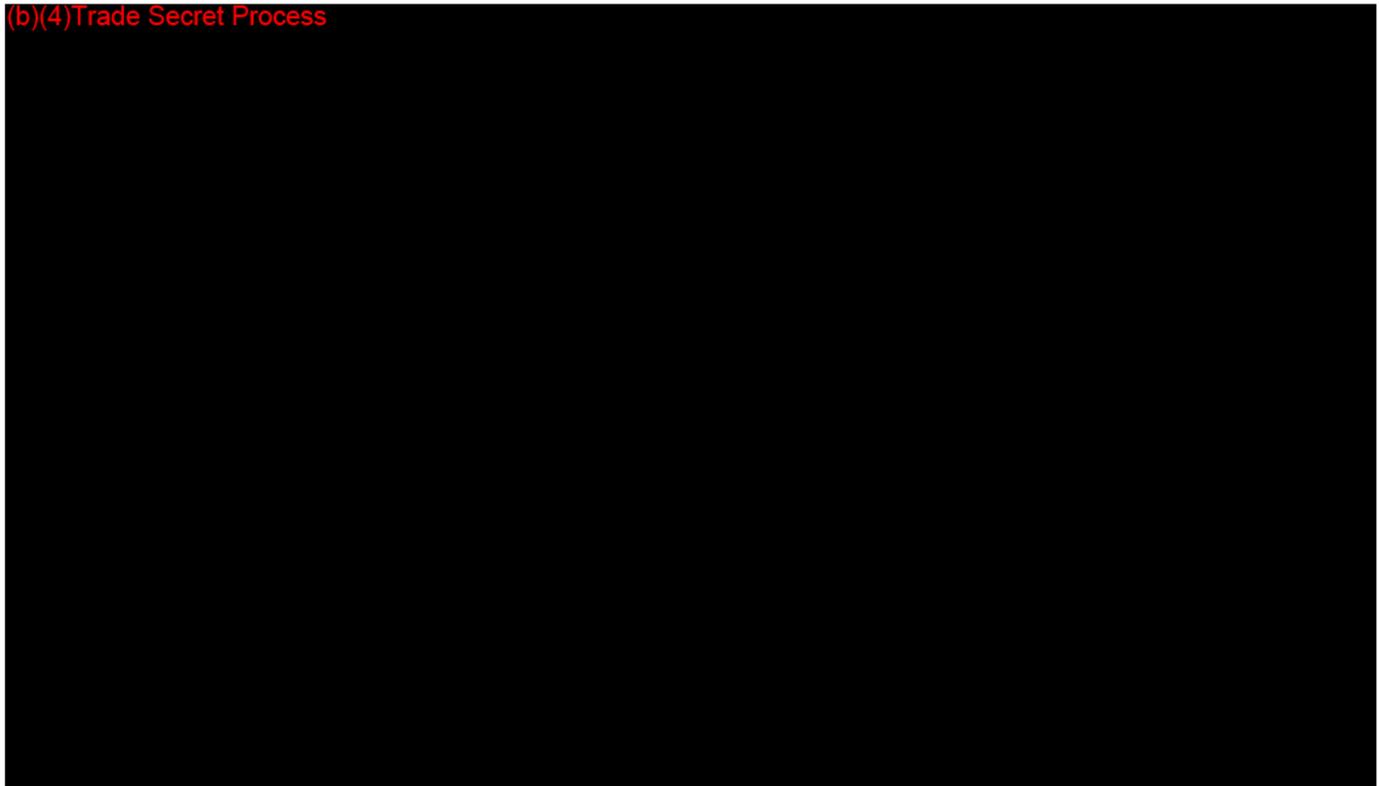
**COMMENTS:**

The following deficiencies were noted during my initial review, and addressed in Supplement 001:

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



**RESPONSE:** The sponsor provided a revised Indications for Use Statement in Supplement 001 that includes "BioloX" within the product name. ***This response is adequate.***

K083762/S001

Reviewer: Ronald P. Jean

Division/Branch: DGRND/OJDB

Device Name: Smith &amp; Nephew Biolox delta Ceramic Femoral Heads

Product To Which Compared (510(K) Number If Known): K071535, K022958, K991162, K981847

	Yes	No	
1. Same Indication Statement?	X		If <b>YES</b> = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If <b>YES</b> = Stop <b>NSE</b>
3. Same Technological Characteristics?	X		If <b>YES</b> = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If <b>YES</b> = Go To 6
5. Descriptive Characteristics Precise Enough?		X	If <b>NO</b> = Go To 8 If <b>YES</b> = Stop <b>SE</b>
6. New Types Of Safety Or Effectiveness Questions?			If <b>YES</b> = Stop <b>NSE</b>
7. Accepted Scientific Methods Exist?			If <b>NO</b> = Stop <b>NSE</b>
8. Performance Data Available?	X		If <b>NO</b> = Request Data
9. Data Demonstrate Equivalence?	X		Final Decision: <b>SE</b>

Note: See

[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: n/a
2. Explain why there is or is not a new effect or safety or effectiveness issue: n/a
3. Describe the new technological characteristics: n/a
4. Explain how new characteristics could or could not affect safety or effectiveness: n/a
5. Explain how descriptive characteristics are not precise enough: need additional preclinical testing and device description information.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: n/a
7. Explain why existing scientific methods can not be used: n/a
8. Explain what performance data is needed: need engineering drawings, disassembly testing, fatigue and post-fatigue burst testing.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: engineering drawings, disassembly rationale, and fatigue and post-fatigue burst test results provided that demonstrate acceptable strength for the subject femoral heads.

**From:** Jean, Ronald P [ronald.jean@fda.hhs.gov]  
**Sent:** Monday, January 12, 2009 2:41 PM  
**To:** Coe, Mandy  
**Subject:** K083762 - FDA "Telephone Hold"

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

Re: K083762  
Trade Name: Smith & Nephew Biolox Delta Ceramic Femoral Heads

Dear Ms. Coe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies.

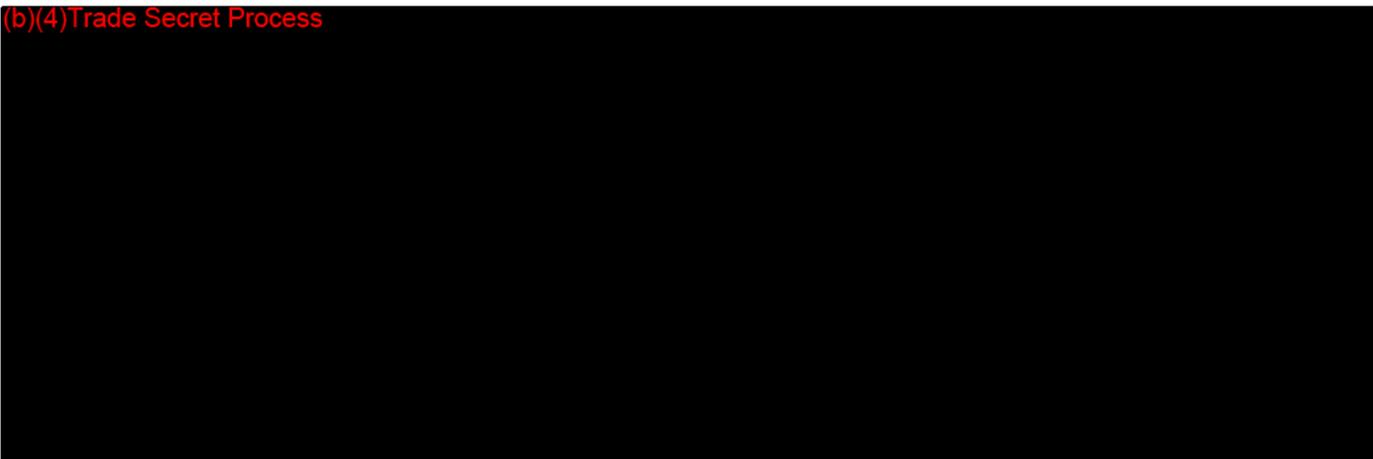
1.  (b)(4) Trade Secret Process

2. You provided a Design Control Activities Summary (DCAS) Table in Exhibit 12. We have the following concerns with the information provided:

- a.  (b)(4) Trade Secret Process

- b.  (b)(4) Trade Secret Process

(b)(4)Trade Secret Process



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Ronald P. Jean, Ph.D. at (240) 276-3676. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Ronald

---

**Ronald P. Jean, Ph.D.**                      [ronald.jean@fda.hhs.gov](mailto:ronald.jean@fda.hhs.gov)  
Executive Secretary, Orthopaedic & Rehabilitation Devices Panel  
Scientific Reviewer, Orthopedic Joint Devices Branch  
U.S. Food & Drug Administration  
Tel: (240) 276-3676 NEW!              Fax: (240) 276-3602 NEW!

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This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you think you have received this e-mail message in error, please e-mail the sender immediately at [ronald.jean@fda.hhs.gov](mailto:ronald.jean@fda.hhs.gov)







































**Tsai, Stanley**

**From:** Shea, Jeff  
**Sent:** Friday, January 30, 2009 9:31 AM  
**To:** Tsai, Stanley; Thomas, Reginald  
**Subject:** (b)(4)Trade Secret  
**Attachments:** (b)(4)Trade Secret

Stan,

I [REDACTED] (b)

Jeff

**From:** Tsai, Stanley  
**Sent:** Friday, January 30, 2009 7:26 AM  
**To:** Shea, Jeff; Thomas, Reginald  
**Subject:** (b)(4)Trade Secret

Jeff,

Just need to get either an e-mail approval or written signature for the attached study plan. Thanks

Stan

**Stanley Tsai**  
Research Manager  
Hip Testing & Analysis/Memphis Labs  
Smith & Nephew, Inc.  
1450 Brooks Road  
Memphis, TN 38116

stanley.tsai@smithnephew.com  
T 901-399-5146  
F 901-399-6020

This electronic transmission is strictly confidential to Smith & Nephew and intended solely for the addressee. It may contain information which is covered by legal, professional, or other privilege. If you are not the intended addressee, or someone authorized by the intended addressee to receive transmissions on the behalf of the addressee, you must not retain, disclose in any form, copy or take any action in reliance on this transmission. If you have received this transmission in error, please notify us as soon as possible and destroy this message.





















## Indications for Use

**510(k) Number (if known):**

**Device Name:** BioloX Delta Ceramic Femoral Heads

**Indications for Use:**

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew BioloX Delta Ceramic femoral heads are for single use only.

Prescription Use  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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of \_\_\_\_\_



**COVER SHEET MEMORANDUM**

From: Reviewer Name Ronald P. Jean  
 Subject: 510(k) Number K083762  
 To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU		
510(k) Summary /510(k) Statement	Attach Summary		
Truthful and Accurate Statement.	Must be present for a Final Decision		
Is the device Class III?			
If yes, does firm include Class III Summary?	Must be present for a Final Decision		
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )			
Is this a combination product? (Please specify category _____, see <a href="http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of Clinical Trials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age <= 21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days - < 2 years old)			
Child (2 years - < 12 years old)			
Adolescent (12 years - < 18 years old)			
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 - <= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			



**SPECIAL 510(k): Device Modification**  
**ODE Review Memorandum (Decision Making Document is Attached)**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K083762

---

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

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)

**K981847, K991162, K022958  
K071535**

**Smith & Nephew BioloX forte Ceramic Femoral Heads  
Zimmer BioloX delta Ceramic Femoral Head**

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

Total hip components are indicated for individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew Delta Ceramic femoral heads are for single use only.

*The Indications for Use Statement is identical to that of the sponsor's unmodified predicate device (BioloX forte Ceramic Femoral Heads) cleared under K022958. However, the sponsor will be asked to insert "BioloX" into the product description of the last sentence.*

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

The purpose of this 510(k) submission is for the following modifications to the Smith & Nephew Ceramic Femoral Heads (articulating against polyethylene):

- Material change from BioloX forte to BioloX delta (CeramTec)

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device.

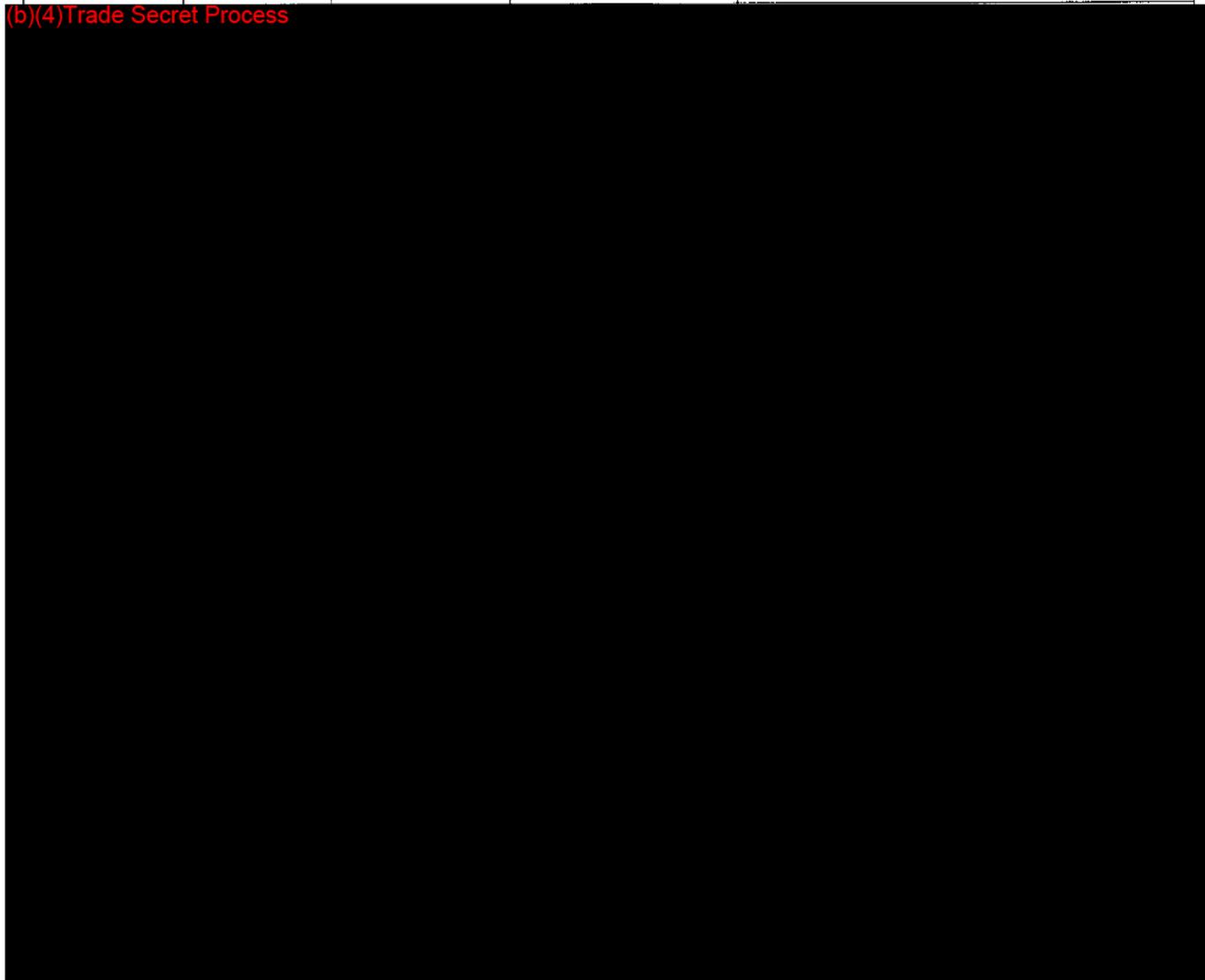
The subject device is similar in indications and design to the unmodified predicate ceramic femoral heads; the only difference is the ceramic material. Both femoral heads are offered in 28 mm, 32 mm, and 36 mm diameters with +4 mm and +8 mm offsets, and both are intended for articulation against a polyethylene acetabular surface. The manufacturer for both the predicate BioloX forte and subject BioloX delta materials is the same (CeramTec).

5. A **Design Control Activities Summary** which includes:
- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
  - b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
  - c) A declaration of conformity with design controls. The declaration of conformity should include:
    - i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
    - ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.

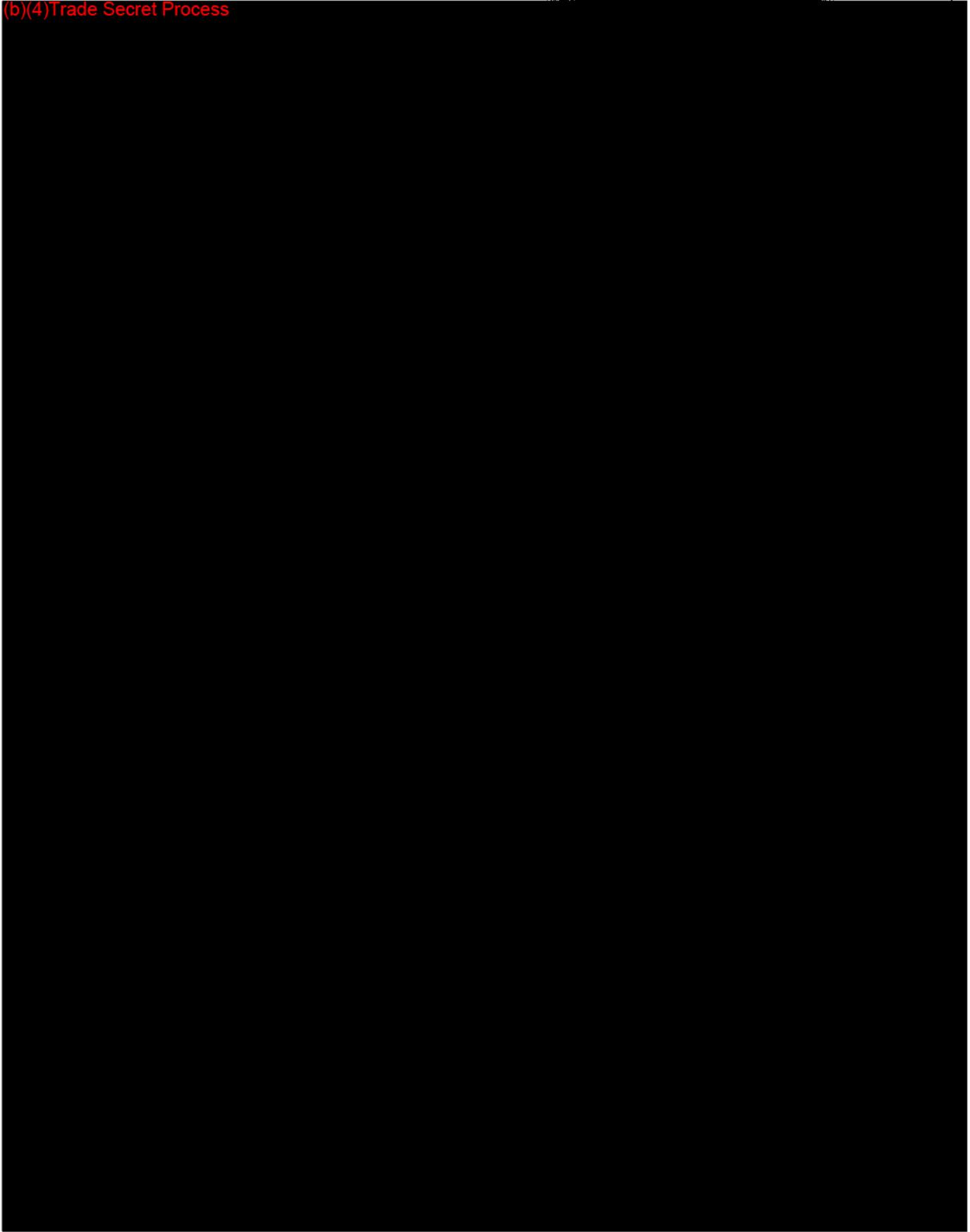
The sponsor provided the required declaration of conformity with design controls pertaining to the risk analysis and manufacturing facility in Exhibit 3 for the following Design Control Activities Summary Table (Exhibit 12):

Change	Risk	Verification Activity	Acceptance Criteria	Results
--------	------	-----------------------	---------------------	---------

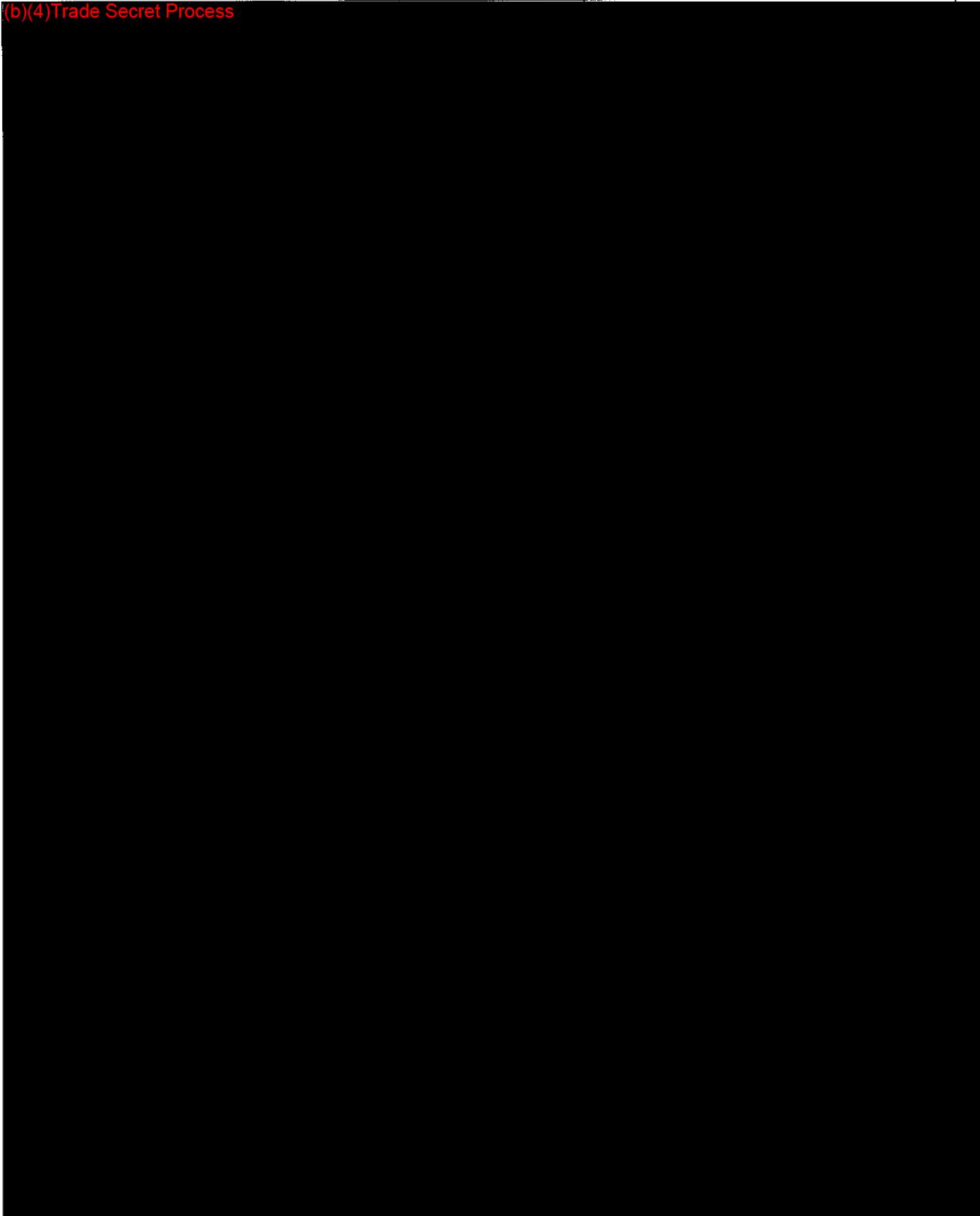
(b)(4) Trade Secret Process



(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

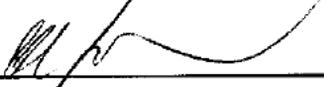


Clinical Data – No change	N/a	N/a	N/a	Based on the equivalence in intended use, design and materials, clinical data is not required
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**6. A Truthful and Accurate Statement, a 510(k) Summary or Statement and the Indications for Use Enclosure (and Class III Summary for Class III devices).**

In accordance with 21 CFR 807.87(k), the sponsor provided a truthful and accurate statement in Exhibit 1.

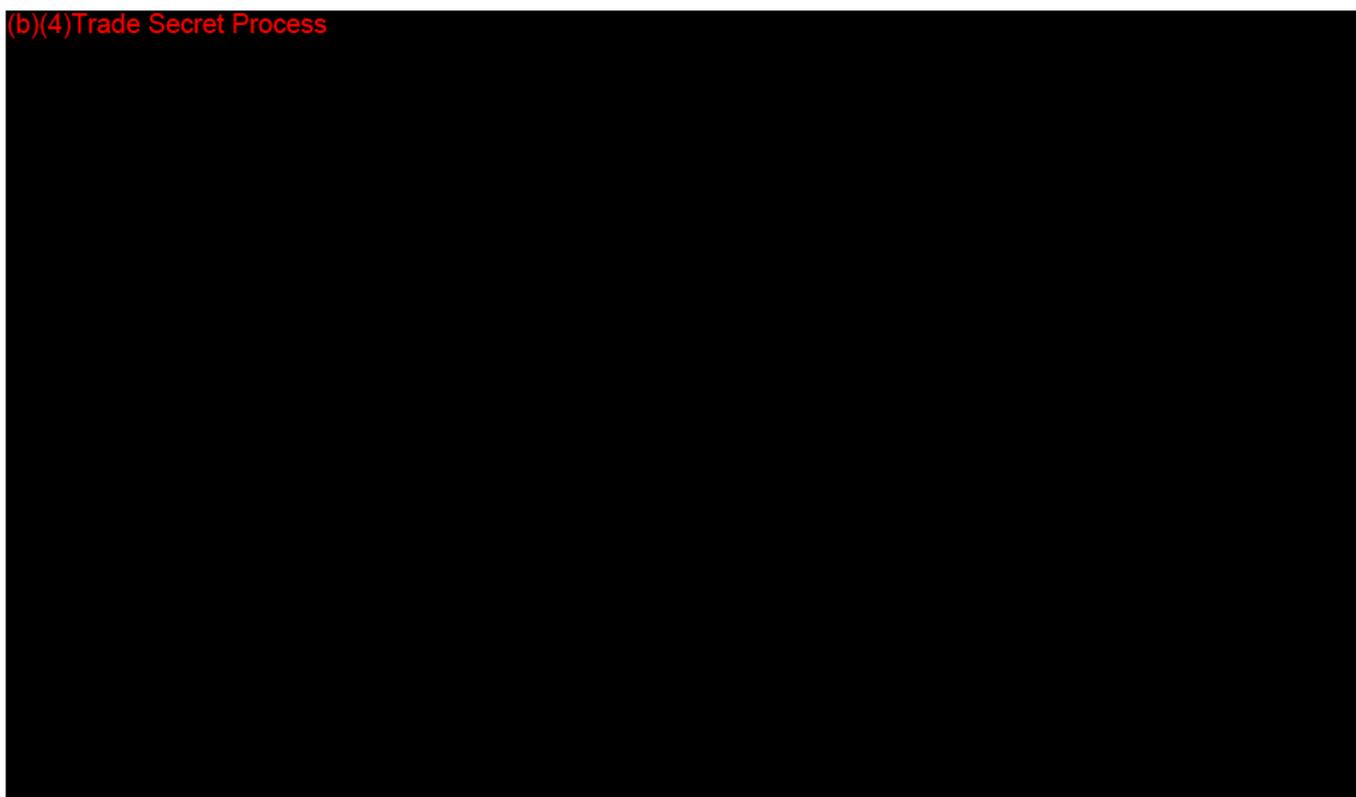
The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm. Based upon the information provided, there are a few outstanding issues described below. Therefore, I recommend that the current 510(k) submission be placed on **telephone hold (TH)** for additional information before a SE/NSE determination is made.

  
 \_\_\_\_\_  
 (Reviewer's Signature)  
*Jonita Z* 1/12/09

01/12/2009  
 \_\_\_\_\_  
 (Date)

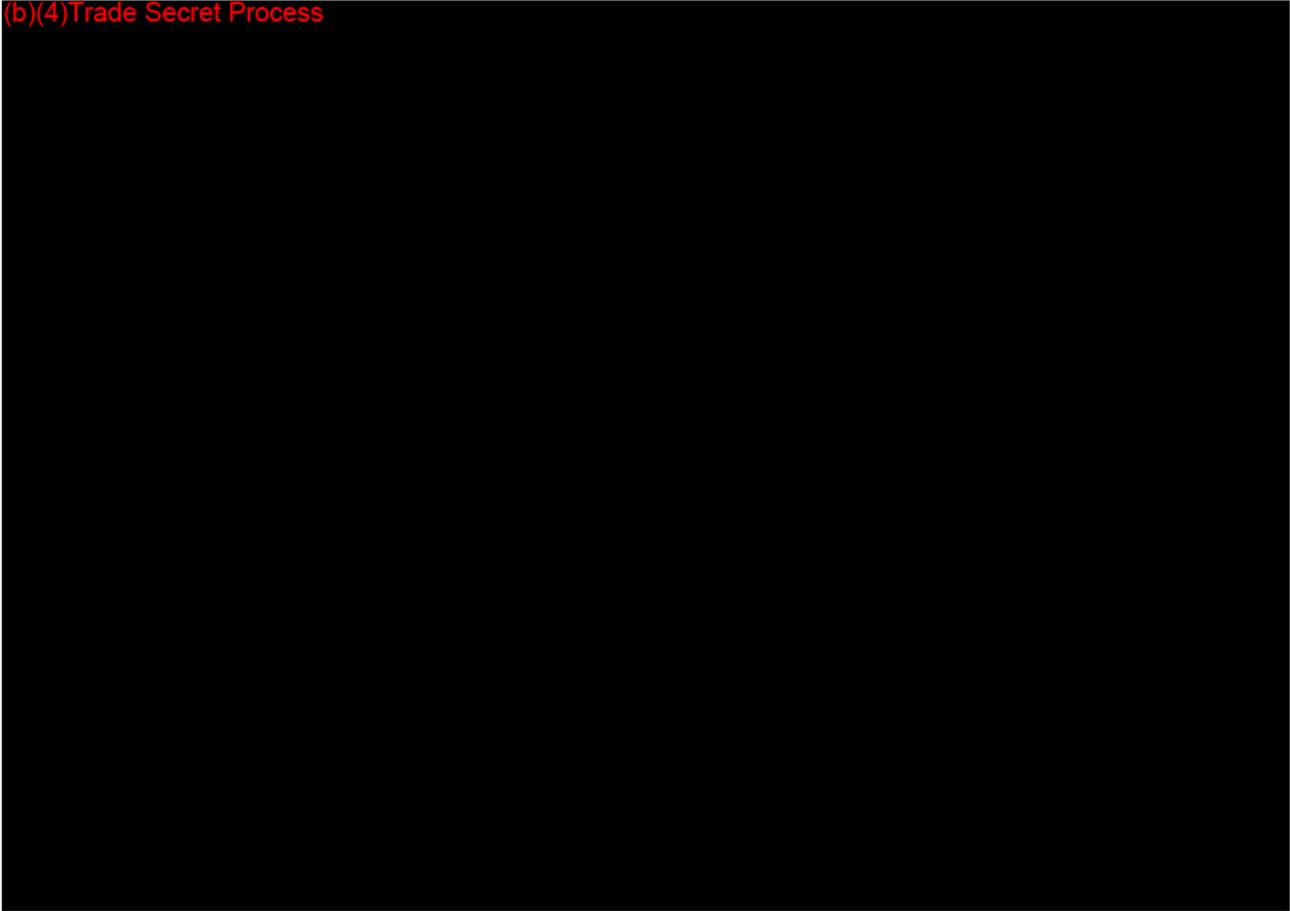
**COMMENTS:**

The following deficiencies were noted during my review, and communicated to the sponsor on 01/12/2009 via e-mail:



(b)(4)Trade Secret Process

(b)(4)Trade Secret Process



K083762

Reviewer: Ronald P. Jean

Division/Branch: DGRND/OJDB

Device Name: Smith & Nephew BioloX delta Ceramic Femoral Heads

Product To Which Compared (510(K) Number If Known): K071535, K022958, K991162, K981847

	Yes	No
1. Same Indication Statement?	X	If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?	X	If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?		X If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		X If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: SE

Note: See

[http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0\\_4148/FLOWCHART%20DECISION%20TREE%20.DOC](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPreMarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC) for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: n/a
2. Explain why there is or is not a new effect or safety or effectiveness issue: n/a
3. Describe the new technological characteristics: n/a
4. Explain how new characteristics could or could not affect safety or effectiveness: n/a
5. Explain how descriptive characteristics are not precise enough: need additional preclinical testing and device description information.
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: n/a
7. Explain why existing scientific methods can not be used: n/a
8. Explain what performance data is needed: need engineering drawings, disassembly testing, fatigue and post-fatigue burst testing.
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: n/a

**Jean, Ronald P**

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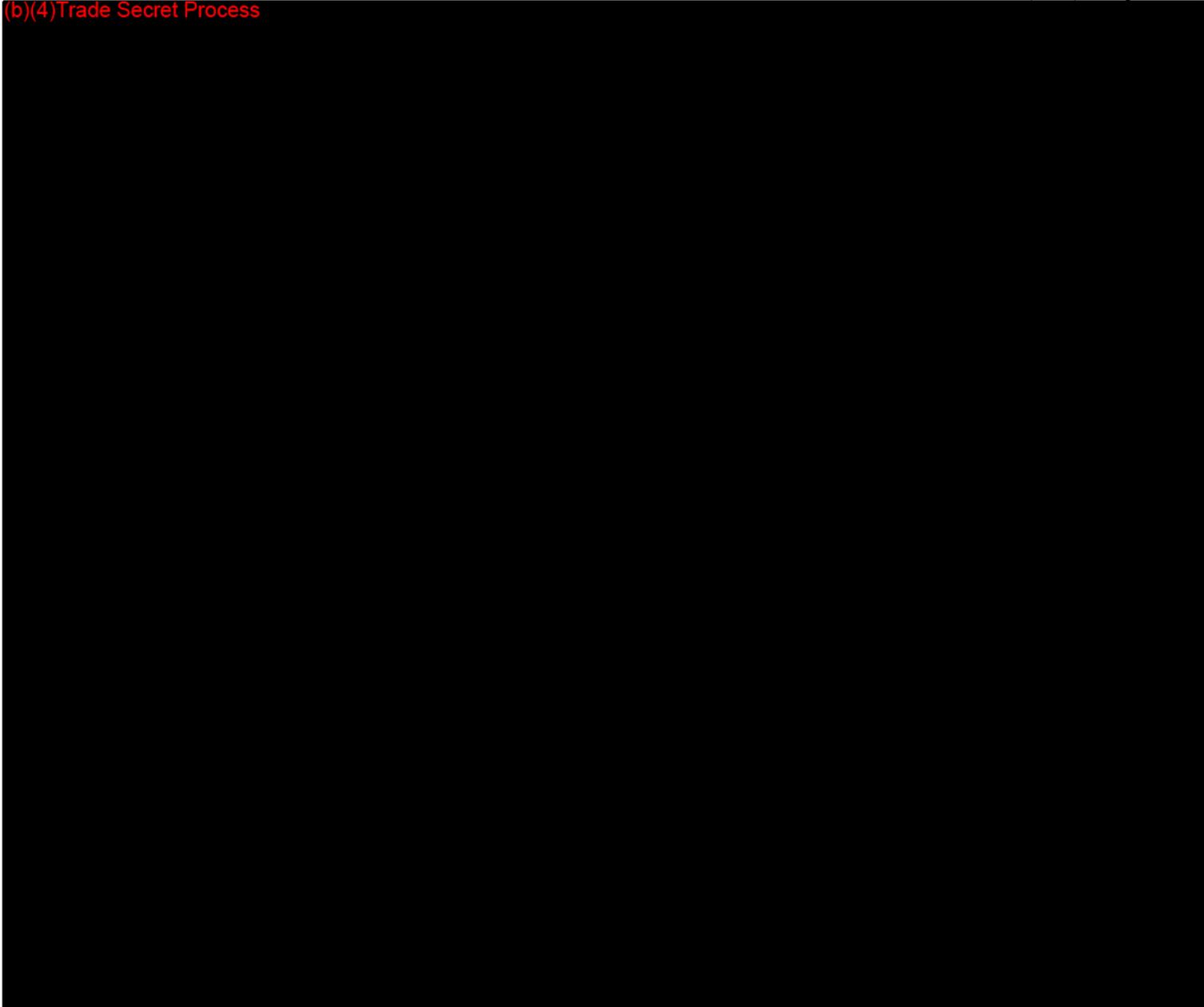
**From:** Jean, Ronald P  
**Sent:** Monday, January 12, 2009 3:41 PM  
**To:** 'mandy.coe@smith-nephew.com'  
**Subject:** K083762 - FDA "Telephone Hold"

Re: K083762  
Trade Name: Smith & Nephew Biolox Delta Ceramic Femoral Heads

Dear Ms. Coe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies.

(b)(4)Trade Secret Process



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device.

We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Federal Food, Drug, and Cosmetic Act (Act). You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

Food and Drug Administration  
Center for Devices and  
Radiological Health  
Document Mail Center (HFZ-401)  
9200 Corporate Boulevard  
Rockville, Maryland 20850

If you have any questions concerning the contents of the letter, please contact Ronald P. Jean, Ph.D. at (240) 276-3676. If you need information or assistance concerning the IDE regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (240) 276-3150, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Ronald

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