

Page 1 of 2

K082991 (pg 1/2)

B. 510(k) SUMMARY (as required by 21 CFR 807.92)**BIOLOX® *delta* Ceramic Femoral Head**

NOV 20 2008

October 6, 2008

COMPANY: Aesculap Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

TRADE NAME: BIOLOX® *delta* Ceramic Femoral Head

COMMON NAME: Ceramic Femoral Head

CLASSIFICATION NAME: Hip joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Non-Porous Uncemented Prosthesis
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate
Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented

REGULATION NUMBER: 888.3353, 888.3360, 888.3353, 888.3390

PRODUCT CODE: LZO, LWJ, MEH, KWY

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, Inc. believes that the BIOLOX® *delta* Ceramic Femoral Head is a line extension of Aesculap Implant Systems Excia (K042344, K060918, and K062684) - Hip Systems and Metha Short Stem Hip System (K080584) that were previously cleared. It is also substantially equivalent to the Zimmer BIOLOX *delta* Ceramic Femoral Head (K071535).

DEVICE DESCRIPTION

The Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Heads are manufactured from an alumina matrix composite. The ceramic femoral head is offered in three diameters of 28, 32, and 36 mm with a range of neck lengths. The BIOLOX® *delta* Ceramic head provides the surgeon another option to both the metal and alumina ceramic femoral heads for use in total hip arthroplasty.

K082991 (pg 2/2)

Page 2 of 2

INDICATIONS FOR USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ -CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Heads are offered in similar shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Points to Consider for Femoral Stem Prostheses",
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap Implant Systems, Inc.
% Ms. Kathy A. Racosky
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

NOV 20 2008

Re: K082991

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: II
Product Code: LZO, LWJ, MEH, KWY
Dated: November 7, 2008
Received: November 10, 2008

Dear Ms. Racosky:

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.

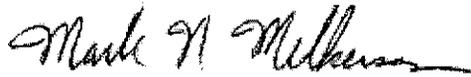
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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 CDRII'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

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K082991 (pg 1/1)

Device Name: BIOLOX® delta Ceramic Femoral Head
For use with the Aesculap Implant Systems Excia and Metha Hip System

Indications for Use:

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

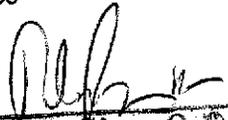
- Patients suffering from severe hip and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ -CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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.
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- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures



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

510(k) Number K082991

Prescription Use X and/or Over-the-Counter Use _____
(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap Implant Systems, Inc.
% Ms. Kathy A. Racosky
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

NOV 20 2008

Re: K082991

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

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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

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K082991 (pg 111)

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The device is intended for:

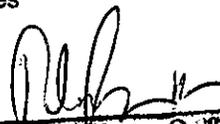
- Patients suffering from severe hip and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
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- patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures



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

510(k) Number K082991

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



November 05, 2008

AESCLAP IMPLANT SYSTEMS, INC.
3773 CORPORATE PWKY.
CENTER VALLEY, PENNSYLVANIA 18034
UNITED STATES
ATTN: KATHY A. RACOSKY

510k Number: K082991

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.

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



October 07, 2008

AESULAP IMPLANT SYSTEMS, INC.
3773 CORPORATE PWKY.
CENTER VALLEY, PENNSYLVANIA 18034
UNITED STATES
ATTN: KATHY A. RACOSKY

510k Number: K082991

Received: 10/7/2008

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). 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. 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/electsub.html.

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

K082991

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 MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade 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: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) AESCULAP IMPLANT SYSTEMS INC 3773 Corporate Parkway Center Valley PA 18034 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 202280090		2. CONTACT NAME Kathy Racosky 2.1 E-MAIL ADDRESS kathy.racosky@aesculap.com 2.2 TELEPHONE NUMBER (include Area code) 610-984-9291 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 610-791-6882
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma) Select an application type: <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice 		
3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application Supplement Types: <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)		
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <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. <ul style="list-style-type: none"> <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 		
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)		18-Sep-2008

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

K7
OR
II

4.2

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Date of Submission
 10/6/08

User Fee Payment ID Number

(b)(4) Trade Secret
 Process

FDA Submission Document Number (if known)

SECTION A

TYPE OF SUBMISSION

<p>PMA</p> <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	<p>PMA & HDE Supplement</p> <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	<p>PDP</p> <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	<p>510(k)</p> <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	<p>Meeting</p> <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):
<p>IDE</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	<p>Humanitarian Device Exemption (HDE)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	<p>Class II Exemption Petition</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Evaluation of Automatic Class III Designation (De Novo)</p> <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	<p>Other Submission</p> <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 Aesculap Implant Systems, Inc.		Establishment Registration Number (if known) 3005673311	
Division Name (if applicable)		Phone Number (including area code) (610) 984-9291	
Street Address 3773 Corporate Parkway		FAX Number (including area code) (610) 791-6882	
City Center Valley	State / Province PA	ZIP/Postal Code 18034	Country USA
Contact Name Kathy A. Racosky			
Contact Title Regulatory Affairs Specialist		Contact E-mail Address kathy.racosky@aesculap.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 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"/> 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"/> 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"/> Other Reason (<i>specify</i>):		

SECTION D3

REASON FOR SUBMISSION - 510(k)

<input 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>): Line extension		

SECTION E

ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LZO	2	LWJ	3	MEH	4	KWY
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- 510 (k) summary attached
 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K042344	1	Excia Total Hip System	1	Aesculap Implant Systems, Inc.
2	K060918	2	Excia Total Hip System 12/14 Trunnion with Ceramic Head	2	Aesculap Implant Systems, Inc.
3	K062684	3	Excia Total Hip System 36mm Ceramic Head	3	Aesculap Implant Systems, Inc.
4	K080584	4	Metha Short Stem Hip System	4	Aesculap Implant Systems, Inc.
5	K071535	5	BIOLOX® delta Ceramic Femoral Head	5	Zimmer, Inc.
6		6		6	

SECTION F

PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification

Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Non-Porous Uncemented Prosthesis

	Trade or Proprietary or Model Name for This Device		Model Number
1	BIOLOX® delta Ceramic Femoral Head	1	various
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
K042344	K060437	K061344	K061699	K060918	K062684
7	8	9	10	11	12
K080584					

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) 888.3353	Device Class <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopedic		<input checked="" type="checkbox"/> Class II

Indications (from labeling)

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ -CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

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 type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete	FDA Establishment Registration Number 9610612	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer	<input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Repackager / Relabeler
Company / Institution Name Aesculap AG & Co KG		Establishment Registration Number 9610612	
Division Name (if applicable)		Phone Number (including area code) (011-49) 7461 95 2625	
Street Address Am Aesculap Platz		FAX Number (including area code) (011-49) 7461095 2177	
City Tuttlingen		State / Province	ZIP/Postal Code D-78532
		Country Germany	
Contact Name Konrad Kobel	Contact Title VP of Regulatory Affairs & Quality Management	Contact E-mail Address konrad.kobel@aesculap.de	

(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	7206-10	ISO	Implants for surgery: Partial and total hip – joint prosthesis – Part 10 Determination of the resistance to static load of modular femoral heads		2003
2	F 2345-03	ASTM	Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads		
3					
4					
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

...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

**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 Aesculap Implant Systems, Inc	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 10/6/08
3. ADDRESS (Number, Street, State, and ZIP Code) 3773 Corporate Parkway Center Valley, PA 18034	4. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 610-984-9291 (Fax) 610-791-6882

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)

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) Kathy A. Racosky (Title) Regulatory Affairs Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12) 3773 Corporate Parkway Center Valley, PA 18034	14. TELEPHONE AND FAX NUMBER (Include Area Code) (Tel.) 610-984-9291 (Fax) 610-791-6882
	15. DATE OF CERTIFICATION 10/6/08

Aesculap Implant Systems, Inc.
 3773 Corporate Parkway
 Center Valley, PA 18034
 Telephone: (610) 797-9300
 Facsimile: (610) 791-6882
 E-Mail: kathy.racosky@aesculap.com

October 6, 2008

FDA CDRH DMC
 OCT 7 2008
 Received

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

Re: SPECIAL 510(k) Notification – Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Head

Dear Document Control:

In accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in accordance with 21 CFR Part 807.87, please find enclosed an application for the Aesculap Implant Systems Inc. BIOLOX® *delta* Ceramic Femoral Head.

CONFIDENTIALITY NOTICE:

This document contains information and data which Aesculap Implant Systems, Inc. considers "Trade Secret", commercial, privileged and confidential to Aesculap Implant Systems, Inc. In accordance with CFR Title 21, §807.95 and Part 20, §20.61, this information may not be disclosed to the public in accordance with the Freedom of Information (FOI) Act. The appropriate pages have been marked "CONFIDENTIAL".

Aesculap Implant Systems, Inc. requests that FDA hold as confidential information its intent to market the BIOLOX® *delta* Ceramic Femoral Head as we consider this to be confidential commercial information and therefore, exempt from public disclosure, pursuant to the requirements of 21 CFR §807.95(b).

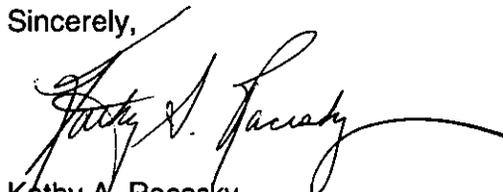
Design and Use of Device:

Question	YES	NO
Is the device intended for prescription use [21 CFR 801(d)]?	X	
Is the device intended for over-the-counter use [21 CFR 807(c)]?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?	X	
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

In order to comply with ¶920, §513 of the Safe Medical Devices Act of 1990, we have provided a 510(k) Summary of Safety and Effectiveness, as well as, a Truthful and Accurate Statement [as required by 21 CFR 807.87(j)] and the Indications for Use statement.

Lastly, we ask that notification of clearance be sent to Aesculap Implant Systems, Inc. via fax at (610) 791-6882.

Sincerely,

A handwritten signature in black ink, appearing to read "Kathy A. Racosky", with a long, sweeping horizontal flourish extending to the right.

Kathy A. Racosky
Regulatory Affairs Specialist

enclosure

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SECTION I
REQUIRED STATEMENTS

INDICATIONS FOR USE STATEMENT
510(k) SUMMARY
TRUTHFUL AND ACCURATE STATEMENT
DECLARATION OF CONFORMITY

A. INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: BIOLOX® *delta* Ceramic Femoral Head
For use with the Aesculap Implant Systems Excia and Metha Hip System

Indications for Use:

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ -CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Prescription Use _____ _____ and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 2

B. 510(k) SUMMARY (as required by 21 CFR 807.92)**BIOLOX® *delta* Ceramic Femoral Head**

October 6, 2008

COMPANY: Aesculap Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

TRADE NAME: BIOLOX® *delta* Ceramic Femoral Head

COMMON NAME: Ceramic Femoral Head

CLASSIFICATION NAME: Hip joint Metal/Ceramic/Polymer Semi-Constrained Cemented or Non-Porous Uncemented Prosthesis
Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate
Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented

REGULATION NUMBER: 888.3353, 888.3360, 888.3353, 888.3390

PRODUCT CODE: LZO, LWJ, MEH, KWY

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, Inc. believes that the BIOLOX® *delta* Ceramic Femoral Head is a line extension of Aesculap Implant Systems Excia (K042344, K060918, and K062684) - Hip Systems and Metha Short Stem Hip System (K080584) that were previously cleared. It is also substantially equivalent to the Zimmer BIOLOX *delta* Ceramic Femoral Head (K071535).

DEVICE DESCRIPTION

The Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Heads are manufactured from an alumina matrix composite. The ceramic femoral head is offered in three diameters of 28, 32, and 36 mm with a range of neck lengths. The BIOLOX® *delta* Ceramic head provides the surgeon another option to both the metal and alumina ceramic femoral heads for use in total hip arthroplasty.

Page 2 of 2

INDICATIONS FOR USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ -CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Heads are offered in similar shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems device is the same as that used to manufacture the predicate devices.

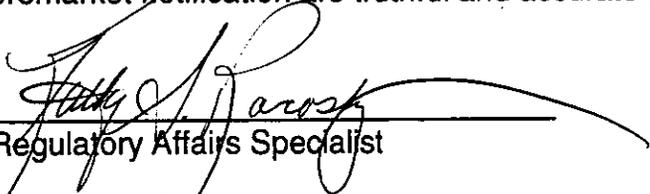
PERFORMANCE DATA

All required testing per “Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements” were done where applicable. In addition, testing per the;

- “Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement”,
- “Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements”,
- “Guidance Document for Testing Non-articulating, “Mechanically Locked” Modular Implant Components”,
- “Draft Guidance Document for Testing Acetabular Cup Prostheses”,
- “Points to Consider for Femoral Stem Prostheses”,
- “Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems” and
- “Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices” was completed where applicable.

C. PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT
[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Specialist for Aesculap Implant Systems, Inc., 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.



Regulatory Affairs Specialist

10/6/08

Date

Premarket Notification 510(k) Number

D. DECLARATION OF CONFORMITY

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

1. 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.


..... date signed *15. Sept. 2008*
Wilhelm Blömer, Vice President Research & Development, Orthopedics
AESCULAP AG & CO. KG

2. 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.


..... date signed *11. Sept. 2008*
Konrad Kobel, Vice President Quality Management / Regulatory Affairs
AESCULAP AG & CO. KG

SECTION II
GENERAL INFORMATION

DEVICE NAME
DEVICE SPONSOR
REGULATORY CLASSIFICATION
PURPOSE FOR PREMARKET NOTIFICATION
DEVICE DESCRIPTION
INDICATIONS FOR USE
SUBSTANTIAL EQUIVALENCE
PERFORMANCE DATA
QUALITY CONTROL
FUNDAMENTAL SCIENTIFIC TECHNOLOGY
MANUFACTURING/STERILIZATION FACILITIES

II. GENERAL INFORMATION**A. DEVICE NAME**

1. Trade Name: BIOLOX® *delta* Ceramic Femoral Head
2. Common Name: Ceramic Femoral Head

B. DEVICE SPONSOR

1. Est. Registration No: 3005673311
2. Name / Address: Aesculap Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
3. Contact Person: Kathy A. Racosky
Regulatory Affairs Specialist
800-258-1946 x 5291 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

C. REGULATORY CLASSIFICATION

1. Device Class: Class II
2. Product Code: LZO, LWJ, MEH, KWY
3. Classification Number: 888.3353, 888.3360, 888.3353, 888.3390
4. Classification Name: Hip joint Metal/Ceramic/Polymer semi-Constrained Cemented or Non-Porous Uncemented Prosthesis Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented
5. Review Panel: Orthopedics

D. PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Head additions.

E. DEVICE DESCRIPTION

The Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Heads are manufactured from an alumina matrix composite. The ceramic femoral head is offered in three diameters of 28, 32, and 36 mm with a range of neck lengths. The BIOLOX® *delta* Ceramic head provides the surgeon another option to both the metal and alumina ceramic femoral heads for use in total hip arthroplasty.

F. INDICATIONS FOR USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ -CaP®.

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

G. SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, Inc. believes that the Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Heads additions are substantially equivalent to the following legally marketed devices:

- Excia Total Hip System, Aesculap Implant Systems, Inc. (K042344)
- Excia Total Hip System 12/14 Trunnion with Ceramic Head, Aesculap Implant Systems, Inc. (K060918)
- Exica Total Hip System 36mm Ceramic Head, Aesculap Implant Systems, Inc. (K062684)
- Metha® Short Stem Hip Sysem, Aesculap Implant Systems, Inc. (K080584)
- BIOLOX® *delta* Ceramic Femoral Head, Zimmer, Inc. (K071535)

H. PERFORMANCE DATA

All required testing per “Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements” were done where applicable. In addition, testing per the;

- “Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement”,
- “Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements”,
- “Guidance Document for Testing Non-articulating, “Mechanically Locked” Modular Implant Components”,
- “Draft Guidance Document for Testing Acetabular Cup Prostheses”,
- “Points to Consider for Femoral Stem Prostheses”,
- “Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems” and
- “Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices” was completed where applicable.

I. QUALITY CONTROL

The BIOLOX® *delta* Ceramic Femoral Heads additions are manufactured by Aesculap AG, and distributed by Aesculap Implant Systems, Inc. These devices are manufactured and processed to applicable standards. Quality control checks are done on all finished products to ensure that product specifications are met before the product is released.

J. FUNDAMENTAL SCIENTIFIC TECHNOLOGY

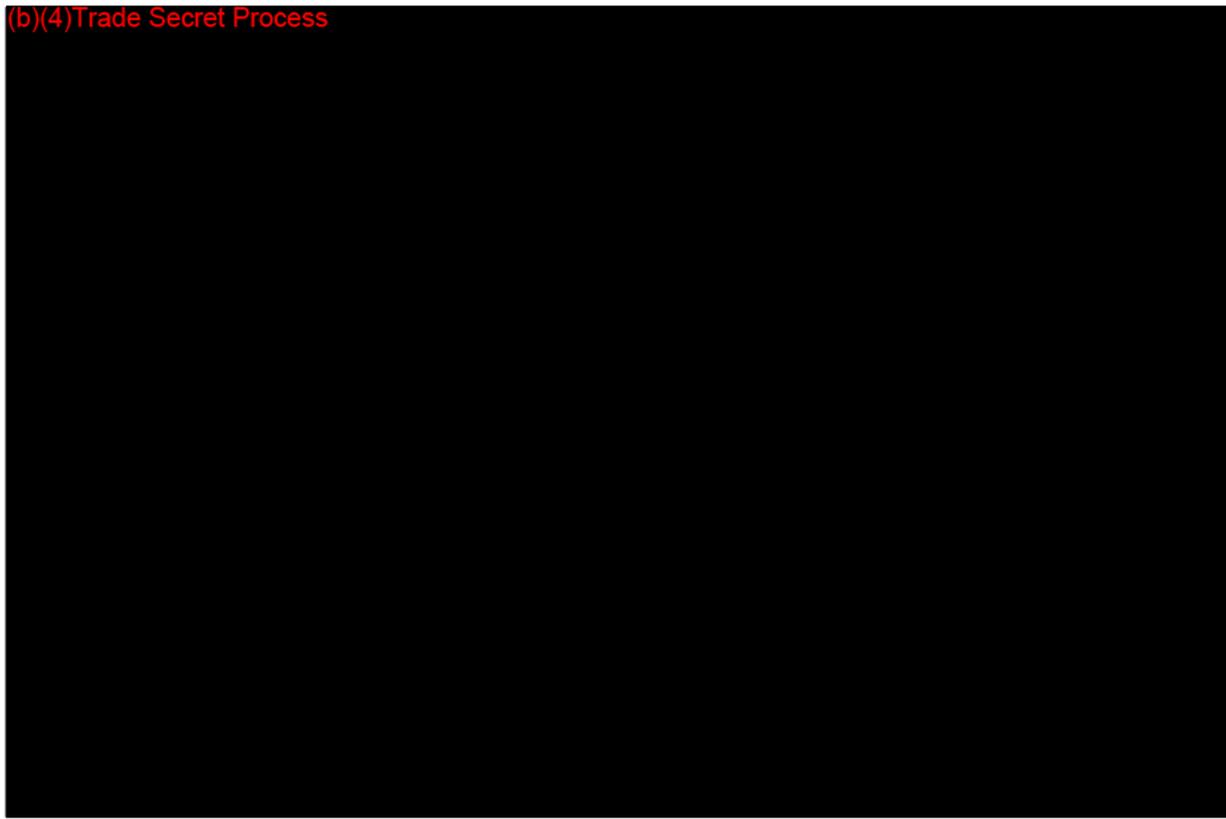
There have been **no changes to the fundamental scientific technology** of the Excia Total Hip Systems or the Metha Short Stem Hip System. These devices operate the same as the previously identified predicate devices and other similar devices on the market.

K. MANUFACTURING AND STERILIZATION FACILITIES

1. Manufacturing Facility for Excia Hip Systems and Metha Short Stem Hip System:

Aesculap AG
Am Aesculap-Platz
Tuttlingen Germany
Tel: +497461952625
Fax: +497461952969
Konrad Kobel
VP of Regulatory Affairs and Quality Management

(b)(4) Trade Secret Process



SECTION III
DEVICE DESCRIPTION

BACKGROUND
NEW COMPONENT
PRODUCT LIST
DRAWINGS

D. DRAWINGS

Available on the following pages.

SECTION IV
SUBSTANTIAL EQUIVALENCE

COMPARATIVE TABLE
PREDICATE DEVICE INFORMATION

**IV. SUBSTANTIAL EQUIVALENCE
A. COMPARATIVE TABLE**

	<p>BILOX® delta Ceramic Femoral Head</p> <p>Pending</p> <p>Aesculap Implant Systems</p> <p>The Excia Hip System is intended to replace a hip joint. The device is intended for:</p> <ul style="list-style-type: none"> • Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis • Patients suffering from disability due to previous fusion • Patients with acute femoral neck fractures <p>The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint. The device is intended for:</p> <ul style="list-style-type: none"> • skeletally mature individuals undergoing primary surgery for total hip replacement • 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, protrusion acetabuli, or slipped capital femoral epiphysis • patients suffering from disability due to previous fusion • patients with acute femoral neck fractures 	<p>BILOX® delta Ceramic Femoral Head</p> <p>K071535</p> <p>Zimmer, Inc</p> <p>The BILOX delta Ceramic Femoral Heads are modular components used in total hip arthroplasty and indicated for the following:</p> <p>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, protrusion 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.</p>	<p>Excia Total Hip System</p> <p>K042344 – K062684</p> <p>Aesculap Implant Systems</p> <p>The Excia Hip System is intended to replace a hip joint. The device is intended for:</p> <ul style="list-style-type: none"> • Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis • Patients suffering from disability due to previous fusion • Patients with acute femoral neck fractures 	<p>Metha Short Stem Hip System</p> <p>K080584</p> <p>Aesculap Implant Systems</p> <p>The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint. The device is intended for:</p> <ul style="list-style-type: none"> • skeletally mature individuals undergoing primary surgery for total hip replacement • 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, protrusion acetabuli, or slipped capital femoral epiphysis • patients suffering from disability due to previous fusion • patients with acute femoral neck fractures
K#				
Manufacturer				
Indication				

B. Determination of Substantial Equivalence: [ref. Office of Device Evaluation (ODE) Blue Book Memorandum #86-3, Attachment I "510(k) "Substantial Equivalence" Decision-Making Process (Detailed)"]

New Device [Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Head] is Compared to the Marketed Device(s) [Aesculap Implant Systems Excia Total Hip Systems (K042344, K060918, K062684), Aesculap Implant Systems Metha® Short Stem Hip System (K080584) and Zimmer Inc. BIOLOX® *delta* Ceramic Femoral Head (K071535).

Does New Device Have Same Indication Statements?

Yes. The indications for the Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Head is similar to the indications to the Aesculap Implant Systems Excia Total Hip Systems (K042344, K060918, K062684) and Aesculap Implant Systems Metha® Short Stem Hip System (K080584)

New Device Has Same Intended Use and May be "Substantially Equivalent".

Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?

Design: **Yes.** The design/ features of the subject device and the predicate devices are similar in system components offered, indications for use, dimensional ranges, and fundamental scientific technology.

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

A large black rectangular redaction box covers the majority of the page content below the design description.

Could the New Characteristics Affect Safety or Effectiveness? No.

When compared to the predicate devices, the subject device demonstrates substantial equivalency in terms of design, performance characteristics and indications for use. Performance test data can be found in Section VIII.

Substantial Equivalence Determination.

C. PREDICATE DEVICE INFORMATION

Aesculap Implant Systems, Inc. believes that the Aesculap Implant Systems BIOLOX® *delta* Ceramic Femoral Head additions are substantially equivalent to:

- Excia Total Hip System, Aesculap Implant Systems, Inc. (K042344)
- Excia Total Hip System 12/14 Trunnion with Ceramic Head, Aesculap Implant Systems, Inc. (K060918)
- Excia Total Hip System 36 mm Ceramic Head, Aesculap Implant Systems, Inc. (K062684)
- Metha® Short Stem Hip System, Aesculap Implant Systems, Inc. (K080584)
- BIOLOX *delta* Ceramic Femoral Head, Zimmer, Inc. (K071535)

The indications for use do not affect the basic technology or operating principles already established for hip systems, as well as existing competitor devices. The material compositions and intended use are substantially equivalent to existing devices currently in commercial distribution.

A presentation of the 510(k) summaries and/or statement of the abovementioned predicate devices are located in Appendix A.

SECTION V
LABELING INFORMATION

PACKAGE LABEL
PACKAGE INSERT

V. LABELING INFORMATION**A. PACKAGE LABEL**

The BIOLOX® *delta* Ceramic Femoral Heads are marked with the company name, catalog number, size, and lot number. They are packaged sterile with a package insert under the same controls and conditions as Aesculap Implant Systems current product line.

The following information will appear on the pouch and carton labels for the BIOLOX® *delta* Ceramic Femoral Heads.

- Product Name
- Description
- Size (Dimensions)
- Item Number
- Lot Number (w/ bar code)
- Sterilization method (symbol only)
- Sterility Expiration Date (w/ symbol)
- Manufacturer Identification Information
- Do Not Reuse (symbol only)
- Consult Instructions For Use (symbol only)

An example of a current international label for a Ceramic femoral head is available on the following page.

Formular für Etikettenfreigabe

- Ⓢ Keramik Hüftprothesenkopf
- Ⓢ Ceramic hip prosthesis head
- Ⓢ Tête Alumine 5° 43'
- Ⓢ Cabeza de cerámica
- Ⓢ Testa ceramica
- Ⓢ Cabeça de prótese de cerâmica
- Ⓢ Ceramic Heuprothesekopf
- Ⓢ Keramická hlavice kyčelní endoprotézy



(01)04048863310043240941116D



(10)1111111

Ø36mm



- Ⓢ Keramik Hüftprothesenkopf
- Ⓢ Ceramic hip prosthesis head
- Ⓢ Tête Alumine 5° 43'
- Ⓢ Cabeza de cerámica

BIOLOX® delta A203-Matrix-Comp-Ceramic

B/10

S

STERILE R

YYYY-MM

LOT 11111111

- 3.5 mm



REF NJ116D



B. BRAUN
AESCULAP



AESCULAP AG & CO. KG
Am Aesculap-Platz
78532 Tuttlingen / Germany

REF NJ116D

Farbcodierung: gelb

Keramik Hüftprothesenkopf

DATUM: 05/04/07

Etiketten Formblatt zu Deckblatt: 1.02.19

B. PACKAGE INSERT

A copy of the Excia Hip System and Metha Short Stem package inserts are located on the following pages.



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

INDICATIONS FOR USE

- The Excia Hip is intended to replace a hip joint.
- The device is intended for:
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
 - Patients suffering from disability due to previous fusion
 - Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCr, and intended for cemented fixation. The other femoral stem is for uncemented fixation and is manufactured from Ti with a Ti plasma spray.

WARNING: Only Ti plasma sprayed components should be implanted without cement. All other devices are designed for use with bone cement.

DEVICE DESCRIPTION

The Excia hip stem is available with a femoral stem design manufactured from Ti with a Ti plasma spray coating (Plasmapore) with or without μ -CaP \otimes . The femoral stem is available with an 8/10 or 12/14 external taper. The 8/10 taper is available in both coating choices. The 12/14 taper is only available with a Ti plasma spray coating (Plasmapore). Each is available in 11 sizes and is intended for uncemented use. The CoCrMo femoral stems are available with an 8/10 and 12/14 taper and each is available in 10 sizes. The CoCrMo stems are intended for cemented use.

The Excia Hip System can be used with either the Aesculap Plasmapore acetabular cups and inserts or the Consensus acetabular cups and inserts. The Plasmapore acetabular cup is manufactured from Titanium alloy with a Ti plasma spray coating with or without μ -CaP \otimes . The acetabular cup inserts are made solely of UHMWPE and are available in symmetrical and asymmetrical designs. The Consensus acetabular cup is made from also made from Titanium alloy but with a porous coating of CP

Ti beads. The shells are available in either hemispherical or flared rim designs and with or without screw holes. The Consensus acetabular insert is made from highly crosslinked polyethylene featuring a Titanium Alloy X-ray marker. Further details on implantation of the Plasmapore or Consensus acetabular cups can be found in their respective Manuals.

The femoral heads are manufactured from CoCrMo and BIOLOX forte or BIOLOX delta (Ceramic). Ceramic heads are to be used only with uncemented, titanium alloy stems. The ceramic heads should NOT be used with the CoCrMo cemented stems. CoCrMo heads can be used with either cemented or uncemented stems. Femoral heads are available with an 8/10 and 12/14 internal bore in various sizes and dimensions.

MATERIAL

Excia implants are manufactured from wrought cobalt-chromium alloy; CoCrMo (ISO 5832/12), UHMWPE (ISO 5834/2), Ceramic; Al₂O₃ (ISO 6474), Ceramic; Al₂O₃, ZrO₂, and other oxides and a Titanium alloy (ISO 5832). The Plasmapore femoral and acetabular components are coated with a Ti plasma spray with or without a calcium phosphate surface. The specialized instruments are made primarily of surgical grade stainless steel (ISO 7153/1).

HOW SUPPLIED

Excia implants are provided sterile. The instruments are provided non-sterile and must be cleaned and sterilized prior to use according to the procedures outlined in this document.

CONTRAINDICATIONS

- Contraindications include, but are not limited to:
- presence of fever, infection or inflammation (systemic or localized);
 - morbid obesity;
 - pregnancy;
 - mental illness or drug abuse
 - severe osteopenia (or any medical or surgical condition) which would preclude potential benefits of implants;
 - suspected or documented metal allergy or intolerance;
 - mixing of implant components from other manufacturers;
 - any case not listed in the indications; and
 - patients unwilling or unable to follow post-operative care instructions.
 - skeletal immaturity.

WARNINGS and POTENTIAL RISKS

The Excia implants are designed for single patient use only and must never be reused. As with all other orthopedic implants, the Excia components should never be re-implanted under any circumstances.

The mixing of different manufacturer implant components is not recommended due to metallurgical, mechanical and functional reasons. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Do not use implants or instruments from other systems or manufacturers.

Excia ceramic heads should only be used with the Ti plasma sprayed femoral stem.

The Excia implants can become loose or break if subjected to increased loading. Factors such as the patient's weight, activity level and adherence to weight-bearing or load-bearing instructions can affect the implant's longevity. Damage to the weight-bearing bone cement and/or bone structures caused by infection can give rise to loosening of the components and/or fracture of the bone.

These warnings do not include all adverse effects which could occur with surgery, but are important considerations specific to metallic devices. The risks associated with orthopedic surgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. See the PRECAUTIONS and POSSIBLE ADVERSE EFFECTS sections for additional warnings.

PRECAUTIONS

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, fins, or other bone fixation devices.

To correctly position the metallic locking ring, surgeons should consult the manufacturer's instructions for appropriate device assembly. 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.

The Excia Hip System is intended to be used by surgeons specializing in orthopedic surgery who have a thorough knowledge of hip arthroplasty, joint morphology and the biomechanical principles of the hip. Pre-operative assessment of the suitability of the patient's anatomy for accepting implants is made on the basis of x-rays, CT scans and other radiological studies.

Only patients that meet the criteria described in the Indications for Use section should be selected.

Correct selection of the implant is extremely important. The morbidity as well as patient weight height, occupation and/or degree of physical activity should be considered.

Proper implant handling before and during the operation is crucial. Handle the implant components properly. Ensure packaging integrity for implant sterility. Do not use any implant where the packaging has been breached. Do not resterilize an implant. Do not allow the implants surfaces to be damaged.

Adequately instruct the patient. The physician should inform the patient about hip implant advantages and disadvantages, post-operative limitations, weight/load bearing stresses which could affect bone healing, implant limitations, and the fact that premature physical activity and full weight/load bearing stresses have been implicated in premature loosening, damage and/or fracture of hip prostheses.

POSSIBLE ADVERSE EFFECTS

Pre-operatively, the patient should be made aware of the possible adverse effects of orthopedic surgery. Additional surgery may be necessary to correct some of these anticipated events including, but not limited to:

- Early or late loosening, disassembly and/or breakage of any or all implants;
- Metal sensitivity to a foreign body (implant material allergic reaction), including metallosis, staining, tumor formation, auto-immune disease and/or scarring;
- Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown, penetration, pain, irritation and/or wound complications;
- Tissue damage resulting from improper placement of implants or instruments;
- Infection;
- Joint dislocation;
- Nerve or vascular damage due to surgical trauma, including loss of neurological function, neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, appearance of radiculopathy, and paralysis (complete or incomplete);
- Bone loss due to resorption or stress shielding, decrease in bone density or bone fracture at operative site;
- Pain, discomfort or wound healing complications at the surgical site;
- Hemorrhage, hematoma, seroma, damage to blood vessels, embolism, stroke, excessive bleeding, wound necrosis and/or dehiscence;
- Misalignment of anatomical structures, including loss of proper hip alignment, loss of varus and/or valgus correction and/or loss of height;

any alternative method using appropriate laboratory techniques.

STORAGE

The Excia instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

WARRENTRY

Every product bearing the Aesculap Implant Systems name is guaranteed to be free of defects in workmanship and materials when used properly for its intended purpose. Any Aesculap Implant Systems product delivered from Aesculap Implant Systems, Inc. proving to be defective will be replaced or repaired, at Aesculap Implant System's discretion, at no charge to the customer.

These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper care and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer's request.

MAINTENANCE and REPAIR

Warning: Repair of Excia Instruments by parties other than Aesculap Implant Systems will void the above warranty.

If your Excia instruments require repair or maintenance, return the instruments in the Aesculap Implant Systems Instrument Repair (A.I.R.) box or other sturdy box with adequate packaging material to protect the instruments. Send the packaged instruments to:

Aesculap Implant Systems, Inc.
615 Lambert Pointe Dr.
Hazelwood, MO 63042

Attn: Aesculap Implant Systems Technical Services
(or call the Repair Hotline at 800-214-3392)

Note: Instruments returned to Aesculap Implant Systems must have a statement which certifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

Thoroughly rinse all internal lumens, stopcocks and ratchets with distilled water to remove all traces of the disinfecting solution. **USE STERILE WATER ON THE FINAL RINSE.**

6. **Drying**

Instruments must be thoroughly dried to remove all residual moisture before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse can also be used to aid the drying process.

7. **Testing/Preparation for Sterilization**

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Instruments should be visually inspected and prepared for sterilization following the disinfection process. Instruments should be visually clean. Contaminated devices should not be reprocessed. Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

Lubrication is essential every time instruments are processed. Use a non-silicone, water-soluble lubricant prior to sterilization such as Aesculap Implant Systems's Instrument Oil, JGS98. Special attention should be given to boxlocks and moveable parts (joints). Only lubricate dry instruments and do not use mineral oil, paraffin, or silicone-based products.

Reassemble instruments, as necessary, before placing into baskets or trays. Close ratcheted instruments in the first ratchet position to avoid temperature-induced stress cracks in the joints.

STERILIZATION

Warning: Aesculap Implant Systems does not recommend the Excia Instruments be sterilized by Flash, EtO or Chemical sterilization.

Sterilization may be accomplished by steam autoclave in a standard prevacuum cycle. To achieve a sterility assurance level of 10⁻⁶, Aesculap Implant Systems recommends the following parameters:

Aesculap Implant Systems Orga Tray / Sterilcontainer (perforated bottom)	
Minimum Cycle Parameters*	
PRE-VACUUM	TEMPERATURE
	132°C / 270°F
MIN DRYING TIME	TIME
	4 minutes
	20 minutes

*Aesculap Implant Systems has validated the above sterilization cycles and has the data on file. The validation was accomplished in an Aesculap Implant Systems Sterilcontainer cleaned by FDA for the sterilization and storage of these instruments. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate

decontamination process should begin immediately after completion of the surgical procedure.

Remove gross contaminants with a steady stream of lukewarm / cool water (below 110°). Be sure to rinse each instrument thoroughly. Do not use saline or chlorinated solutions as these can damage the instrument surface.

Fully open jaws of hinged instruments for cleaning. Instruments with more than one part or piece must be disassembled in order to expose all surfaces to the cleaning process. Retain all parts for re-assembly

2. **Cleaning**

Hand wash using a low-sudsing, neutral pH (7-9), protein dissolving detergent. Follow the detergent manufacturer's directions regarding the proper concentration, temperature and contact time.

Totally immerse the instruments during the cleaning process in order to prevent aerosolization. Use appropriate-sized, soft nylon brushes - Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

To avoid coagulation of mucus, blood or other body fluids, do not soak instruments in hot water, alcohol, disinfectants or antiseptics. Do not exceed two hours soaking in ANY solution.

3. **Ultrasonic Cleaning**

For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level, concentration, and temperature.

When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.

Rinse the instruments thoroughly with tap water, deionized water or distilled water. Make sure all lumens, stopcocks and ratchets are thoroughly rinsed.

4. **Decontamination / Disinfection**

Warning: The decontamination process does not sterilize instruments. Refer to and process the instruments as outlined in the STERILIZATION section.

Select a proper product for high-level disinfection (examples include the glutaraldehyde-family of disinfectant products). Follow the cleaning agent's recommended directions regarding the proper concentration, temperature, contact time and solution re-use.

Do not use high acid (pH <4.0) or high alkaline (pH >10) products for disinfection, such as bleach, bi-chloride of mercury.

Completely immerse instruments in disinfecting solution - force solution into all areas and cavities. Using a large syringe or pulsating water jet, thoroughly flush all channels and lumens with the disinfecting solution to remove debris.

5. **Rinsing**

- Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium;
- Loss of hip mobility or operation and/or inability to perform daily living activities;
- Peri-articular adhesion and fibrosis; and
- Death.

DIRECTIONS FOR USE

To implant the Excia implants, use only the specialized Excia instrumentation. Do not use implants or instruments from any other system or manufacturer.

The Excia implants are provided sterile. Excia instruments are provided non-sterile and must be cleaned and sterilized prior to use according to the procedures outlined in this document. All Excia device system components should be carefully inspected to ensure proper working condition. Critical areas, including joint surfaces, should be checked for wear, damage or irregularities. Damaged or broken Excia devices must not be used or processed and should be returned to Aesculap Implant Systems for evaluation.

Before using the Excia Hip System for the first time, the surgeon should be thoroughly familiar with the Excia Surgical Technique Manual as well as the functionality and assembly of the various components. Pre-operative planning by the surgeon should determine the type of implant required and an adequate supply of the implant sizes should be available prior to surgery, including larger and smaller sizes than those expected to be used.

For complete instructions regarding the proper use and application of all Excia implants and instruments, please refer to the Excia Surgical Technique Manual (available at no charge upon request).

CARE AND HANDLING

Excia hip implants are provided sterile and should be stored in the original packaging until used. Excia hip instruments are provided non-sterile and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the STERILIZATION section for recommended parameters.

Instruments

Before being used for the first time and each use thereafter, the procedures outlined below should be followed to ensure safe handling of biologically contaminated instruments: (For Consensus instrument sets consult the Consensus CS2 Instrument Care Guide):

1. **Pre-Cleaning**

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The

CUSTOMER SERVICE
For further information regarding the Excia Hip System or a copy of the Excia Surgical Technique Manual, PlasmaCup Manual, or Consensus Acetabular Cup Manual, please contact Aesculap, Inc.

AESCLAP.
Implant Systems

Aesculap Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

SOP-AIS-5000165 Rev. 5

053



Metha® Short Stem

The Metha® Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- Skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

Materials

The materials used in the implant are listed on the package.

Prosthesis stem:

- ISOTAN® titanium forged alloy Ti6Al4V according to ISO 5832-3
 - PLASMAPORE® μ -CaP surface coating made of pure titanium according to ISO 5832-2 with additional calcium phosphate layer
- ISOTAN® and PLASMAPORE® are registered trademarks of Aesculap AG & Co. KG, 78532 Tuttlingen / Germany.

Acetabular Components

The Metha Hip System can be used with either the Aesculap Plasmacup acetabular cups and inserts or the Consensus acetabular cups and inserts. The Plasmacup acetabular cup is manufactured from Titanium alloy with a Ti plasma spray coating with or without μ -CaP®. The acetabular cup inserts are made solely of UHMWPE and are available in symmetrical and asymmetrical designs. The Consensus acetabular cup is made from also made from Titanium alloy but with a porous coating of CP Ti beads. The shells are available in either hemispherical or flared rim designs and with or without screw holes. The Consensus acetabular insert is made from highly crosslinked polyethylene featuring a Titanium Alloy X-ray marker. Further details on implantation of the PlasmaCup or Consensus acetabular cups can be found in their respective manuals/guides.

Contraindications

Do not apply in the presence of:

- Joint diseases that can be treated with reconstructive surgery (e.g. displacement osteotomy)
- Acute or chronic infections near the joint or systemic infections
- Secondary diseases that could influence joint implant functionality
- Systemic diseases and metabolic disturbances
- Acute osteoporosis or osteomalacia
- Severely damaged bone structures that could prevent stable implantation of implant components
- Bone tumors in the region of implant fixation
- Bone deformities, axis misalignments, or other bone conditions that rule out the implantation of a hip joint prosthesis preserving the collum femoris
- Anticipated excessive load on the joint implant
- Dependency on pharmaceutical drugs, drug abuse, or alcoholism Medicinal
- Inadequate patient compliance
- Foreign body sensitivity to the implant materials
- Skeletal immaturity
- Neuromuscular diseases impairing the affected extremity

Side-effects or adverse interactions

- Stem loosening or fracture, particularly of smaller sized stems, is most likely to occur in patients who are young, physically active, and/or heavy.
- Dislocation, loosening, wear, corrosion and fracture of implant components
- Joint dislocation and postoperative changes in leg length

- Primary and secondary infections
- Venous thrombosis, lung embolism, and cardiac arrest
- Tissue reaction to implant materials
- Injury to vessels and nerves
- Hematoma and impaired wound healing
- Periarticular calcification
- Decreased joint mobility and flexibility
- Arthralgia and decreased tolerance for exercise

Safety information

- It is the operating surgeon's responsibility to ensure that the operative procedure is performed properly.
- General risk factors associated with surgical procedures are not described in the present documentation.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be thoroughly familiar with bone anatomy, including the pathways of nerves, blood vessels, muscles and tendons.
- It is the operating surgeon's responsibility to ensure the correct combination of implant components and their implantation.
- Aesculap is not responsible for any complications arising from incorrect establishment of indication, choice of incorrect implant, improperly combined implant components and/or operating techniques, limitations of the therapeutic method, or inadequate asepsis.
- The instructions for use of the individual Aesculap implant components must be observed.
- Under no circumstances may modular implant components from different suppliers be combined.
- Under no circumstances should damaged components or surgically excised components be used.
- Implants that have been used once for their designated purpose may not be reused.
- The implant components applied, along with their article numbers, the name of the implant, as well as the batch number and serial number (if available) must be documented in all patient records.
- In addition to mobility and muscle training, it is of particular importance that the individual patient is kept well informed during the postoperative period.
- Damage to load-bearing bone structures can result in loosening of the components, bone or implant fractures or other acute complications.
- To ensure the earliest possible detection of such catalysts of implant dysfunction, the prosthetic joint must be checked periodically, using appropriate techniques.

Sterility

- The implant components come individually packed in protective packaging that is labeled according to its contents.
- The implant components are sterilized by irradiation (minimum dose 25 kGy).
 - Store implant components in their original packaging. Do not remove them from their original protective packaging until immediately before their application.
 - Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use implant components that are past their expiration dates or if the packaging is damaged.
 - Do not resterilize the prosthesis stem.
 - Do not resterilize the protective sleeve.

➤ **Never resterilize or reuse the implant components.**

Application

The operating surgeon shall devise an operation plan that specifies and accurately documents the following:

- Selection of the implant components and their dimensions
- Positioning of the implant components in the bones
- Location of intraoperative landmarks

The following conditions must be fulfilled prior to application:

- All requisite implant components must be ready to hand
- Operating conditions must be highly aseptic
- Implantation instruments, including the dedicated Aesculap implant system instruments, must be complete and in working condition.
- The operating surgeon and operating room team must be thoroughly conversant with the operating technique, as well as the range of implants and instruments to be applied; complete information on these subjects must be readily available at the workplace.
- **Those performing operations must be thoroughly conversant with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant articles by medical specialists from the professional literature.**
- **The manufacturer has been consulted if the preoperative situation was unclear and if implants were found in the area operated on.**

The operative procedure has been explained to the patient, and the latter's understanding of the following information has been documented:

- The functionality of the prosthetic joint is always inferior to that of the natural joint.
- The prosthetic joint can only result in relative improvement compared to the preoperative situation.
- The prosthetic joint insert can become loose owing to excessive load, wear and tear, or infection.
- The durability of the prosthetic joint depends on the body weight of the patient and the load on the joint.
- The prosthetic joint replacement must not be subjected to overload through extreme strain, heavy physical labor or sporting activities.
- Corrective surgery may be necessary if the implant becomes loose.
- If such revision becomes necessary, there are conditions that may rule out the restoration of the functionality of the joint.
- The patient has to comply with regular check-ups of the prosthetic joint, carried out by a physician.

The implantation site is prepared in the following way:

- Following a high femoral neck osteotomy, open the femur with the implant-specific awl.
- Introduce the awl until it reaches the lateral cortex.

Bone fractures/perforations in the implant bed will adversely affect the implant fixation!

- **Avoid bone fractures by operating cautiously.**
 - **Treat bone fractures through appropriate intraoperative and postoperative measures.**
 - **Handle the implant components properly.**
-
- Gradually prepare the implant bed with the implant-specific form rasps (starting with the smallest size).
 - Check and, if necessary, correct the implant position, depth and anteversion.
 - Check the stem size against the form rasp that was introduced last in the correct position.
 - Insert the stem component and hammer it into the implant bed with well dosed blows.
 - Carry out a trial reduction.
 - Check joint mobility/range of movement, joint stability and leg length.
 - Select a prosthesis ball according to the trial heads.
 - Verify that the cone size of the neck matches the sizes of the prosthesis ball (see cone size on the implant packaging, e.g. 12/14).
 - Rinse, clean and dry the outside cone of the neck and, if necessary, the inside cone of the prosthesis balls.
 - Do not remove the protective sleeve until immediately before positioning the prosthesis head.
 - Attach the prosthesis ball to the stem at room temperature only. If necessary, allow the implant to cool down to room temperature.
 - Put the prosthesis ball in its position.
 - To prevent abnormal wear of the prosthesis: Remove all obvious bone cement residues and bone chips before closing the wound.

CARE AND HANDLING

Metha® hip implants are provided sterile and should be stored in the original packaging until used. **Metha® hip instruments are provided non-sterile** and should be stored in the original packaging until cleaned and sterilized. Prior to use, they must be sterilized according to the standard hospital procedure. Refer to the **STERILIZATION** section for recommended parameters.

Instruments

Before being used for the first time and each use thereafter, the procedures outlined below should be followed to ensure safe handling of biologically contaminated instruments:

1. Pre-Cleaning

Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments. The decontamination process should begin immediately after completion of the surgical procedure.

Remove gross contaminants with a steady stream of lukewarm / cool water (below 110°). Be sure to rinse each instrument thoroughly. Do not use saline or chlorinated solutions as these can damage the instrument surface.

Fully open jaws of hinged instruments for cleaning. Instruments with more than one part or piece must be disassembled in order to expose all surfaces to the cleaning process. Retain all parts for re-assembly

2. Cleaning

Hand wash using a low-sudsing, neutral pH (7-9), protein dissolving detergent. Follow the detergent manufacturer's directions regarding the proper concentration, temperature and contact time.

Instruments should be thoroughly cleaned. Totally immerse the instruments during the cleaning process in order to prevent aerosolization. Use appropriate-sized, soft nylon brushes - Do not use steel wool, wire brushes, pipe cleaners or abrasive detergents.

To avoid coagulation of mucus, blood or other body fluids, do not soak instruments in hot water, alcohol, disinfectants or antiseptics. Do not exceed two hours soaking in ANY solution.

3. Ultrasonic Cleaning

For ultrasonic cleaning, follow the manufacturer's specifications for suggested water level, concentration, and temperature.

When using mechanical washers, make sure the instruments are secured in place, and do not touch or overlap.

Rinse the instruments thoroughly with tap water, deionized water or distilled water. Make sure all lumens, stopcocks and ratchets are thoroughly rinsed.

4. Decontamination / Disinfection

Warning: The decontamination process does not sterilize instruments. Refer to and process the instruments as outlined in the **STERILIZATION section.**

Select a proper product for disinfection. Follow the cleaning agent's recommended directions regarding the proper concentration, temperature, contact time and solution re-use.

Do not use high acid (pH <4.0) or high alkaline (pH >10) products for disinfection.

Completely immerse instruments in disinfecting solution - force solution into all areas and cavities. Using a large syringe or pulsating water jet, thoroughly flush all channels and lumens with the disinfecting solution to remove debris.

5. Rinsing

Thoroughly rinse all internal lumens, stopcocks and ratchets with distilled water to remove all traces of the disinfecting solution. **USE STERILE WATER ON THE FINAL RINSE.**

6. Drying

Instruments must be thoroughly dried to remove all residual moisture before they are stored. Use a soft, absorbent towel/cloth to dry external surfaces. Compressed air or a 70% alcohol rinse can also be used to aid the drying process.

7. Testing / Preparation for Sterilization

Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of operative procedures.

Instruments should be visually inspected and prepared for sterilization following the disinfection process. Contaminated devices should not be reprocessed. Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.

Reassemble instruments, as necessary, before placing into baskets or trays. Close ratcheted instruments in the first ratchet position to avoid temperature-induced stress cracks in the joints.

STERILIZATION

Warning: Aesculap Implant Systems does not recommend the Metha® instruments be sterilized by Flash, EtO or Chemical sterilization.

Sterilization may be accomplished by steam autoclave in a standard prevacuum cycle. To achieve a sterility assurance level of 10⁻⁶, Aesculap Implant Systems recommends the following parameters:

Aesculap Orga Tray / Sterilcontainer (perforated bottom) Minimum Cycle Parameters*		
PRE-VACUUM	TEMPERATURE	TIME
		132°C / 270°F

MINIMUM DRYING TIME – 20 minutes

**Aesculap Implant Systems has validated the above sterilization cycle and has the data on file. The validation was accomplished in an Aesculap Implant Systems Sterilcontainer cleared by FDA for the sterilization and storage of these instruments. Other sterilization cycles may also be suitable, however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques. Use an FDA cleared accessory to maintain sterility after processing, such as a wrap, pouch, etc.*

STORAGE

The Metha® instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.

WARRANTY

Every product bearing the Aesculap Implant Systems name is guaranteed to be free of defects in workmanship and materials when used properly for its intended purpose. Any Aesculap Implant Systems product delivered from Aesculap Implant Systems, Inc. proving to be defective will be replaced or repaired, at Aesculap Implant System’s discretion, at no charge to the customer.

These warranties shall not apply to conditions or defects resulting from, but not limited to: negligence, improper use, improper care and handling, improper opening techniques, unauthorized repair work, caustic or abrasive cleaners, or items modified or customized by the customer at the customer’s request.

MAINTENANCE and REPAIR

Warning: Repair of Metha® instruments by parties other than Aesculap Implant Systems will void the above warranty.

If your Metha® instruments require repair or maintenance, return the instruments in the Aesculap Implant Systems Instrument Repair (A.I.R.) box or other sturdy box with adequate packaging material to protect the instruments. Send the packaged instruments to:

Aesculap Implant Systems, Inc.
615 Lambert Pointe Dr.
Hazelwood, MO 63042

Attn: Aesculap Implant Systems Technical Services
(or call the Repair Hotline at 800-214-3392)

Note: Instruments returned to Aesculap Implant Systems must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.

CUSTOMER SERVICE

For further information regarding the Metha® Short Stem Hip System or a copy of the Metha® Short Stem Surgical Technique Manual, please contact Aesculap Implant Systems, Inc. or your local Aesculap Implant Systems Orthopaedic Distributor.

AESCULAP

Implant Systems

Aesculap Implant Systems, Inc.

3773 Corporate Parkway

Center Valley, PA 18034

1-800-234-9179

SOP-AIS-5000541 Rev. 2

SECTION VI
STERILIZATION

SECTION VII
BIOCOMPATIBILITY INFORMATION

VII. BIOCOMPATIBILITY INFORMATION

The BIOLOX® *delta* alumina matrix composite ceramics have been tested for biocompatibility per applicable sections of ISO 10993 as shown in test reports located in Appendix B.

SECTION VIII
PERFORMANCE DATA

VIII. PERFORMANCE DATA

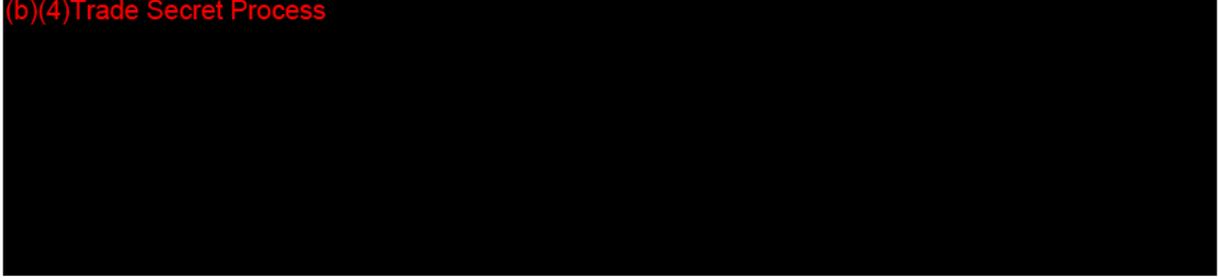
Biomechanical testing

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Non-clinical Information for Femoral Stem Prostheses"
- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Adjoining Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Points to Consider for Femoral Stem Prostheses",
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.

The following test reports are available in Appendix C.

(b)(4)Trade Secret Process



SECTION IX
DESIGN CONTROL ACTIVITIES SUMMARY

IX. DESIGN CONTROL ACTIVITIES SUMMARY

A Design Control Activities Summary has been completed which addressed the addition of the BIOLOX® *delta* Ceramic Femoral Head. The Design Control Activities Summary can be found on the following page. Potential Risks are addressed and mitigation actions identified. It is concluded that the potential risks are effectively managed by the stated controls.

ISO 14971 (Medical devices – Application of risk management to medical devices) was used to determine the risks.

APPENDIX A
Predicate Device Information



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

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510(k) Premarket Notification Database

Device Classification Name	<u>Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented</u>
510(K) Number	K042344
Device Name	EXCIA TOTAL HIP SYSTEM
Applicant	AESCULAP, INC. 3773 Corporate Pkwy. Center Valley, PA 18034
Contact	Joyce Kilroy
Regulation Number	<u>888.3360</u>
Classification Product Code	<u>LWJ</u>
Subsequent Product Codes	<u>JDI LZO</u>
Date Received	08/30/2004
Decision Date	03/16/2005
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	<u>Summary</u>
Type	Abbreviated
Reviewed By Third Party	No
Expedited Review	No

Database Updated 09/08/2008

MAR 16 2005

K042344

PAGE 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
in Accordance with SMDA of 1990

EXCIA TOTAL HIP SYSTEM

February 25, 2005

COMPANY: Aesculap[®], Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Joyce Kilroy, Dir of RA & QA
800-258-1946 (phone)
610-791-6882 (fax)
joyce.kilroy@aesculap.com (email)

TRADE NAME: Excia Total Hip System

COMMON NAME: Hip System

DEVICE CLASS: CLASS II

PRODUCT CODE: LWJ, JDI, LZO

CLASSIFICATION: 888.3350, 888.3353

REVIEW PANEL: Orthopedics

INTENDED USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCr and is intended for cemented fixation. The other femoral stem is for uncemented fixation and is manufactured from Ti with a Ti plasma spray.

DEVICE DESCRIPTION

The Excia Total Hip System is available with two femoral designs. One is manufactured from Ti with a Ti plasma spray coating (Plasmapore). This component is intended for uncemented use. The other femoral component design is manufactured from CoCrMo and is intended for cemented use. Distal centralizers maintain the stem's alignment in the femoral canal. The centralizers are manufactured from PMMA.

The acetabular cup (Plasmacup) is manufactured from Ti and is coated with Plasmapore as well. Acetabular cup screws can be used for further cup fixation. The acetabular inserts are UHMWPE and available in symmetrical and asymmetrical designs.

Two femoral heads are available. The CoCrMo heads may be used with either the cemented or cementless femoral stems. However, the ceramic heads are for use only with the Ti alloy cementless stems.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements"
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Draft Guidance for Femoral Stem Prostheses" ,
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.

SUBSTANTIAL EQUIVALENCE

Aesculap believes that the new Excia Total Hip System is substantially equivalent in design to:

- BiCONTACT Hip System (K040191)
- 36mm V40 Femoral Head Components (K022077)
- Alloclassic Zweymueller (K030373)
- SC Total Hip System (K031474)
- Smith & Nephew Hip System (K022902)
- Pinnacle Duofix HA Acetabular Cup (K031495)
- Trident Porous Ti Acetabular Component with Coating (K013475)



MAR 16 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Joyce Kilroy
Director of Regulatory Affairs & Quality Assurance
Aesculap, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K042344

Trade/Device Name: Excia Total Hip System
Regulation Number: 21 CFR 888.3353; 21 CFR 888.3350
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis; Hip joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: II
Product Code: LZO, JDI, LWJ
Dated: February 25, 2005
Received: February 25, 2005

Dear Ms. Kilroy:

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

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

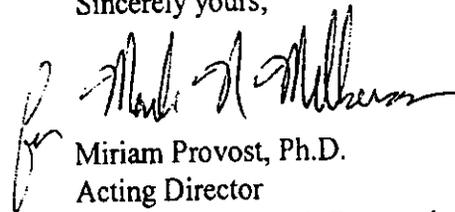
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely yours,

A handwritten signature in black ink, appearing to read "Miriam Provost", is written over a printed name. The signature is fluid and cursive.

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

Enclosure



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

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510(k) Premarket Notification Database

Device Classification Name	<u>Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</u>
510(K) Number	K060918
Device Name	EXCIA TOTAL HIP SYSTEM 12/14 TRUNNION WITH CERAMI
Applicant	AESCULAP, INC. 3773 Corporate Parkway Center Valley, PA 18034
Contact	Kathy A Racosky
Regulation Number	<u>888.3353</u>
Classification Product Code	<u>LZO</u>
Subsequent Product Codes	<u>JDI LWJ</u>
Date Received	04/04/2006
Decision Date	05/26/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	<u>Summary</u>
Type	Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 09/08/2008

Page 1 of 2

K060918

MAY 26 2006

B. 510(k) SUMMARY (as required by 21 CFR 807.92)**Excia Total Hip System
(12/14 Trunnion with Ceramic Head)**

April 3, 2006

COMPANY: Aesculap[®], Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
800-258-1946 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

TRADE NAME: Excia Total Hip System 12/14 Trunnion with Ceramic Head

COMMON NAME: Femoral Hip Stem and ceramic head

CLASSIFICATION NAME: Prosthesis, hip, semi-constrained, metal/polymer, uncemented
Prosthesis, hip, semi-constrained, metal/polymer, cemented
Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented

REGULATION NUMBER: 888.3360, 888.3350, 888.3353

PRODUCT CODE: LWJ, JDI, LZO

SUBSTANTIAL EQUIVALENCE

Aesculap[®], Inc. believes that the 12/14 Trunnion with Ceramic Head is a line extension of Aesculap's Excia Total Hip System that was cleared (K042344). It is also substantially equivalent to the BiContact Hip System (K040191), DePuy Ceramic Femoral Heads (K031803) and Alumina Ceramic Femoral Heads, 28 and 32 MM (K030724).

DEVICE DESCRIPTION

The Excia femoral component is available in two designs. One is manufactured from Ti with a plasma spray coating (Plasmapore). This component is intended for uncemented use. The other femoral component is manufactured from CoCrMo and is intended for cemented use. Both femoral components have a 12/14 trunnion.

The ceramic heads are available in head diameters of 28mm, 32mm, and 36mm in three neck lengths each. They are for use only with the Ti alloy cementless stems. The cemented or cementless femoral stems may be used with the CoCrMo head that was cleared in BiContact (K040191). The acetabular insert is UHMWPE and is available

Page 2 of 2

in a 36mm symmetrical design. The 12/14 femoral component and ceramic head are used in conjunction with Plasmacup (K042344) for total hip arthroplasty.

INDICATIONS FOR USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with a Ti plasma spray.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The new components of the Excia Total Hip System are offered in similar shapes and sizes as the predicate devices. The material used for the Aseculap device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the:

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Points to Consider for Femoral Stem Prostheses",
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2006

Aesculap, Inc.
c/o Ms. Kathy A. Racosky
Regulatory Affairs Associate
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K060918

Trade/Device Name: Excia Total Hip system 12/14 Trunnion with Ceramic 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, JDI, LWJ

Dated: May 2, 2006

Received: May 4, 2006

Dear Ms. Racosky:

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

Page 2 – Ms. Kathy Racosky

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

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

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

Sincerely yours,



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

Enclosure

Page 1 of 1

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K060918

Device Name: Excia 12/14 Trunnion with Ceramic Head

Indications for Use:

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Ti plasma spray.

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

510(k) Number K060918

Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)



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510(k) Premarket Notification Database

Device Classification Name	<u>Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</u>
510(K) Number	K062684
Device Name	EXCIA TOTAL HIP SYSTEM 36MM CERAMIC HEAD
Applicant	AESCULAP, INC. 3773 Corporate Pkwy. Center Valley, PA 18034
Contact	Kathy A Racosky
Regulation Number	<u>888.3353</u>
Classification Product Code	<u>LZO</u>
Subsequent Product Codes	<u>JDI LWJ MEH</u>
Date Received	09/19/2006
Decision Date	11/22/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary	<u>Summary</u>
Type	Special
Reviewed By Third Party	No
Expedited Review	No

Database Updated 09/08/2008

Page 1 of 2

B. 510(k) SUMMARY (as required by 21 CFR 807.92)

NOV 22 2006

**Excia Total Hip System
(Excia 36mm Ceramic Head)
September 8, 2006**

COMPANY: Aesculap[®], Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
800-258-1946 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

TRADE NAME: Excia Total Hip System 36mm Ceramic Head

COMMON NAME: Ceramic Ball Head

CLASSIFICATION NAME: Prosthesis, hip, semi-constrained,
metal/ceramic/polymer, cemented or non-porous
uncemented prosthesis
Prosthesis, hip, semi-constrained, uncemented,
metal/polymer, non-porous, calicum-phosphate
Prosthesis, hip, semi-constrained, metal/polymer,
uncemented
Prosthesis, hip, semi-constrained, metal/polymer,
cemented

REGULATION NUMBER: 888.3353, 888.3353, 888.3360, 888.3350

PRODUCT CODE: LZO, MEH, LWJ, JDI

SUBSTANTIAL EQUIVALENCE

Aesculap[®], Inc. believes that the 36mm Ceramic Head is a line extension of Aesculap's Excia Total Hip System that was cleared (K042344). It is also substantially equivalent to the Excia Total Hip System 12/14 Trunion with Ceramic Head (K060918).

DEVICE DESCRIPTION

The Excia 36mm Ceramic Head is manufactured from ceramic (Al₂O₃) and conforms to ISO 6474. The 36mm diameter head is offered in three different head lengths (-3.5 mm, 0 mm, and +3.5mm). These ceramic heads allow the surgeon further option to meet the patient's needs.

Page 2 of 2

INDICATIONS FOR USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ CaP®.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The new 36mm ceramic head of the Excia Total Hip System are offered in similar shapes and sizes as the predicate devices. The material used for the Aseculap device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Points to Consider for Femoral Stem Prostheses",
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap, Inc.
% Ms. Kathy A. Racosky
Regulatory Affairs Associate
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

NOV 22 2006

Re: K062684

Trade/Device Name: Excia Total Hip System 36mm Ceramic 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, JDI, LWJ, MEH
Dated: November 14, 2006
Received: November 15, 2006

Dear Ms. Racosky:

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

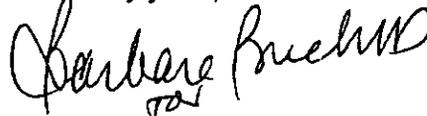
Page 2 - Ms. Kathy A. Racosky

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

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

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

Sincerely yours,



Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Page 1 of 1

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K062684

Device Name: Excia 36mm Ceramic Head

Indications for Use:

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ CaP®.

Prescription Use X and/or Over-the-Counter Use _____
(per 21 CFR 801.109)

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

Farah Buehler
 (Division Sign-Off) *for NCM*
 Division of General, Restorative,
 and Neurological Devices

510(k) Number K062684



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510(k) Premarket Notification Database

Device Classification Name	<u>Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calicum-Phosphate</u>
510(K) Number	K080584
Device Name	METHA SHORT STEM HIP SYSTEM AESCULAP IMPLANT SYSTEM, INC.
Applicant	3773 Corporate Parkway Center Valley, PA 18034
Contact	Kathy A Racosky
Regulation Number	<u>888.3353</u>
Classification Product Code	<u>MEH</u>
Subsequent Product Codes	<u>KWY LWJ LZO</u>
Date Received	03/03/2008
Decision Date	05/09/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement/Summary/Purged Status	Summary Only
Summary Type	<u>Summary</u> Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 09/08/2008

B. 510(k) SUMMARY (as required by 21 CFR 807.92)**Metha® Short Stem Hip System**
February 29, 2008

COMPANY: Aesculap Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

CONTACT: Kathy A. Racosky
610-984-9291 (phone)
610-791-6882 (fax)

TRADE NAME: Metha®

COMMON NAME: Metha® Short Stem Hip System

CLASSIFICATION NAME: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Uncemented
Prosthesis, Hip, Semi-Constrained, Uncemented, Metal/Polymer, Non-Porous, Calcium-Phosphate
Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-Porous, Uncemented
Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented

REGULATION NUMBER: 888.3360, 888.3353, 888.3353, 888.3390

PRODUCT CODE: LWJ, MEH, LZO, KWY

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, Inc. believes that the Metha® Short Stem Hip System is substantially equivalent to:

- Excia Total Hip System (K042344)
- Excia Total Hip System with μ -CaP® (K060437)
- Excia Total Hip System 12/14 Trunnion with Ceramic Head (K060918)
- MAYO® Conservative Hip Prosthesis (K030733)

DEVICE DESCRIPTION

Metha® is a femoral short stem intended to replace the hip joint in total hip arthroplasty. The femoral stem is collarless, conical shaped and is intended for cementless, press-fit application. The femoral stem is manufactured from titanium alloy and is available in various sizes. The proximal area of the femoral stem is plasma sprayed (Plasmapore®) with a secondary coating of Calcium Phosphate (μ -CaP®). It is designed for use with currently available Aesculap Implant Systems femoral heads, acetabular components and Bipolar cups.

INDICATIONS FOR USE

The Metha® Short Stem Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The components of the Aesculap Implant Systems Metha® Short Stem Hip System are offered in a similar range of shapes and sizes as the predicate devices. The material used for the Aesculap Implant Systems device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance for Femoral Stem Prostheses",
- "Draft Guidance for Calcium Phosphate (Ca-P) Coating" was completed where applicable.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap Implant Systems, Inc.
c/o Ms. Kathy A. Racosky
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

MAY - 9 2008

Re: K080584
Trade/Device Name: Metha Short Stem Hip
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented
or uncemented prosthesis
Regulatory Class: Class II
Product Code: MEH, LZO, LWJ, KWY
Dated: April 24, 2008
Received: April 25, 2008

Dear Ms. Racosky:

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.

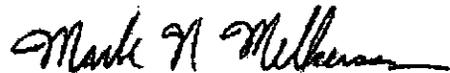
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

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

Page 1 of 1

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K080584

Device Name: Metha® Short Stem Hip System

Indications for Use:

The Metha® Short Stem Hip System (uncemented, press-fit fixation) is intended to replace a hip joint.

The device is intended for:

- skeletally mature individuals undergoing primary surgery for total hip replacement
- 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, protrusion acetabuli, or slipped capital femoral epiphysis
- patients suffering from disability due to previous fusion
- patients with acute femoral neck fractures

Prescription Use X and/or Over-the-Counter Use _____
(per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *W. R. D. [Signature]*

Division of General, Restorative,
and Neurological Devices

510(k) Number ⁰⁹⁴ K080584



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510(k) Premarket Notification Database

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

Database Updated 09/08/2008

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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[®] *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[™] 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* *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 endoprostheses 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 Bruch
(Division Sign-off)

Division of General, Restorative,
and Neurological Devices

*Trademark of CeramTec AG

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510(k) Number K071535

026

APPENDIX B
Biological Test Reports

CONFIDENTIAL

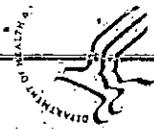
Archiving

The following records will be stored in the scientific archives of BSL BIOSERVICE Scientific Laboratories GmbH according to the GLP-Regulations:

A copy of the final report, the project protocol, the study plan and a documentation of all raw data generated during the conduct of the study (documentation forms as well as any other notes of raw data, printouts of instruments and computers) and the correspondence with the sponsor concerning the project.

If test item is left over a sample will be stored according to the period fixed by the GLP-Regulations. Samples that are unstable may be disposed of before that time. Remaining test item will be returned to the sponsor as requested.

APPENDIX C
Biomechanical Test Reports



COVER SHEET MEMORANDUM

From: Reviewer Name Tara Shepherd
Subject: 510(k) Number K082991/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/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/Screening Checklist](http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/ScreeningChecklist))
 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 http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4136/ABB_REVIATED STANDARDS DATA FORM.DOC)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-08).DOC)			✓
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, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
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)?			✓
Does this device include an Animal Tissue Source?			✓
Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.		✓
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.		✓

Regulation Number 888.3353 Class* II Product Code L70
(*If unclassified, see 510(k) Staff)

Additional Product Codes: LWJ MEH KWH

Review: [Signature] (Branch Chief) DTAB (Branch Code) 11/9/08 (Date)

Final Review: [Signature] (Division Director) [Signature] (Date)

AKO Dia
11/20/08

PRE-REVIEW FORM: COMPANY/DEVICE HISTORY

Please complete the pre-review form prior to beginning the review of this 510(k). This form is designed to be a tool to identify key items that may be important to consider regarding the regulation of the subject device and if you should even begin the review of the 510(k).

If you answer YES to questions 1, 2 or 3; do NOT begin the review of this 510(k):		YES	NO
1.	Are you aware of the submitter being the subject of an integrity investigation? (Please see H:\INTEGRITY LIST\CDRH REVIEWER SCREENING LIST.DOC)		✓
2.	Is the device exempt from 510(k) by regulation (Please see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4134/510(K)%20EXEMPT%20%20FORM.DOC or subject to enforcement discretion (No regulation - See 510(k) Staff)?		✓
3.	Does this device type require a PMA by regulation? (Please see management.)		✓
Questions 4-8 are intended to help you start your review:		YES	NO
4.	Is this 510(k) a candidate for "Refuse to Accept"? (If so, please use the Traditional/Abbreviated or Special 510(k) Refuse to Accept Screening Checklist, http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4d69/Screening%20Checklist.doc)		✓
5.	a. Did the firm request expedited review? (See management.) b. Was expedited review granted? (See <i>Guidance for Industry and FDA Staff: Expedited Review of Devices for Premarket Submissions</i> , http://www.fda.gov/cdrh/mdufma/guidance/108.html)		✓
6.	To the best of your knowledge, was there a pre-IDE, 513(g) or other pre-submission for this type of device?	Please list document number and/or date, here:	✓
7.	To the best of your knowledge, has a 510(k) previously been submitted for this specific device (i.e., previously found NSE or withdrawn)?	Please list document number, here:	✓
8.	Does this device have indications or technology that are cross-cutting and impact the review policy of another branch(es)? (Please contact other branch(es) and see <i>Guidance for Industry and FDA Staff on Bundling Multiple Devices or Multiple Indications in a Single Submission</i> http://www.fda.gov/cdrh/mdufma/guidance/1215.html)		✓

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

To: THE FILE

RE: DOCUMENT NUMBER

K082991 S001

Date: November 18, 2008

TNS 11/18/08

From: Tara Shepherd, Biomedical Engineer (HFZ-410)

Division: DGRND/OJDB

Device Name: Biolog Delta Ceramic Femoral Head

Classification: 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. LZO, LWJ, MEH, KWY

Company: Aesculap Implant Systems, Inc.
3773 Corporate Pwky
Center Valley, PA 18034

Contact: Kathy A. Racosky

Phone: 610-984-9291; Fax: 610-791-6882; Email: kathy.racosky@aesculap.com

*Free
11/20/08*

Recommendation: Substantial Equivalence (SE)

(b)(4) Trade Secret Process

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).

The Excia Hip System is intended to replace a hip joint. The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ -CaP.

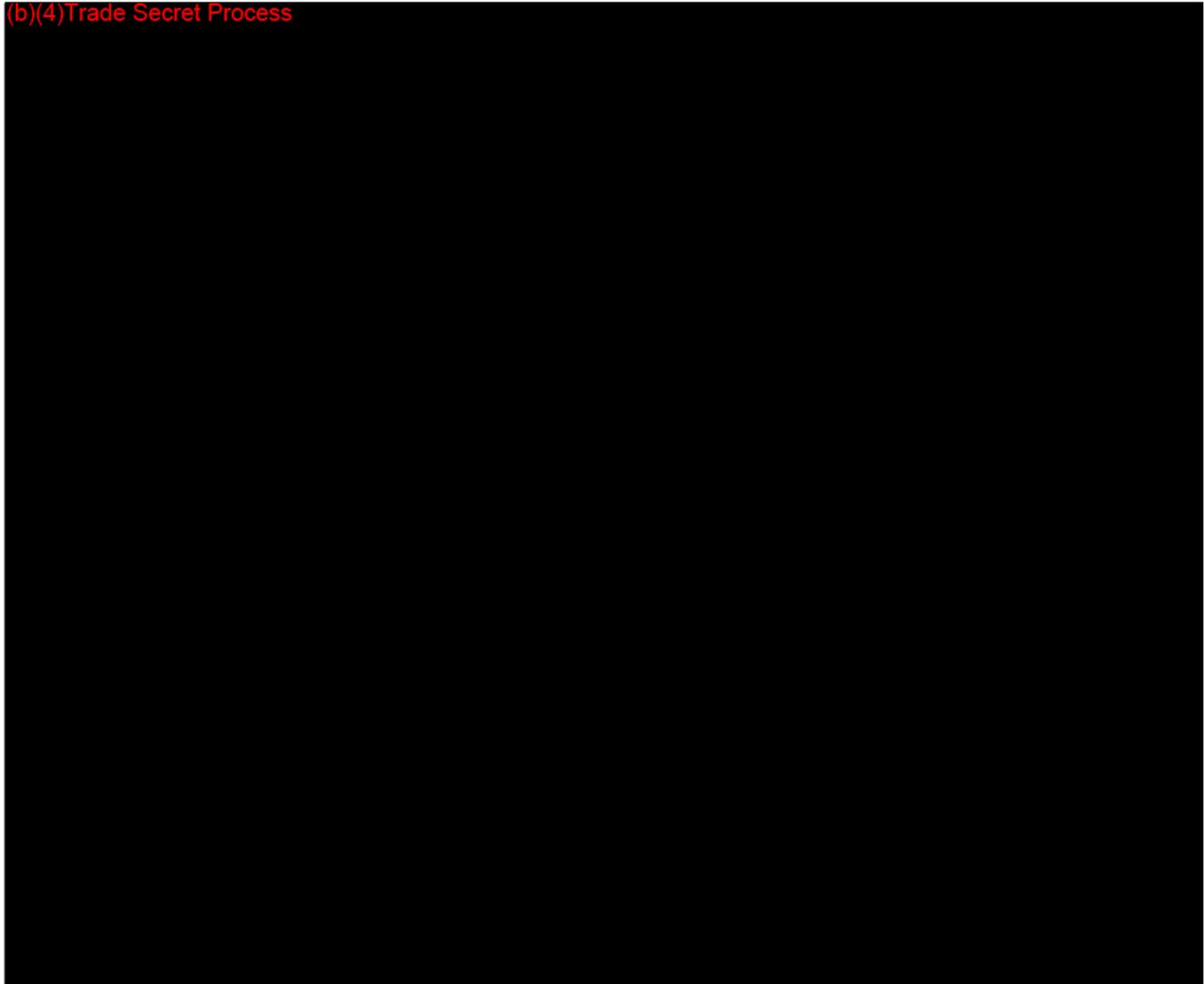
The Metha Hip System (uncemented, press-fit fixation) is intended to replace a hip joint. The device is intended for:

- Skeletally mature individuals undergoing primary surgery for total hip replacement
- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collage disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

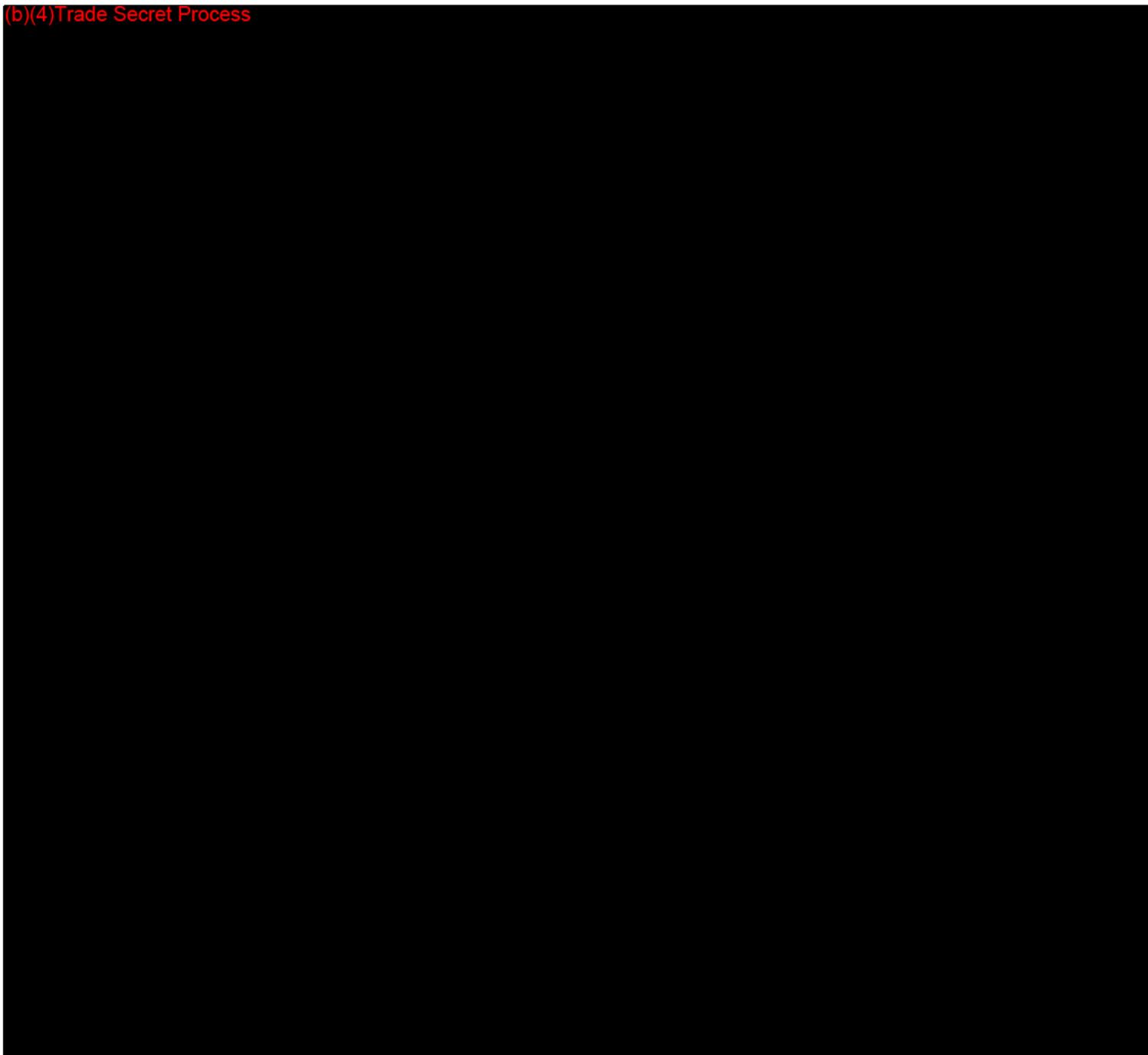
(b)(4)Trade Secret Process

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(b)(4)Trade Secret Process

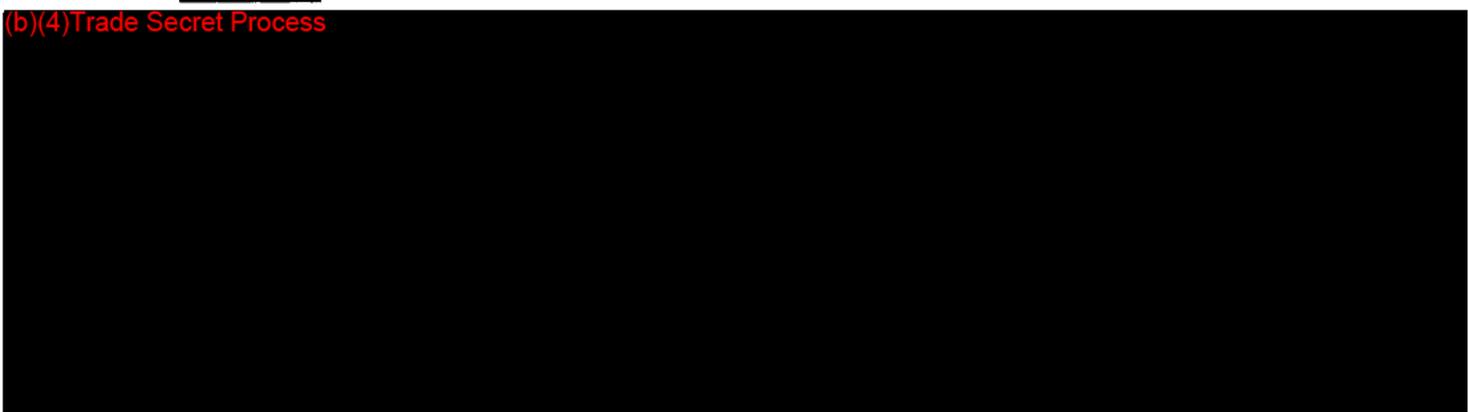
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(b)(4)Trade Secret Process

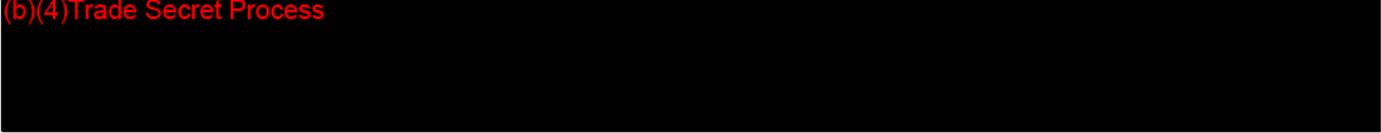


Sterilization

(b)(4)Trade Secret Process

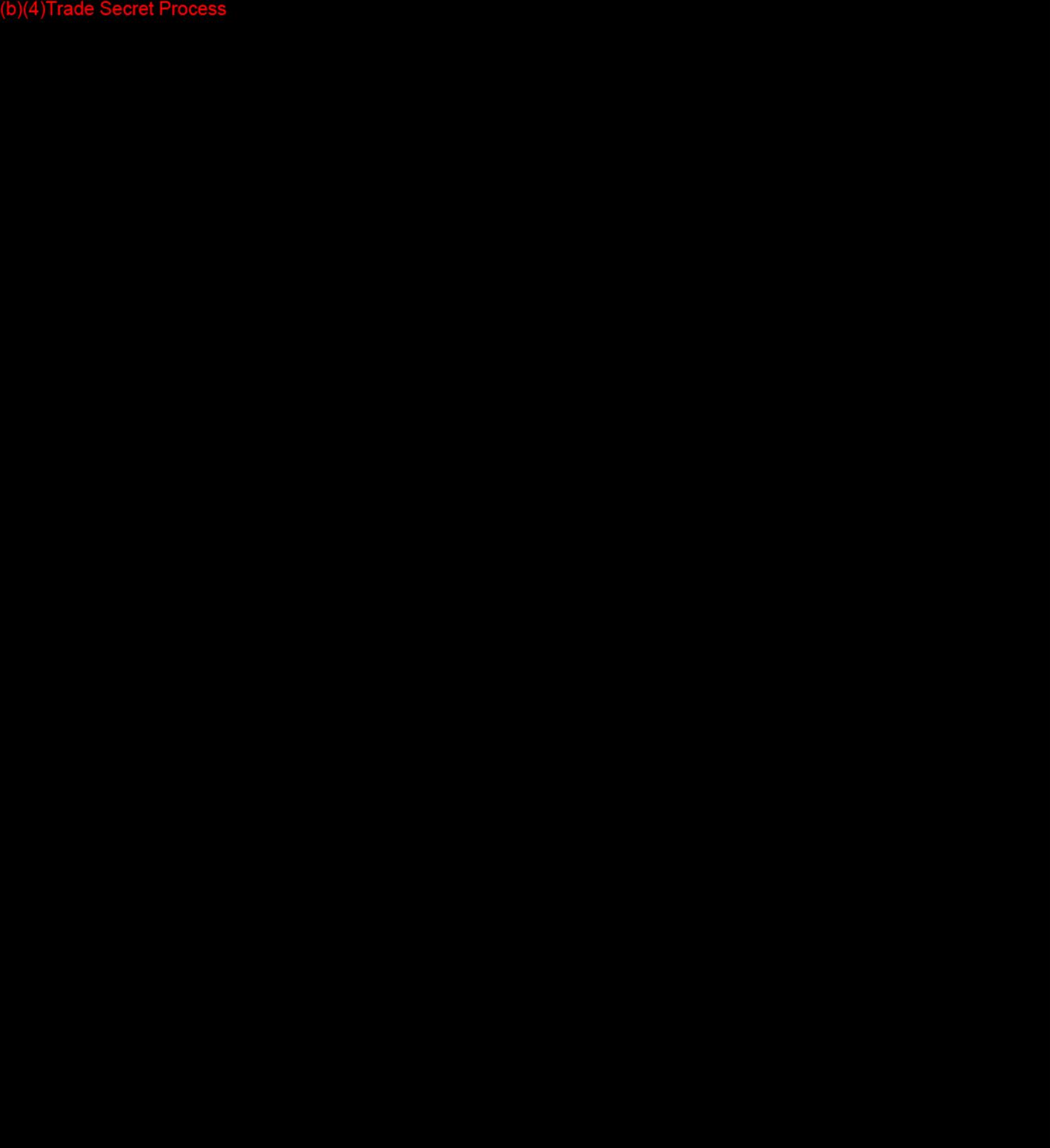


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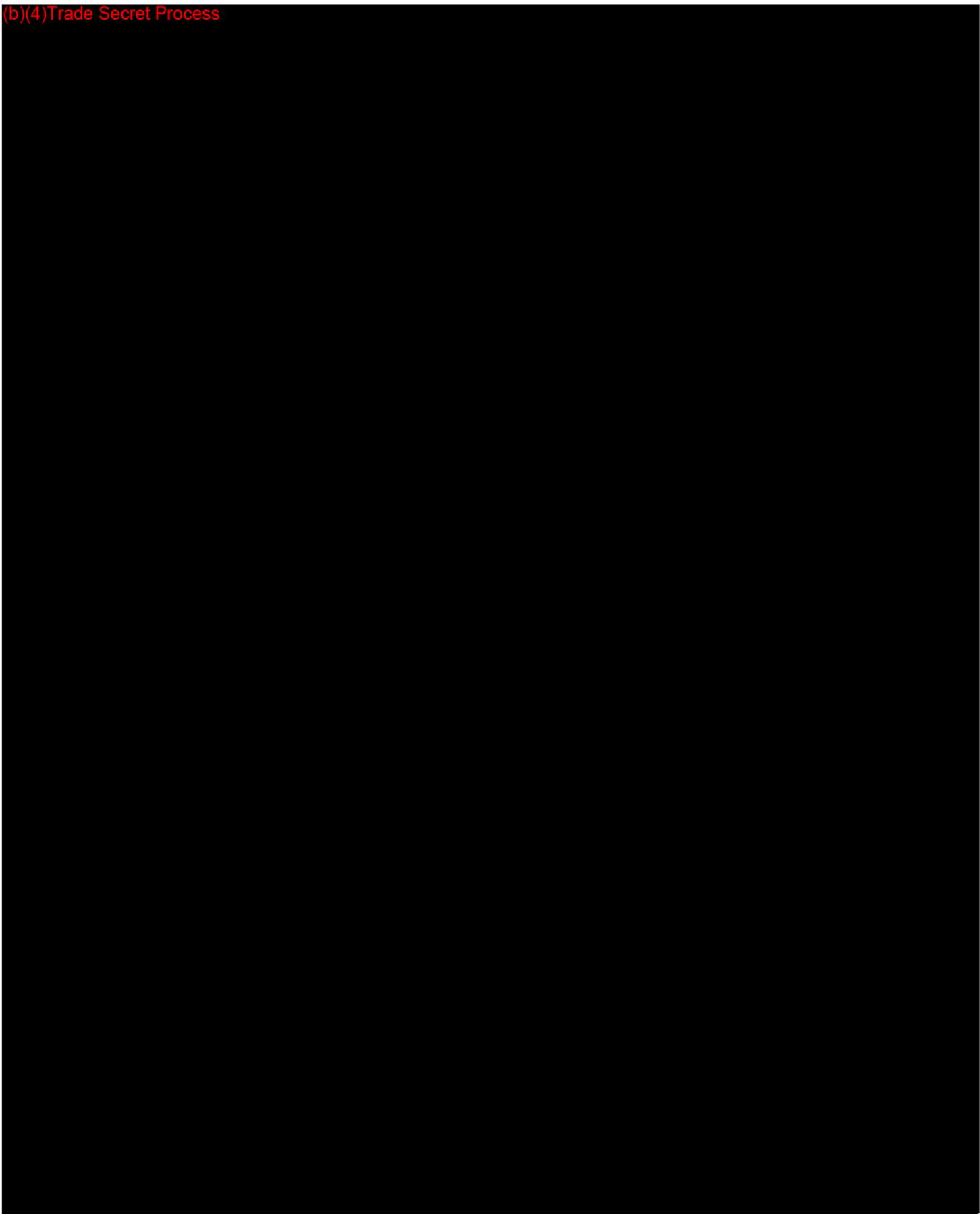
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4. A Design Control Activities Summary which includes:

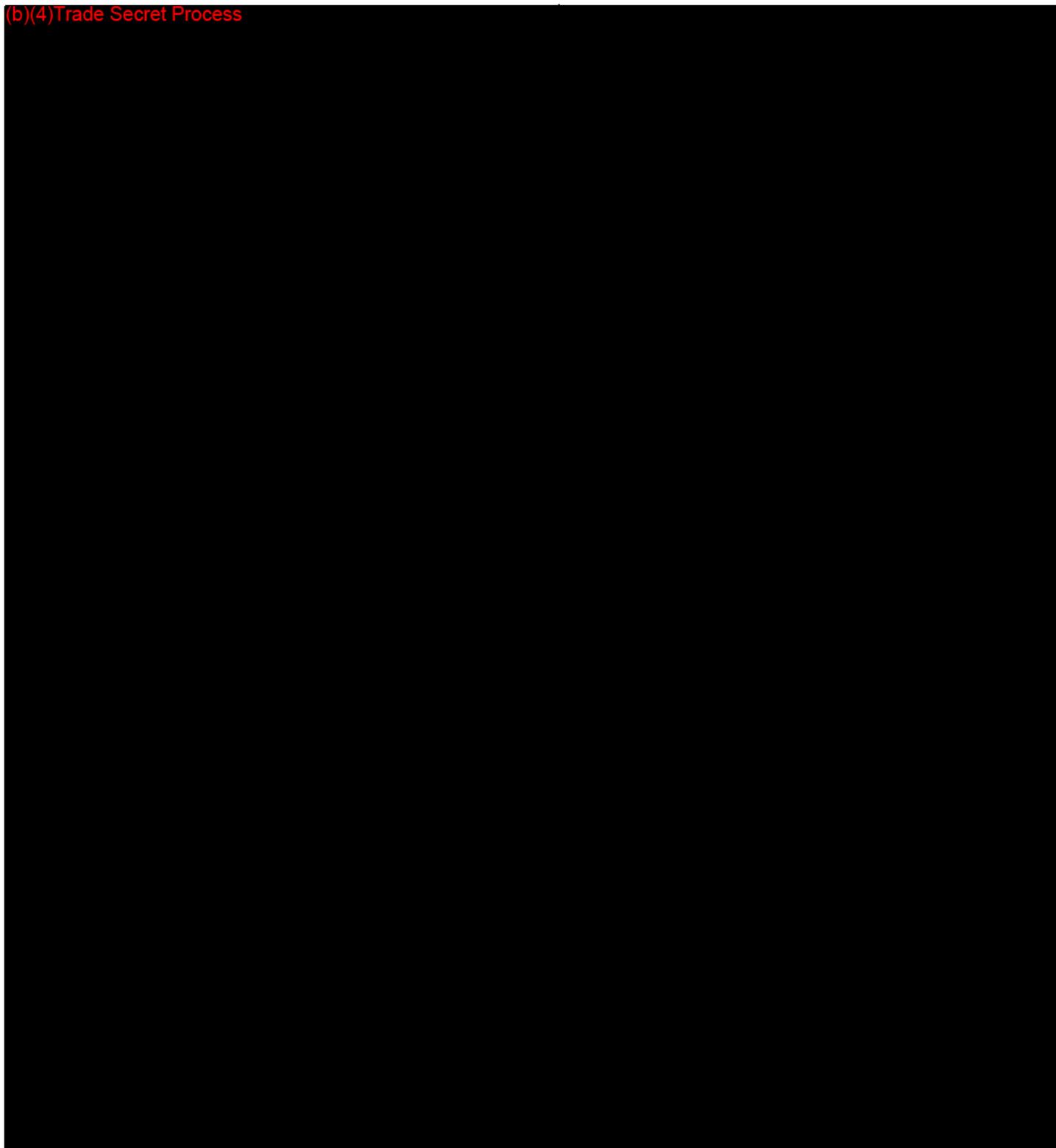
(b)(4)Trade Secret Process

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(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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

(b)(4)Trade Secret Process



COVER SHEET MEMORANDUM

From: Reviewer Name Tara Shepherd
Subject: 510(k) Number K082991
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/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information of 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 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			
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, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
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

K082991

Date: November 4, 2008

From: Tara Shepherd, Biomedical Engineer (HFZ-410)

Division: DGRND/OJDB

TNS 11/4/08

Device Name: BioloX Delta Ceramic Femoral Head

Classification: 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. LZO, LWJ, MEH, KWY

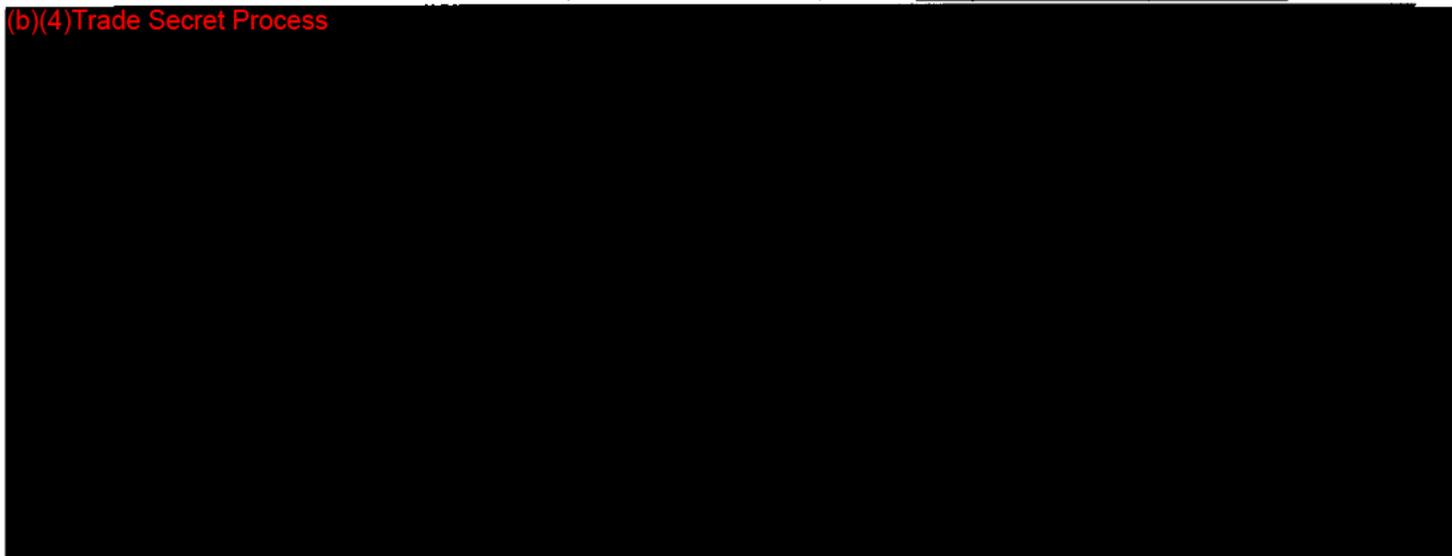
Company: Aesculap Implant Systems, Inc.

3773 Corporate Pwky
Center Valley, PA 18034

Contact: Kathy A. Racosky

Phone: 610 – 984 – 9291; Fax: 610-791-6882; Email: kathy.racosky@aesculap.com

(b)(4)Trade Secret Process



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).

The Excia Hip System is intended to replace a hip joint. The device is intended for:

- Patients suffering from severe hip 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, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ -CaP.

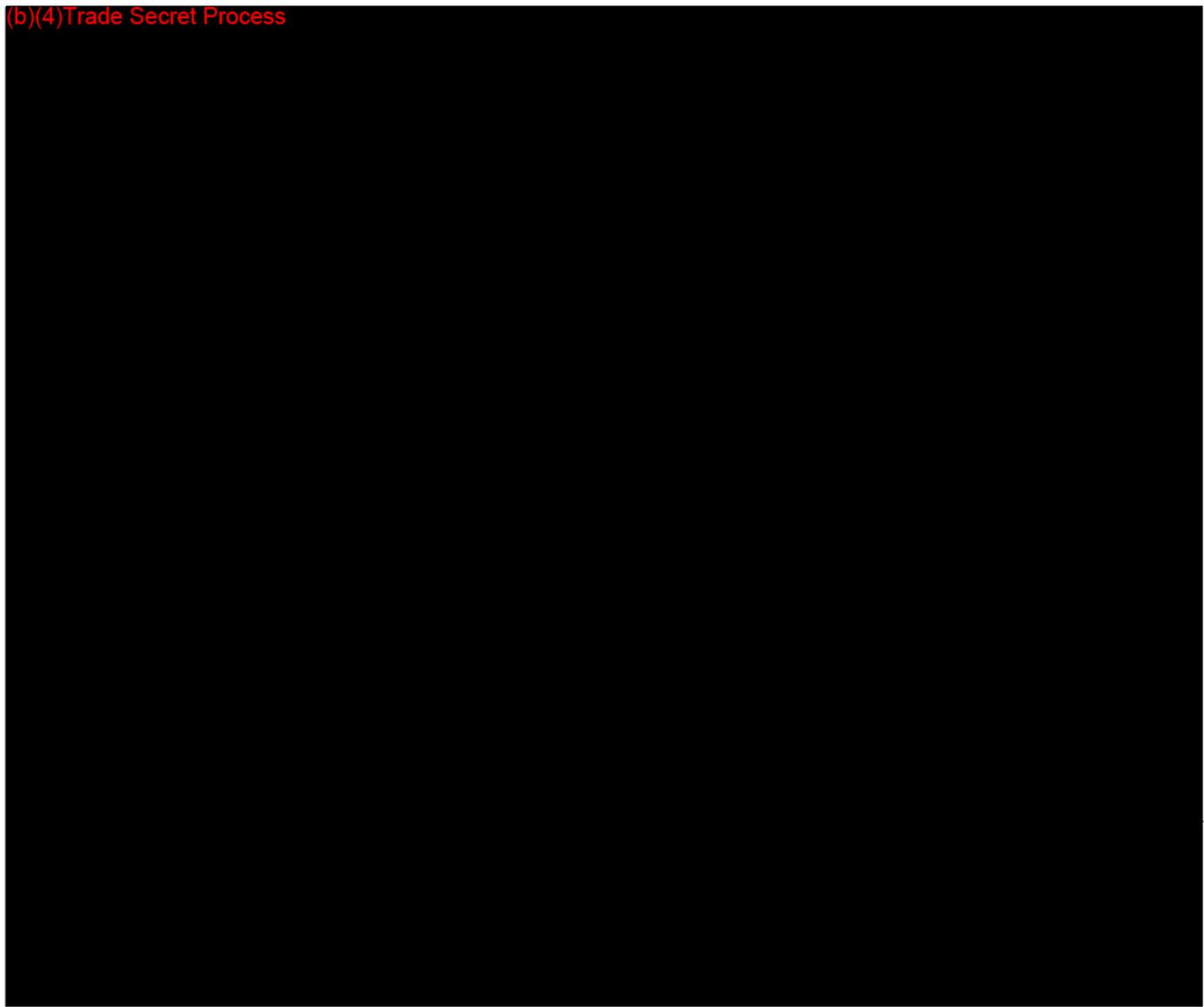
The Metha Hip System (uncemented, press-fit fixation) is intended to replace a hip joint. The device is intended for:

- Skeletally mature individuals undergoing primary surgery for total hip replacement
- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collage disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

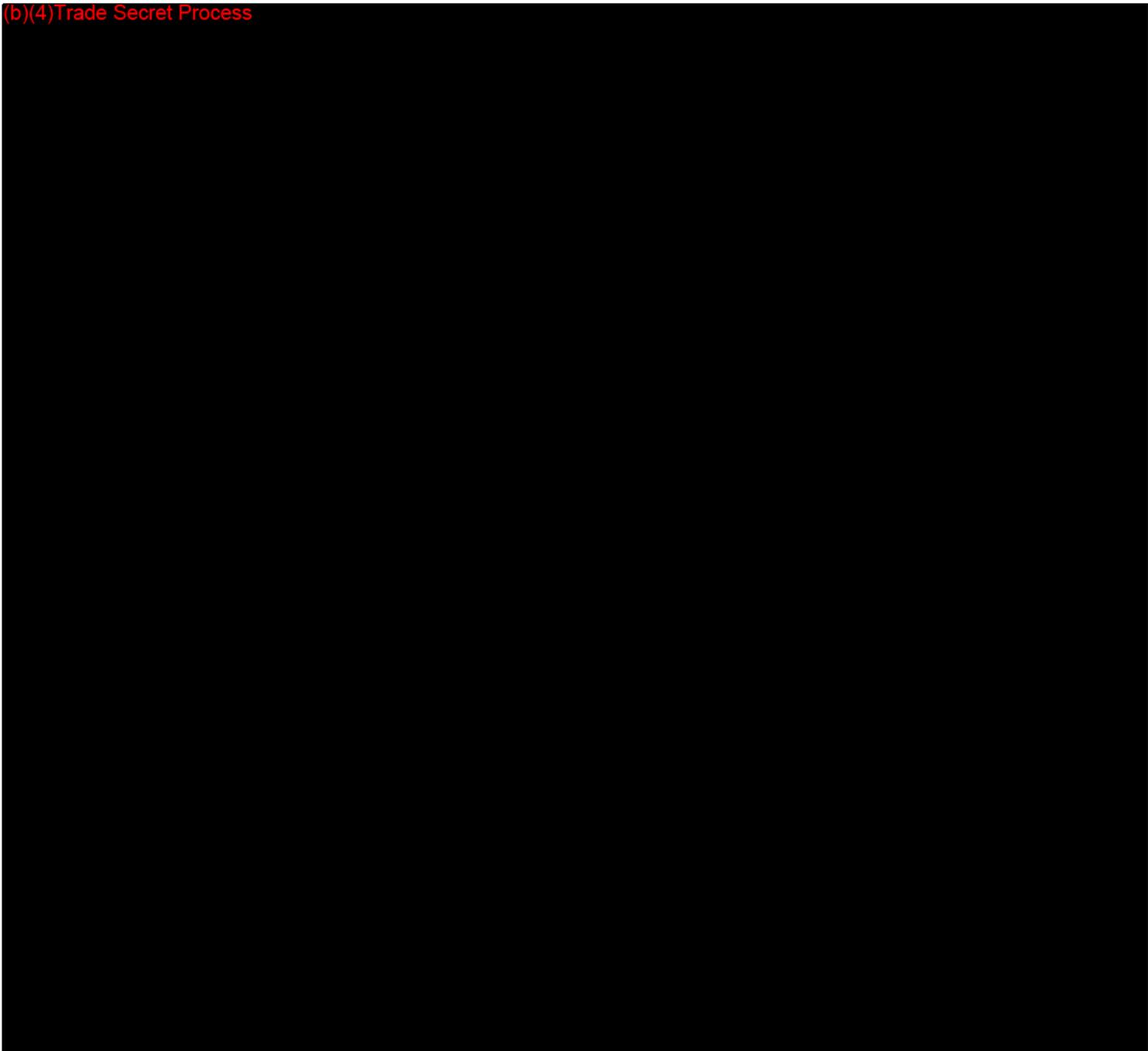
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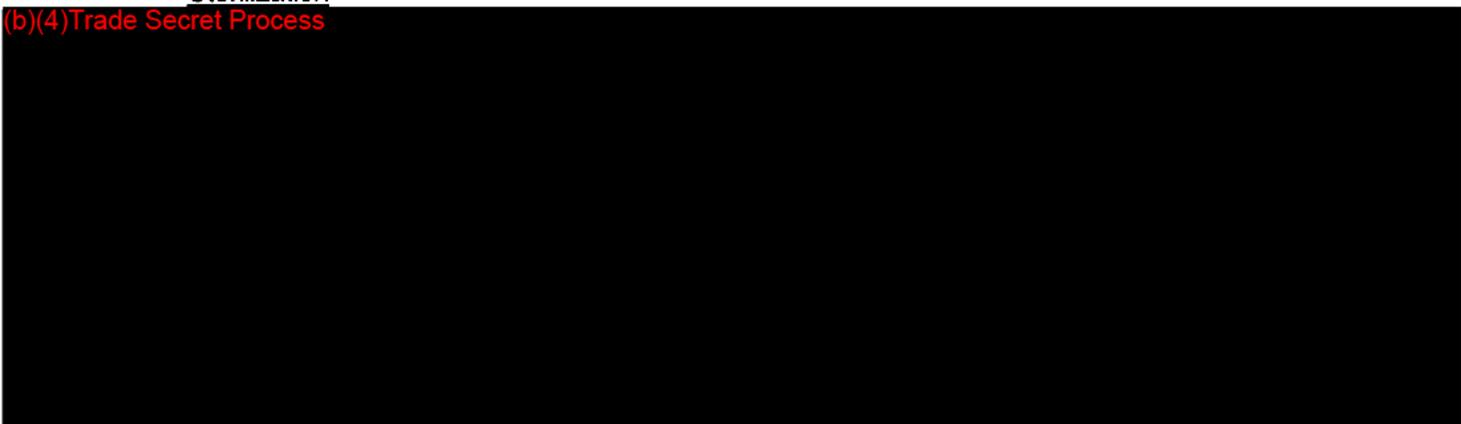
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Sterilization

(b)(4)Trade Secret Process

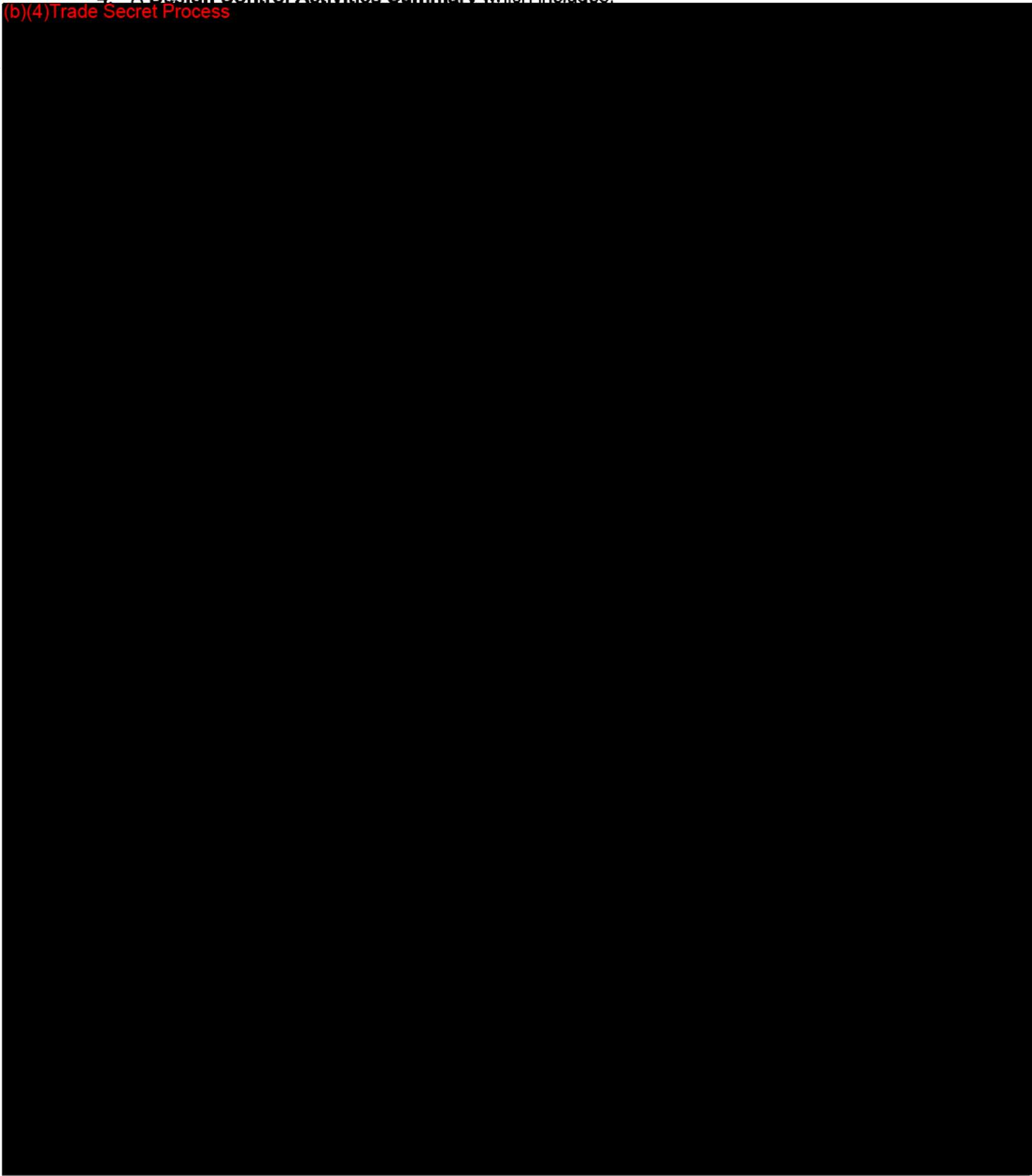


(b)(4)Trade Secret Process

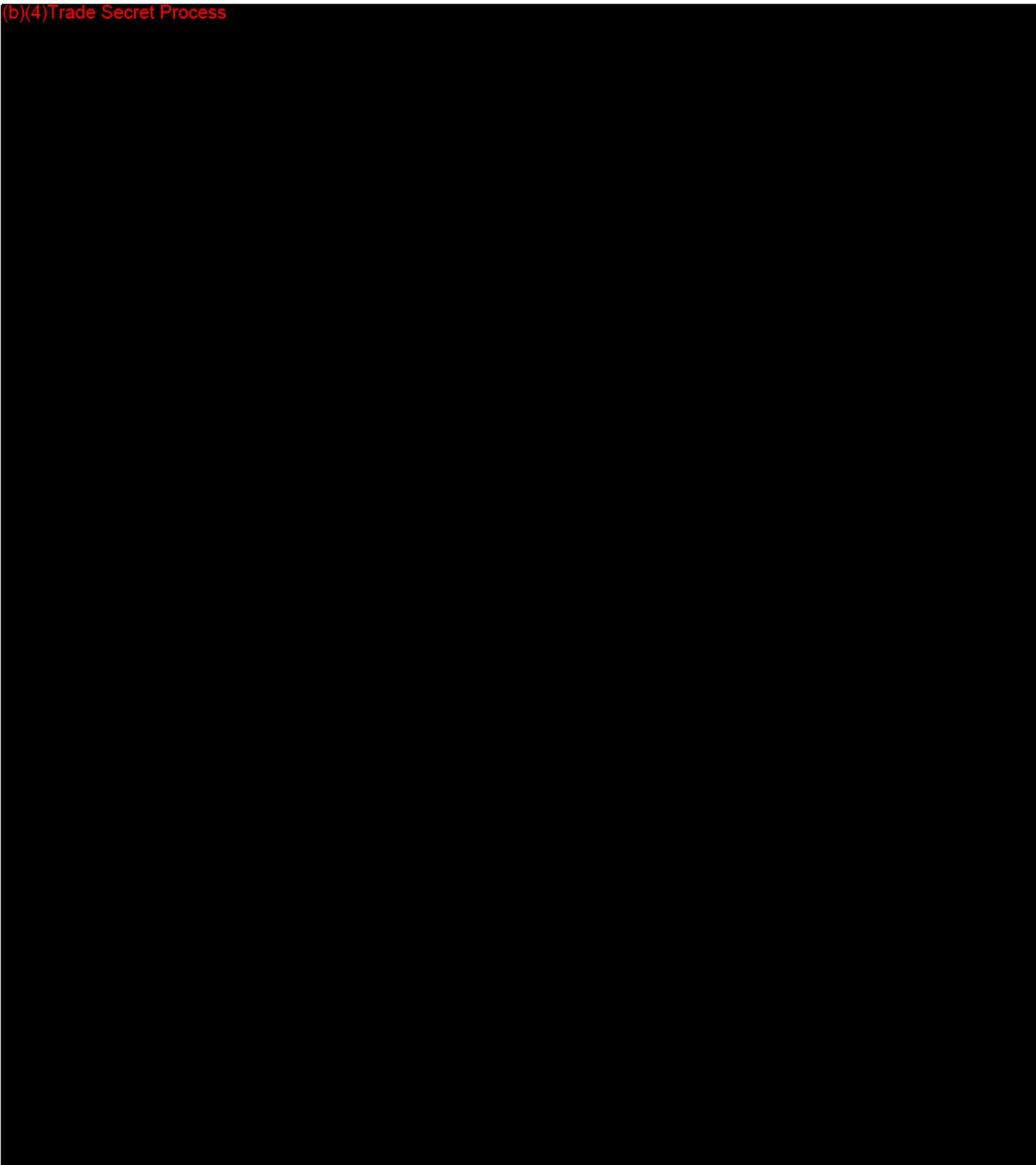
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4. A Design Control Activities Summary which includes:

(b)(4)Trade Secret Process

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(b)(4)Trade Secret Process



"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

	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: TH

(b)(4) Trade Secret Process



November 10, 2008

AESCLAP IMPLANT SYSTEMS, INC.
3773 CORPORATE PWKY.
CENTER VALLEY, PENNSYLVANIA 18034
UNITED STATES
ATTN: KATHY A. RACOSKY

510k Number: K082991

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. 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

K082991/14

Aesculap Implant Systems Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Telephone: (610) 984-9291
Facsimile: (610) 791-6882
E-Mail: kathy.racosky@aesculap.com
www.aesculap.com

November 7, 2008

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

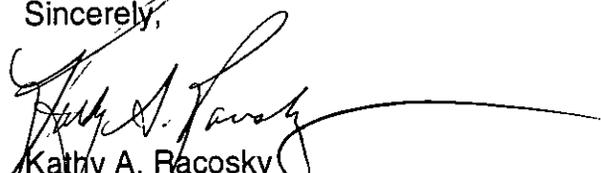
Re: BIOLOX® *delta* Ceramic Head (K082991)

Dear Ms. Shepherd:

Enclosed, please find Aesculap's response to your list of questions/concerns sent to me via email on November 5, 2008.

If you have any questions or require additional data, do not hesitate to contact me directly via phone at (800) 258-1946, ext. 5291 or via e-mail.

Sincerely,


Kathy A. Racosky
Regulatory Affairs Specialist

FDA CDRH DMC

NOV 10 2008

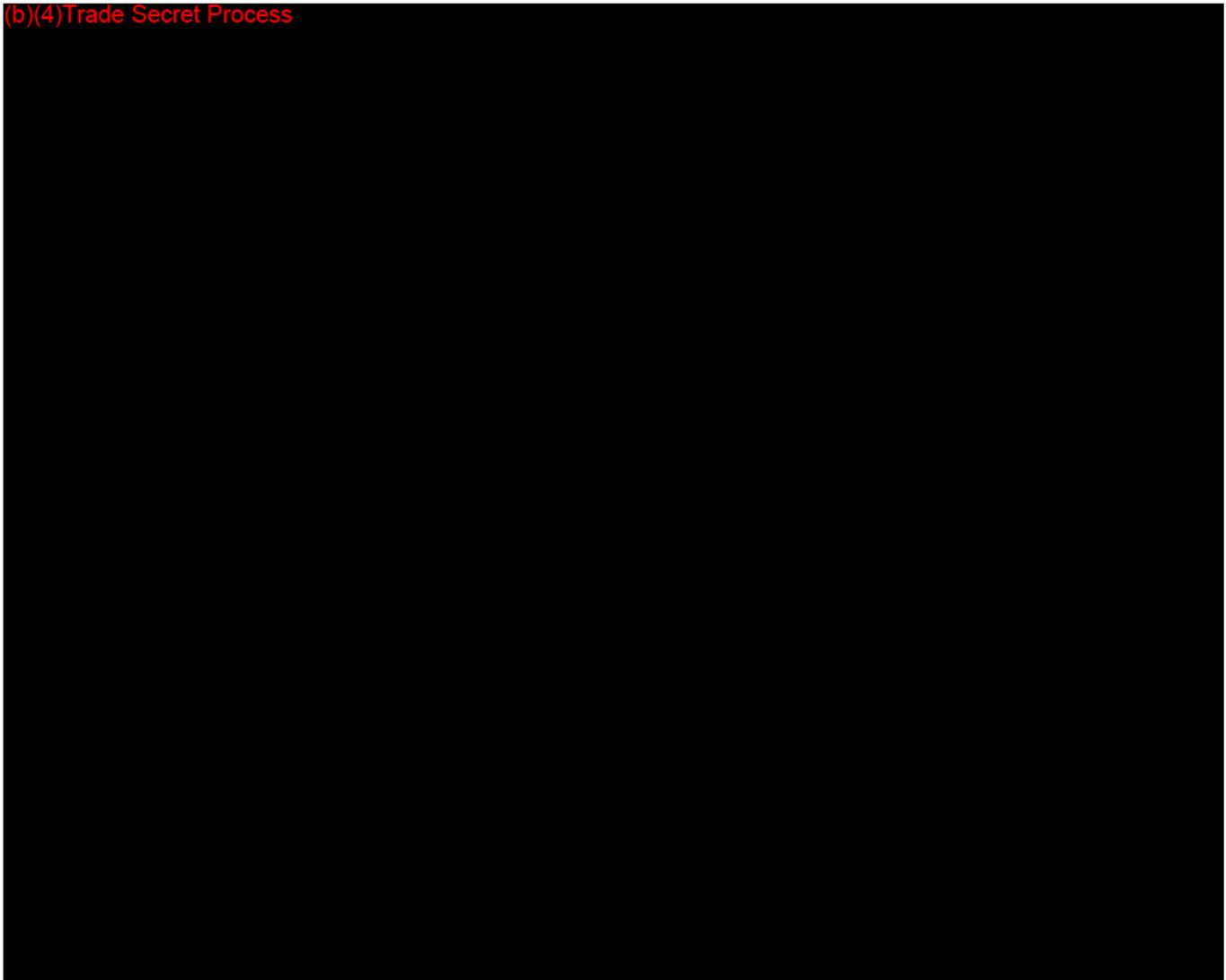
Received

Enclosure

~~EST~~
K51

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, therefore your submission is being placed on Telephone Hold. To complete the review of your submission, we require the following information:

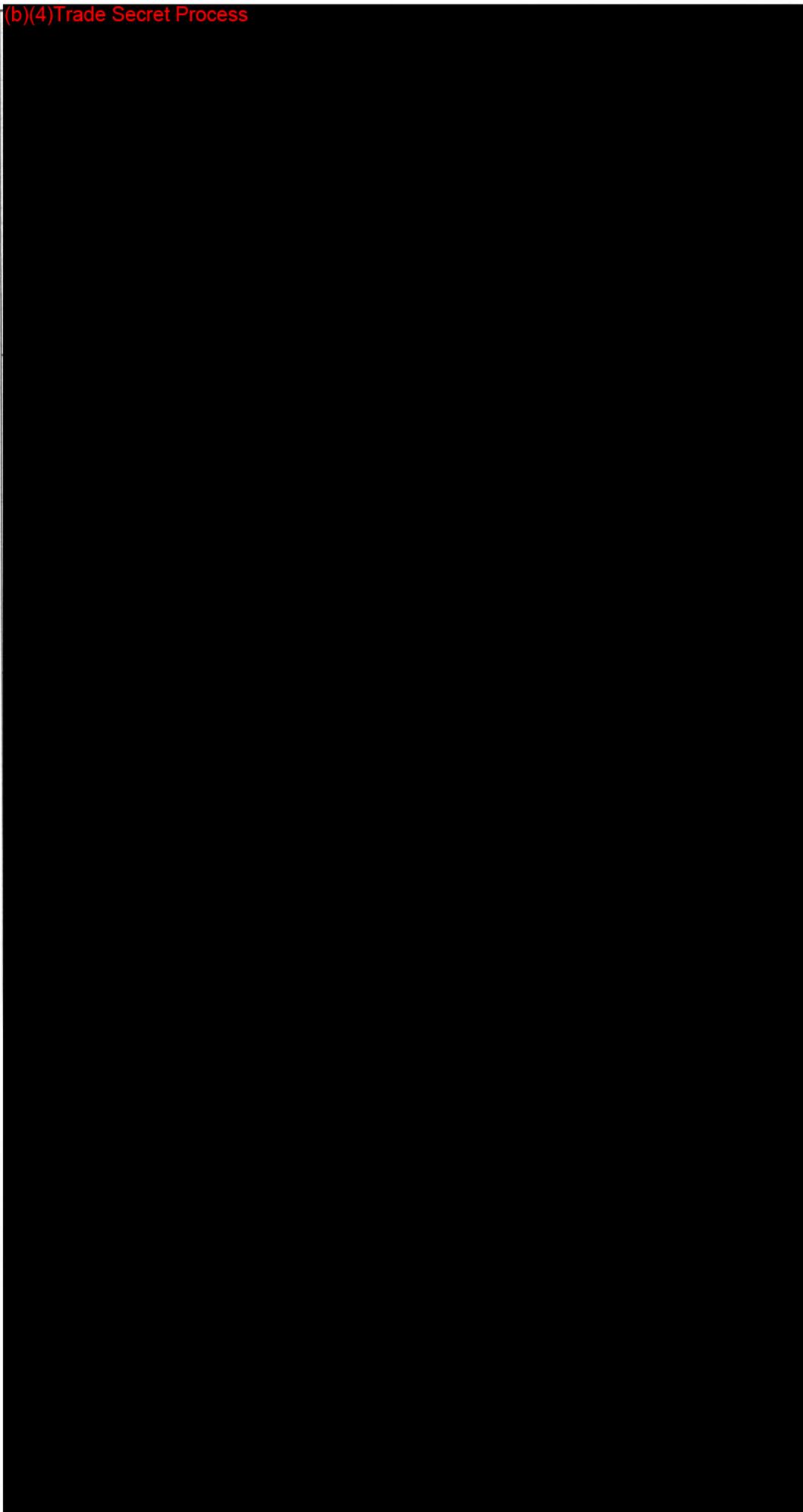
(b)(4)Trade Secret Process



APPENDIX A

Design Control Activities Summary Ceramic Heads

(b)(4)Trade Secret Process



APPENDIX B

Table 1 Tests for Biological Evaluation of Materials (acc. to ISO 10993-1) and testing results of Biolo^xforte (Alumina) and Biolo^xdelta (AMC)

Biological Effect	Biolo ^x forte	Biolo ^x delta
Cytotoxicity	+	+
Sensitisation	+	+
Genotoxicity	+	+
Implantation	+	+
Chronic Toxicity	+	+
Carcinogenicity	+	+

AMC eluate served as a base for an assessment on the following biological effects: sensitisation, genotoxicity and carcinogenicity, irritation of tissue in direct contact, systemic and subchronical toxicity. No release of trace ingredients in toxicologically relevant concentrations could be found.

With the success of these tests, an series of implantation trails in rats and rabbits have been performed. The subcutaneous, intra-muscular

and intra-osseous implantation of AMC particles produced only a slight local irritant effect in the implantation sites after implantation periods of 4 weeks and 6 months.

On the basis of these results, it can be concluded that the abraded material is tolerated after long-lasting contact with tissues [5]. So far, no implantation tests have been done on human patients.

Mechanical Characterisation

AMC is an Alumina matrix material, tailored to high performance in the orthopaedics domain. To start the mechanical qualification program a series of tests have been performed according to an international standards. These showed the results depicted in Table 2, below.

Some values are specific data used by ceramists to characterise ceramic materials, and can be translated into more commonly used terms, like

Table 2 Average values of Biolo^xdelta and other bioceramics

Material Properties	Units & Standards	Biolo ^x forte (Alumina)	Biolo ^x zirconia (Y-TZP)	ZTA ceramic material [3]	Biolo ^x delta (AMC)
Density	g/cm ³ DIN EN 623-3	3980	6040	5020	4365
Colour	-	ivory	off white	off white	mauve
Young's Modulus	GPa DIN EN 843-2	380	210	285	350
Poisson's Ratio	- DIN EN 843-2	0.23	0.3	0.25	0.22
Flexural Strength	MPa DIN EN 843-1	580	1050	912	1150
Weibull's Modulus	- DIN V ENV 843-5	5	10	7	13
Compressive Strength	MPa ASTM C695	5000	2200	-	4700
Fracture Toughness	MPam ^{1/2} (notched beam)	4.3	10.5	6.9	8.5
Hardness	HV0,5 DIN V ENV 843-4	2300HV0,5	1250HV0,5	1500HV1	1975HV1
Thermal Stress Factor	K (calculated value)	203	304	-	317
Water Absorption	% ASTM C373	0	0	-	0
Wetting Angle	° -	water: 45 Ringer's: 5	Ringer's: 10	-	Ringer's: 2.5

