

K110542

APR - 1 2011

## 2. 510(k) SUMMARY

**Sponsor Name:** Consensus Orthopedics, Inc.  
1115 Windfield Way, Suite 100  
El Dorado Hills, CA 95762

**510(k) Contact:** Matthew M. Hull, RAC  
Phone: (916) 355-7156/ Fax: (916) 355-7190  
mhull@consensusortho.com

**Date Prepared:** 24 February, 2011

**Trade Name:** Consensus<sup>®</sup> Hip System, Unisyn Hip System, TaperSet<sup>™</sup> Hip System

**Common Name:** Porous-coated hip prostheses for uncemented use  
Non-porous coated hip prostheses for uncemented or cemented use

**Classification Name:** Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis is a Class II device per 21 CFR 888.3358 (Product Code LPH).  
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis is a Class II device per 21 CFR 888.3353 (Product Code LZ0).

### Device Description:

The Consensus hip systems are semi-constrained, hip prosthesis designed for either primary or revision hip surgery. They include the Consensus<sup>®</sup> Hip System (CHS), the Unisyn<sup>™</sup> Hip System, and the TaperSet<sup>™</sup> Hip System (THS). All three hip systems utilize the exact same 12/14 Morse taper trunnion. These hip stems are compatible with previously cleared CoCr heads, zirconia heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups.

### Indications for Use:

The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.

The indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.

K110542

- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

**Substantial Equivalence:**

***Technological Characteristics/Substantial Equivalence:***

The Consensus hip systems are similar to the predicate Aesculap system in basic design and indications. The predicate Aesculap stems and heads were cleared for use with the Consensus CS2 Acetabular Cup System under K081973. Zirconia ceramic femoral heads were previously cleared with CHS, Unisyn, and THS under various 510(k) submissions. The subject BioloX *delta* ceramic femoral heads were cleared for use with the predicate Aesculap hip systems under K082991. Based on the material, characterization data, geometry and mechanical testing, use of the BioloX *delta* femoral head with the Consensus hip systems is substantially equivalent to legally marketed predicates.

***Legally Marketed Devices to which Substantial Equivalence is claimed:***

- K935193 (U.S. Medical Products) Consensus' Hip System – Porous Coated Titanium Femoral Stem
- K935453 (U.S. Medical Products) CONSENSUS(TM) HIP SYSTEM-HA COATED TITANIUM FEMORAL STEM
- K933499 (U.S. Medical Products) CONSENSUS HIP SYSTEM- NON-POROUS TITANIUM FEMORAL STEM
- K922561 (U.S. Medical Products) CONSENSUS(TM) TOTAL HIP SYSTEM
- K070061 (Hayes Medical, Inc.) Consensus Hip System 36 mm CoCr Femoral Head
- K953792 (U.S. Medical Products) CONSENSUS ZIRCONIA HEAD SIZE -3.5, 0, +5
- K955386 (U.S. Medical Products) CONSENSUS ZIRCONIA FEMORAL HEAD
- K960339 (U.S. Medical Products) CONSENSUS 22MM COCRM0 FEMORAL HEAD
- K960156 (U.S. Medical Products) CONSENSUS 32MM COCRM0 FEMORAL HEAD
- K960151 (U.S. Medical Products) CONSENSUS 26MM COCRM0 FEMORAL HEAD
- K060635 (Hayes Medical, Inc.) Consensus Total Hip System, Acetabular Cup
- K021466 (Hayes Medical, Inc.) CONSENSUS ACETABULAR INSERT, CROSS-LINKED POLYETHYLENE
- K020153 (Hayes Medical, Inc.) CONSENSUS ACETABULAR SHELL, TI COATED
- K953198 (Hayes Medical, Inc.) CORTICELLOUS BONE SCREW
- K100933 (Consensus) Consensus Acetabular insert, CS2 Plus
- K030151 (Hayes Medical, Inc.) CONSENSUS HIP SYSTEM, UNISYN HIP SYSTEM
- K102399 (Consensus) TaperSet Hip System
- K081973 (Aesculap) Consensus Acetabular Cups for use with Aesculap Excia and Metha Hip Systems
- K082991 (Aesculap) BioloX Delta Ceramic Femoral Head

K110542

**Non-Clinical Performance Data:**

- All required testing per "Guidance Document for the Preparation of Premarket Notifications of Ceramic Ball Hip Systems" were performed.
- Component testing of BIOLOX *forte* ball head 28-12/14 L on titanium test tapers per CeramTec AG test procedure VA 02 04 4129, ISO 7206-10.
- Influence of diameter and neck length on burst strength of BIOLOX *forte* and BIOLOX *delta* ball heads with taper type 12/14. Burst test setup as per ISO 7206-10.

**Clinical Performance Data:**

No clinical studies were performed..



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room—WO66-G609  
Silver Spring, MD 20993-0002

Consensus Orthopedics, Inc.  
% Matthew Hull, RAC  
1115 Windfield Way, Suite 100  
El Dorado Hills, California 95762-9623

APR - 1 2011

Re: K110542

Trade/Device Name: Consensus Biolox Delta Ceramic Femoral Heads  
Regulation Number: 21 CFR 888.3358  
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis  
Regulatory Class: Class II  
Product Code: LPH, LZO  
Dated: February 22, 2011  
Received: February 24, 2011

Dear Mr. Hull:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

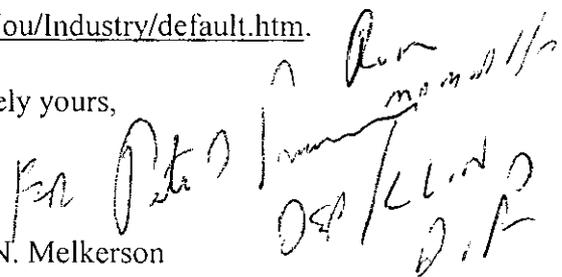
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

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

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K110542

Device Name: BIOLOX<sup>®</sup> delta Ceramic Femoral Heads (w/ Consensus hip systems)

Indications for Use:

The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.

The general indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

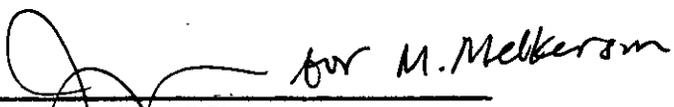
Prescription Use  X   
(21 CFR Part 801 Subpart D)

AND/OR

Over the Counter Use        
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number  K110542



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Consensus Orthopedics, Inc.  
% Matthew Hull, RAC  
1115 Windfield Way, Suite 100  
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APR - 1 2011

Re: K110542  
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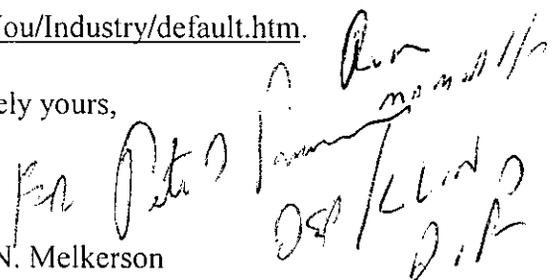
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Sincerely yours,

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

Enclosure

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Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

Prescription Use  X   
(21 CFR Part 801 Subpart D)

AND/OR

Over the Counter Use        
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

 for M. Melkersen

(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K110542



U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Control Center WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

February 25, 2011

CONSENSUS ORTHOPEDICS, INC.  
1115 WINDFIELD WAY, SUITE 100  
EL DORADO HILLS, CALIFORNIA 95762-9623  
ATTN: MATTHEW HULL

510k Number: K110542

Received: 2/24/2011

Product: CONSENSUS BIOLOX DELTA CERAMIC

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) 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/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> 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/AboutFDA/ReportsManualsForms/Forms/default.htm>.

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/AboutFDA/ReportsManualsForms/Forms/default.htm> 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/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. 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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. 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 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

**Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.**

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

K110542

24 February 2011



FDA CDRH DMC

FEB 25 2011

Received

125

Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - W066-G6099200  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: Premarket Traditional 510(k) Notification of intention to market the BioloX<sup>®</sup> delta ceramic femoral heads with Consensus Orthopedics hip systems

Dear Sir/Madam:

Consensus Orthopedics is submitting a Traditional Premarket 510(k) application at least 90 days prior to marketing of their new device: BioloX<sup>®</sup> delta ceramic heads for use with Consensus hip systems.

The Consensus<sup>®</sup> Hip System, the TaperSet<sup>™</sup> Hip System, and the Unisyn<sup>™</sup> Hip System are total hip prostheses designed to replace a single component, or entire system, of a primary or previous revision total hip arthroplasty. The BioloX delta femoral head is designed to be used as a component in a total hip system. The hip systems currently offered by Consensus Orthopedics are cleared for use with CoCr and Zirconia femoral heads.

Design and Use of the BioloX<sup>®</sup> delta ceramic heads for use with Consensus hip systems:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR Subpart C)?		X
Does the device contain components derived from a tissue of 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
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	
Does the device contain a drug?		X

For any questions regarding this submission please contact me at 916-355-7156.

Sincerely,

Matthew M. Hull, RAC  
QS & RA Director

24 February 2011



Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - W066-G6099200  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: Premarket Traditional 510(k) Notification of intention to market the BioloX<sup>®</sup> *delta* ceramic femoral heads with Consensus Orthopedics hip systems

Dear Sir/Madam:

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Is the device implanted?	X	
Does the device contain a drug?		X

For any questions regarding this submission please contact me at 916-355-7156.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Matthew M. Hull', is written over a light blue horizontal line.

Matthew M. Hull, RAC  
QS & RA Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: <b>(b)(4)Trade Secret</b> Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <a href="http://www.fda.gov/oc/mdufma/cover sheet.html">http://www.fda.gov/oc/mdufma/cover sheet.html</a>		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)  CONSENSUS ORTHOPEDICS INC 1115 Windfield Way Suite 100 El Dorado Hills CA 95762 US  1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1680	2. CONTACT NAME Matthew Hull  2.1 E-MAIL ADDRESS mhull@consensusortho.com  2.2 TELEPHONE NUMBER (include Area code) 916-3557156  2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <a href="http://www.fda.gov/oc/mdufma">http://www.fda.gov/oc/mdufma</a> ) Select an application type:		
<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 a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 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 checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number: SBD118017		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see <a href="http://www.fda.gov/cdrh/mdufma">http://www.fda.gov/cdrh/mdufma</a> for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially		
7. 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		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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 the address below.  Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 (Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.)		
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION <b>(b)(4)Trade Secret</b>		

08-Feb-2011

**CDRH PREMARKET REVIEW SUBMISSION COVER SHEET**

Date of Submission 2/24/2011	User Fee Payment ID Number <b>(b)(4)Trade</b> Secret Process	FDA Submission Document Number (if known)
---------------------------------	--------------------------------------------------------------------	-------------------------------------------

**SECTION A TYPE OF SUBMISSION**

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

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

**SECTION B SUBMITTER, APPLICANT OR SPONSOR**

Company / Institution Name Consensus Orthopedics, Inc.		Establishment Registration Number (if known) 2952369	
Division Name (if applicable)		Phone Number (including area code) 916-355-7100	
Street Address 1115 Windfield Way Suite 100		FAX Number (including area code) 916-355-7190	
City El Dorado Hills	State / Province CA	ZIP/Postal Code 95762	Country USA
Contact Name Matthew Hull			
Contact Title Director, QS & RA		Contact E-mail Address mhull@consensusortho.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 Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

**SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE**

<input type="checkbox"/> New Device <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 (specify below)	<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"/> Packaging <input type="checkbox"/> Sterilization <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance Characteristics <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<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

Other Reason (specify):

**SECTION D2 REASON FOR APPLICATION - IDE**

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

Other Reason (specify):

**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
-------------------------------------	-------------------------------------------------------------	-----------------------------------------------

Other Reason (specify):

Addition of another ceramic material formulation (Biolox delta) for the femoral heads in various Consensus hip systems.

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

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

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

	510(k) Number		Trade or Proprietary or Model Name		Manufacturer
1	K953792	1	Consensus Zirconia Head	1	Consensus Orthopedics, Inc.
2	K030151	2	Consensus Hip System, Unisyn Hip System	2	Consensus Orthopedics, Inc.
3	K082991	3	Aesculap BIOLOX delta Ceramic Femoral Head	3	Aesculap Implant Systems
4	K081973	4	Aesculap Excia and Metha Hip Systems w/ Consensus Acetabular Cup	4	Aesculap Implant Systems/ Consensus Orthopedics
5		5		5	
6		6		6	

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

Common or usual name or classification name  
Ceramic femoral head for hip system

	Trade or Proprietary or Model Name for This Device		Model Number
1	Consensus Biolox delta ceramic femoral head	1	see attached list of catalog numbers
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission  
 Laboratory Testing       Animal Trials       Human Trials

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

Product Code LPH	C.F.R. Section (if applicable) 888.3358	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopedic		

Indications (from labeling)  
  
 The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.  
 Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

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

FDA Document Number (if known)

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

<input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number 2952369	<input checked="" type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name Consensus Orthopedics, Inc.		Establishment Registration Number 2952369		
Division Name (if applicable)		Phone Number (including area code) 916-355-7156		
Street Address 1115 Windfield Way, Suite 100		FAX Number (including area code) 916-355-7190		
City El Dorado Hills		State / Province CA	ZIP Code 95762-9623	Country USA
Contact Name Matthew Hull		Contact Title Director, QS & RA		Contact E-mail Address mhull@consensusortho.com

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

<input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete		Facility Establishment Identifier (FEI) Number	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Sterilizer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number		
Division Name (if applicable)		Phone Number (including area code)		
Street Address		FAX Number (including area code)		
City		State / Province	ZIP Code	Country
Contact Name		Contact Title		Contact E-mail Address

**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	see attached list of standards		see attached list of standards		
2					
3					
4					
5					
6					
7					

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

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

Department of Health and Human Services  
 Food and Drug Administration  
 Office of the Chief Information Officer (HFA-710)  
 5600 Fishers Lane  
 Rockville, Maryland 20857

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

**Consensus Orthopedics, Inc.**  
**BILOX<sup>®</sup> delta Ceramic Femoral Heads**  
**510(k) Submission**

**SUMMARY TABLE OF STANDARDS**

Standard Title and Organization	FDA Recognition Number	Extent of Compliance		Standard has acceptance criteria		Deviations	Sections not applicable	Certification Body or third party Laboratory
		Full	Part	Yes	No			
ISO 6474	8-194		X	X		None	3.3 Chemical composition of BILOX <sup>®</sup> delta is different than laid out in the standard	(b)(4)Trade Secret Process
ISO 14971:2007	5-40	X			X	None		
ISO 14630:2008	11-208	X		X		None	9.3.1 products supplied non-sterile	
ISO 21534:2007	None	X		X		None		
ISO 21535:2007	None	X		X		None		
ISO 7206-1:2008(E)	None	X			X	None		
ISO 10993-1:2009	None	X			X	None	Note 1- Section 6.2	
ISO 10993-7:2008	14-279	X		X		None		
ISO 11135-1:2007	14-228	X		X		None		
ISO 11737-1:2006	14-227	X		X	X	None		
ISO 11737-2:1998 (withdrawn)	14-54	X		X		None		
ISO 11737-2:2009	None	X		X		None		
ISO 11607-1:2006	14-193	X		X		None		
ISO 7206-10	None	X		X		None		

Note 1: ISO 10993-1 - Section 6.2. Testing was not performed because the materials used have a demonstrated successful history of use as an implant material in orthopedic applications in alignment with Section 6.1.

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

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 10993-7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals - 2008

**Please answer the following questions**

Yes    No

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

FDA Recognition number <sup>3</sup> ..... # 14-279

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 10993-7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
all	various	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED ♦

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Center for Devices and Radiological Health  
1350 Piccard Drive  
Rockville, MD 20850

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

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

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

TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11135-1 Sterilization of health care products-Ethylene Oxide-Part 1:Requirements for development...medical devices - 2007

*Please answer the following questions*

Yes    No

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

FDA Recognition number <sup>3</sup> ..... # 14-228

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 11135-1 Sterilization of health care products-Ethylene Oxide-Part 1:Requirements for development...medical devices - 2007

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER all sections	SECTION TITLE various	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
--------------------------------	--------------------------	------------------------------------------------------------------------------------------------------------------

TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	-------------------------------------------------------------------------------------------------------

TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

† Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

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

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing - 2009

*Please answer the following questions* Yes    No

Is this standard recognized by FDA<sup>2</sup>? .....  Yes     No

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

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

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

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes     No

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

Does this standard include more than one option or selection of tests? .....  Yes     No  
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? .....  Yes     No  
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)<sup>5</sup>? .....  Yes     No

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....  Yes     No  
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes     No  
If yes, report these exclusions in the summary report table.

Is there an FDA guidance<sup>6</sup> that is associated with this standard? .....  Yes     No  
If yes, was the guidance document followed in preparation of this 510(k)? .....  Yes     No

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

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

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

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing - 2009

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
all	various	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2 - all subsections	various	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED †

testing not performed

DESCRIPTION

JUSTIFICATION

All materials included in this 510(k) have demonstrated successful history of use as an implant material in orthopedic applications.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE<sup>1</sup>

ISO 7206-10 Implants for surgery - Partial and total hip joint prostheses - Part 10; Determination of resistance to static load... 2003

*Please answer the following questions* Yes    No

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

FDA Recognition number<sup>3</sup> ..... # None

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

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

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

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

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

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

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

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

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

Title of guidance: Guidance document for the preparation of premarket notifications for ceramic ball hip systems Jan 10, '95

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 7206-10 Implants for surgery - Partial and total hip joint prostheses - Part 10: Determination of resistance to static load... 2003

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
all	various	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 7206-1- implants for surgery - Partial and total hip joint prostheses -Part 1- Classification & designation of dimensions-2008E

**Please answer the following questions**

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

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

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

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

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes     No

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

Does this standard include more than one option or selection of tests? .....  Yes     No  
If yes, report options selected in the summary report table.

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SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 7206-1 implants for surgery - Partial and total hip joint prostheses - Part 1 - Classification & designation of dimensions-2008E

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER All	SECTION TITLE various	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 6474-1 Implants for surgery - Ceramic materials - Part 1: Ceramic materials based on high purity alumina 2010

*Please answer the following questions*

Yes    No

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

FDA Recognition number <sup>3</sup> ..... # 8-194

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

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

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

Title of guidance: Guidance document for the preparation of premarket notifications for ceramic ball hip systems Jan 10, '95

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 6474-1 Implants for surgery - Ceramic materials - Part 1: Ceramic materials based on high purity alumina 2010

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3.3	Material Properties	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*  
Adaption

DESCRIPTION  
Table 1 in section 3.3 indicates the chemical composition of alumina based ceramics. BioloX delta does not conform to this.

JUSTIFICATION  
BioloX delta is based on alumina with a different chemical composition and meets or exceeds the performance criteris of ISO 6474.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 21535 Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement impl- 2007

*Please answer the following questions*

Yes    No

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

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 21535 Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement impl- 2007

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER all sections	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 21534 Non-active surgical implants - Joint replacement implants - Particular requirements - 2007

**Please answer the following questions**

Yes    No

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 21534 Non-active surgical implants - Joint replacement implants - Particular requirements - 2007

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER all sections	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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DESCRIPTION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 14971 Medical Devices - Application of risk management to medical devices - 2007

**Please answer the following questions**

Yes    No

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

FDA Recognition number <sup>3</sup> ..... # 5-40

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 14971 Medical Devices - Application of risk management to medical devices - 2007

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER all sections	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	-------------------------------------------------------------------------------------------------------

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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Food and Drug Administration  
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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 14630 Non-active surgical implants - General requirements - 2008

**Please answer the following questions**

Yes    No

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

FDA Recognition number <sup>3</sup> ..... # 11-208

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

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

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

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

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

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

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

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 14630 Non-active surgical implants - General requirements - 2008

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER all except as noted	SECTION TITLE	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 9.3.1	SECTION TITLE Products shipped nonsterile	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

no non-sterile implants

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11737-2 Sterilization of medical devices-Microbiological methods-Part 2: Test of sterility performed in the... - 2009

*Please answer the following questions*

Yes    No

Is this standard recognized by FDA <sup>2</sup>? .....  Yes     No

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

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? .....  Yes     No

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

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? .....  Yes     No

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

Does this standard include more than one option or selection of tests? .....  Yes     No  
If yes, report options selected in the summary report table.

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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) <sup>5</sup>? .....  Yes     No

Were deviations or adaptations made beyond what is specified in the FDA SIS? .....  Yes     No  
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? .....  Yes     No  
If yes, report these exclusions in the summary report table.

Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....  Yes     No  
If yes, was the guidance document followed in preparation of this 510(k)? .....  Yes     No

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11737-2 Sterilization of medical devices-Microbiological methods-Part 2: Test of sterility performed in the... - 2009

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
all	various	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11737-2 Sterilization of medical devices-Microbiological methods-Part 2: Test of sterility performed in the... - 1998

*Please answer the following questions*

Yes    No

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

FDA Recognition number <sup>3</sup> ..... # 14-54

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

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

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

Does this standard include acceptance criteria? .....       
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Were deviations or adaptations made beyond what is specified in the FDA SIS? .....       
If yes, report these deviations or adaptations in the summary report table.

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

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

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

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE  
ISO 11737-2 Sterilization of medical devices-Microbiological methods-Part 2: Test of sterility performed in the... - 1998

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER all	SECTION TITLE various	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED †

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11607-1 Packaging for terminally sterilized medical devices-Part 1: Requirements for materials...packaging systems 2006

*Please answer the following questions*

Yes    No

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

FDA Recognition number <sup>3</sup> ..... # 14-193

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

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

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

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

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Were there any exclusions from the standard? .....       
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Is there an FDA guidance <sup>6</sup> that is associated with this standard? .....       
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Title of guidance: \_\_\_\_\_

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**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 11607-1 Packaging for terminally sterilized medical devices-Part 1: Requirements for materials...packaging systems 2006

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER all sections	SECTION TITLE various	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	-------------------------------------------------------------------------------------------------------

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

Traditional       Special       Abbreviated

STANDARD TITLE <sup>1</sup>

ISO 11737-1 Sterilization of medical devices-Microbiological methods-Part 1: Determination of a population of...-2006

**Please answer the following questions**

Yes    No

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

FDA Recognition number <sup>3</sup> ..... # 14-227

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

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

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

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

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

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

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

**EXTENT OF STANDARD CONFORMANCE  
SUMMARY REPORT TABLE**

STANDARD TITLE

ISO 11737-1 Sterilization of medical devices-Microbiological methods-Part 1: Determination of a population of...-2006

**CONFORMANCE WITH STANDARD SECTIONS\***

SECTION NUMBER all	SECTION TITLE various	CONFORMANCE? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
-----------------------	--------------------------	------------------------------------------------------------------------------------------------------------------

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
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TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
----------------	---------------	-------------------------------------------------------------------------------------------------------

TYPE OF DEVIATION OR OPTION SELECTED \*

DESCRIPTION

JUSTIFICATION

\* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

**Paperwork Reduction Act Statement**

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and 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:

Center for Devices and Radiological Health  
1350 Piccard Drive  
Rockville, MD 20850

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

24 February 2011



Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center - W066-G6099200  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

Re: Premarket Traditional 510(k) Notification of intention to market the BioloX<sup>®</sup> *delta* ceramic femoral heads with Consensus Orthopedics hip systems

Dear Sir/Madam:

Consensus Orthopedics is submitting a Traditional Premarket 510(k) application at least 90 days prior to marketing of their new device: BioloX<sup>®</sup> *delta* ceramic heads for use with Consensus hip systems.

The Consensus<sup>®</sup> Hip System, the TaperSet<sup>™</sup> Hip System, and the Unisyn<sup>™</sup> Hip System are total hip prostheses designed to replace a single component, or entire system, of a primary or previous revision total hip arthroplasty. The BioloX *delta* femoral head is designed to be used as a component in a total hip system. The hip systems currently offered by Consensus Orthopedics are cleared for use with CoCr and Zirconia femoral heads.

Design and Use of the BioloX<sup>®</sup> *delta* ceramic heads for use with Consensus hip systems:

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR Subpart C)?		X
Does the device contain components derived from a tissue of 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
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	
Does the device contain a drug?		X

For any questions regarding this submission please contact me at 916-355-7156.

Sincerely,

A handwritten signature in black ink, appearing to read "Matthew M. Hull".

Matthew M. Hull, RAC  
QS & RA Director

## TABLE OF CONTENTS

1. INDICATIONS FOR USE STATEMENT.....	1
2. 510(k) SUMMARY .....	2
3. TRUTHFUL AND ACCURATE STATEMENT.....	5
4. EXECUTIVE SUMMARY .....	6
5. DEVICE DESCRIPTION.....	9
6. SUBSTANTIAL EQUIVALENCE DISCUSSION .....	11
7. PROPOSED LABELING .....	13
8. STERILIZATION AND SHELF LIFE .....	14
9. BIOCOMPATIBILITY.....	14
10. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY .....	14
11. PERFORMANCE TESTING .....	15
12. ATTACHMENTS.....	17
Attachment I – Engineering Drawings .....	18
Attachment II – Product Catalog Numbers.....	24
Attachment III – Product Specific Standards.....	20
Attachment IV – Predicate Device Information and Labeling .....	27
Attachment V – Package Labeling .....	67
Attachment VI – Packaging & Sterilization .....	90
Attachment VII – Instructions for Use (IFU), Surgical Technique, and Brochure.....	109
Attachment VIII – Master File Reference Letter and Material Info .....	128
Attachment IX – Mechanical Test Reports.....	151

# 1. INDICATIONS FOR USE STATEMENT

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

**Device Name:** BIOLOX<sup>®</sup> *delta* Ceramic Femoral Heads (w/ Consensus hip systems)

**Indications for Use:**

The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.

The general indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

Prescription Use   X    
(21 CFR Part 801 Subpart D)

AND/OR

Over the Counter Use       
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

## 2. 510(k) SUMMARY

**Sponsor Name:** Consensus Orthopedics, Inc.  
1115 Windfield Way, Suite 100  
El Dorado Hills, CA 95762

**510(k) Contact:** Matthew M. Hull, RAC  
Phone: (916) 355-7156/ Fax: (916) 355-7190  
mhull@consensusortho.com

**Date Prepared:** 24 February, 2011

**Trade Name:** Consensus<sup>®</sup> Hip System, Unisyn Hip System, TaperSet<sup>™</sup> Hip System

**Common Name:** Porous-coated hip prostheses for uncemented use  
Non-porous coated hip prostheses for uncemented or cemented use

**Classification Name:** Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis is a Class II device per 21 CFR 888.3358 (Product Code LPH).  
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis is a Class II device per 21 CFR 888.3353 (Product Code LZO).

### **Device Description:**

The Consensus hip systems are semi-constrained, hip prosthesis designed for either primary or revision hip surgery. They include the Consensus<sup>®</sup> Hip System (CHS), the Unisyn<sup>™</sup> Hip System, and the TaperSet<sup>™</sup> Hip System (THS). All three hip systems utilize the exact same 12/14 Morse taper trunnion. These hip stems are compatible with previously cleared CoCr heads, zirconia heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups.

### **Indications for Use:**

The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.

The indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.

- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

**Substantial Equivalence:**

***Technological Characteristics/Substantial Equivalence:***

The Consensus hip systems are similar to the predicate Aesculap system in basic design and indications. The predicate Aesculap stems and heads were cleared for use with the Consensus CS2 Acetabular Cup System under K081973. Zirconia ceramic femoral heads were previously cleared with CHS, Unisyn, and THS under various 510(k) submissions. The subject BioloX *delta* ceramic femoral heads were cleared for use with the predicate Aesculap hip systems under K082991. Based on the material, characterization data, geometry and mechanical testing, use of the BioloX *delta* femoral head with the Consensus hip systems is substantially equivalent to legally marketed predicates.

***Legally Marketed Devices to which Substantial Equivalence is claimed:***

K935193 (U.S. Medical Products) Consensus' Hip System – Porous Coated Titanium Femoral Stem  
 K935453 (U.S. Medical Products) CONSENSUS(TM) HIP SYSTEM-HA COATED TITANIUM FEMORAL STEM  
 K933499 (U.S. Medical Products) CONSENSUS HIP SYSTEM- NON-POROUS TITANIUM FEMORAL STEM  
 K922561 (U.S. Medical Products) CONSENSUS(TM) TOTAL HIP SYSTEM  
 K070061 (Hayes Medical, Inc.) Consensus Hip System 36 mm CoCr Femoral Head  
 K953792 (U.S. Medical Products) CONSENSUS ZIRCONIA HEAD SIZE -3.5, 0, +5  
 K955386 (U.S. Medical Products) CONSENSUS ZIRCONIA FEMORAL HEAD  
 K960339 (U.S. Medical Products) CONSENSUS 22MM COCRM0 FEMORAL HEAD  
 K960156 (U.S. Medical Products) CONSENSUS 32MM COCRM0 FEMORAL HEAD  
 K960151 (U.S. Medical Products) CONSENSUS 26MM COCRM0 FEMORAL HEAD  
 K060635 (Hayes Medical, Inc.) Consensus Total Hip System, Acetabular Cup  
 K021466 (Hayes Medical, Inc.) CONSENSUS ACETABULAR INSERT, CROSS-LINKED POLYETHYLENE  
 K020153 (Hayes Medical, Inc.) CONSENSUS ACETABLAR SHELL, TI COATED  
 K953198 (Hayes Medical, Inc.) CORTICELLOUS BONE SCREW  
 K100933 (Consensus) Consensus Acetabular insert, CS2 Plus  
 K030151 (Hayes Medical, Inc.) CONSENSUS HIP SYSTEM, UNISYN HIP SYSTEM  
 K102399 (Consensus) TaperSet Hip System  
 K081973 (Aesculap) Consensus Acetabular Cups for use with Aescualp Excia and Metha Hip Systems  
 K082991 (Aesculap) BioloX Delta Ceramic Femoral Head

**Non-Clinical Performance Data:**

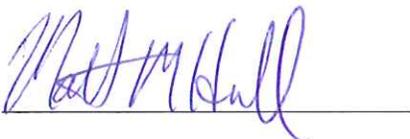
- All required testing per “Guidance Document for the Preparation of Premarket Notifications of Ceramic Ball Hip Systems” were performed.
- Component testing of BIOLOX *forte* ball head 28-12/14 L on titanium test tapers per CeramTec AG test procedure VA 02 04 4129, ISO 7206-10.
- Influence of diameter and neck length on burst strength of BIOLOX *forte* and BIOLOX *delta* ball heads with taper type 12/14. Burst test setup as per ISO 7206-10.

**Clinical Performance Data:**

No clinical studies were performed.

### 3. TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as QS & RA Director at Consensus Orthopedics, Inc. I believe to the best of my knowledge, that all data and information submitted in this 510(k) premarket notification are truthful and accurate and that no material fact has been omitted.



Matthew M. Hull, RAC

24 February 2011

#### 4. EXECUTIVE SUMMARY

##### **Device Description:**

BIOLOX<sup>®</sup> *delta* Ceramic Ball Heads are femoral heads for use with the CONSENSUS<sup>®</sup> HIP SYSTEM, TAPERSET<sup>™</sup> HIP SYSTEM, or the UNISYN<sup>™</sup> HIP SYSTEM from Consensus Orthopedics, Inc. BIOLOX<sup>®</sup> *delta* femoral heads are fabricated from an alumina matrix composite (Al<sub>2</sub>O<sub>3</sub>, ZrO<sub>2</sub>, ISO 6474), are highly polished, and are available in diameters of 28, 32 and 36mm with a range of offsets to accommodate various patient anatomies.

All three hip systems from Consensus Orthopedics utilize Ti-6Al-4V. Additionally, all three hips utilize the exact same 12/14 morse taper trunion design.

##### **Indications for Use:**

The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.

The general indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

##### **Device Comparison:**

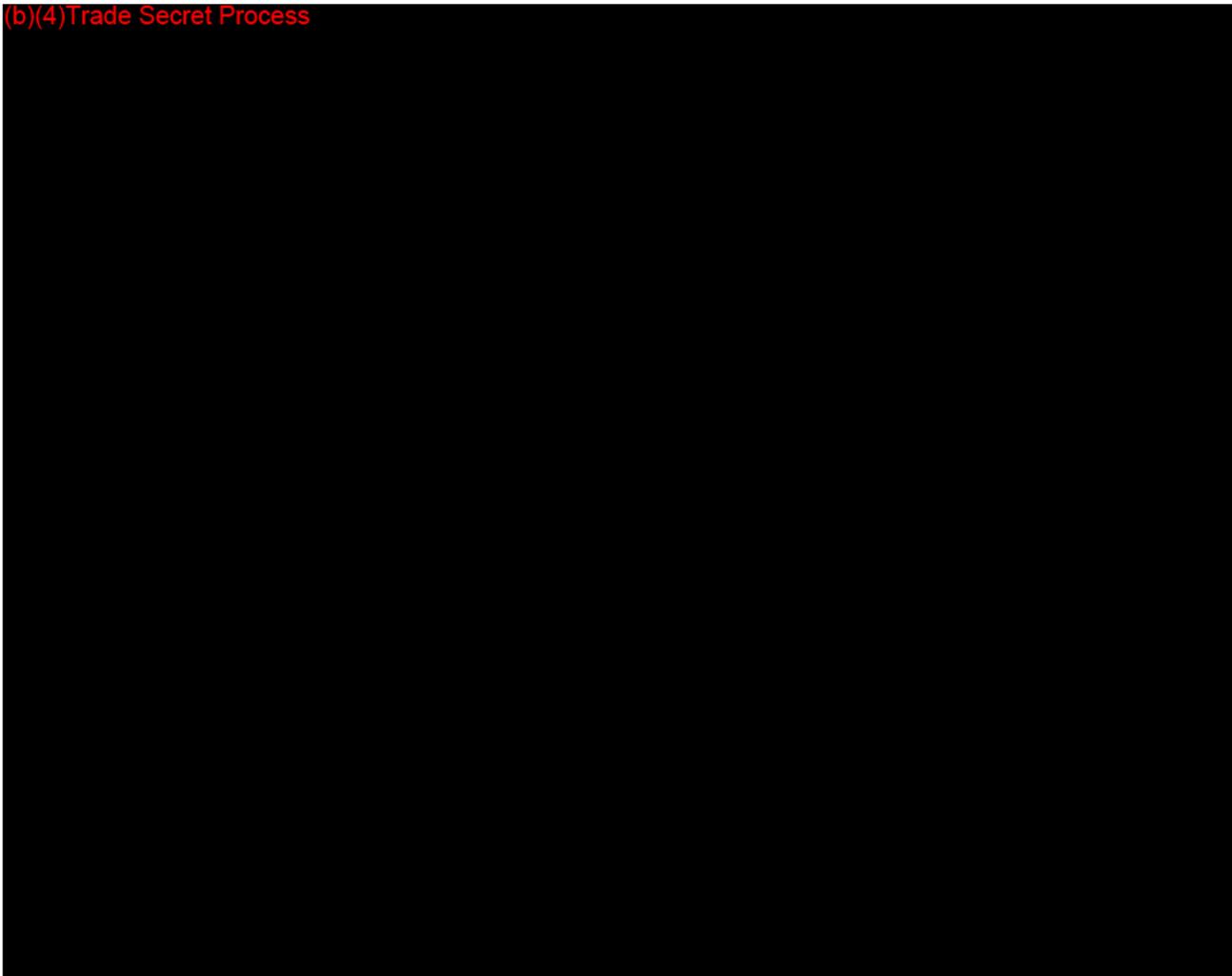
The BIOLOX<sup>®</sup> *delta* ceramic femoral head component is substantially equivalent to the Aesculap BIOLOX<sup>®</sup> *delta* ceramic femoral head regarding their indications for use, technology, and performance (Table 4.1).

**Table 4.1: Device Comparison.**

	<b>Consensus BIOLOX® <i>delta</i> Femoral Head (subject device)</b>	<b>Consensus Zirconia Femoral Head (K953792, K030151)</b>	<b>Aesculap BIOLOX® <i>delta</i> Ceramic Femoral Head (K082991)</b>	<b>Aesculap Excia and Metha Hip Systems w/ Consensus Acetabular Cup (K081973)</b>
<b>Intended Use</b>	Per compatible THA system	Per compatible THA system	Per compatible THA system	Per compatible THA system
<b>Modular Head, primary and revision THA</b>	Yes, cementless	Yes, cementless	Yes, cementless	Yes, cementless
<b>Compatible Components</b>	UniSyn Hip (K003649), Consensus Hip (K935193), TaperSet Hip (K102399), Consensus Acetabular Cup (K020153)	Consensus Hip (K935193), UniSyn Hip (K003649) TaperSet Hip (K102399)	Excia (K042344), Metha (K071916)	Excia (K042344), Metha (K071916), Consensus Acetabular Cup (K020153)
<b>Design</b>				
<b>Taper Design</b>	12/14	12/14	12/14	12/14
<b>Head Diameters</b>	28-36mm	28-36mm*	28-36mm	28-36mm
<b>Head Size &amp; Offsets</b>	28: -3.5, +0, +3.5 32: -4, +0, +4, +7 36: -4, +0, +4, +8	28: -3.5, +0, +5 32: -3.5, +0, +5 36: *(CoCr only)	28: -3.5, +0, +3.5 32: -4, +0, +4, +7 36: -4, +0, +4, +8	N/A
<b>Materials</b>	BIOLOX® <i>delta</i>	Zirconia	BIOLOX® <i>delta</i>	CoCr
<b>Head</b>	72-75% Al <sub>2</sub> O <sub>3</sub> 24-26% ZrO <sub>3</sub>	ISO 13356	72-75% Al <sub>2</sub> O <sub>3</sub> 24-26% ZrO <sub>3</sub>	ASTM F1537
<b>Stem Trunion</b>	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
<b>Packaging and Sterilization</b>				
<b>Packaging</b>	Peelable Tyvek® pouches (1073B Tyvek® Raw/48ga PTE-polyester film coated with low-density polyethylene), double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels.	Peelable Tyvek® pouches (1073B Tyvek® Raw/48ga PTE-polyester film coated with low-density polyethylene), double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels.	N/A	N/A
<b>Sterilization</b>	Ethylene oxide	Ethylene oxide	Ethylene oxide	Ethylene oxide
<b>SAL</b>	10 <sup>-6</sup>	10 <sup>-6</sup>	10 <sup>-6</sup>	10 <sup>-6</sup>

**Performance Testing:**

(b)(4) Trade Secret Process



## 5. DEVICE DESCRIPTION

### General Description:

BIOLOX<sup>®</sup> *delta* Ceramic Ball Heads are femoral heads for use with the CONSENSUS<sup>®</sup> HIP SYSTEM, TAPERSET<sup>™</sup> HIP SYSTEM, or the UNISYN<sup>™</sup> HIP SYSTEM from Consensus Orthopedics, Inc.

### BIOLOX<sup>®</sup> *delta* Femoral Heads

BIOLOX<sup>®</sup> *delta* femoral head components are fabricated from an alumina matrix composite (Al<sub>2</sub>O<sub>3</sub>, ZrO<sub>2</sub>, ISO 6474). All femoral heads are highly polished and available in multiple neck lengths and head diameters including 28, 32 and 36mm.

### Stems

The femoral stem components that are compatible with BIOLOX<sup>®</sup> *delta* femoral head components are manufactured from wrought titanium alloy (Ti6Al4V ELI, ASTM F136) or forged titanium alloy (Ti6Al4V ELI, ASTM F620). Femoral stems are available in a variety of sizes to accommodate variations in patient anatomy.

### Cup

BIOLOX<sup>®</sup> *delta* femoral head components are compatible with the Consensus<sup>®</sup> Acetabular Cup System. The Consensus<sup>®</sup> Acetabular Cup System is composed of an acetabular shell manufactured from wrought titanium alloy (Ti-6Al-4V ELI, ASTM F620 or F136) with a porous coating of commercially pure titanium beads (CP Ti ASTM F67), and an acetabular insert manufactured from either ultra-high molecular weight polyethylene (UHMWPE, ASTM F648) or highly cross linked polyethylene (UHMWPE, ASTM F648), and features a titanium alloy X-ray marker (Ti 6Al-4V ELI, ASTM F136). The Consensus<sup>®</sup> Acetabular Cup System is also cleared for use with previous ceramic and CoCr femoral heads.

**Table 5.1:** BIOLOX<sup>®</sup> *delta* femoral heads patient contacting components included in this 510(k) submission and their respective materials. Each of these components will come in contact with the patient for a protracted period of time and are considered “long-term” implants. The materials of which they are comprised have all been used extensively in predicate devices and are deemed biocompatible.

Component	Material	Material Standard
Femoral Head	BIOLOX <sup>®</sup> <i>delta</i> (Al <sub>2</sub> O <sub>3</sub> , ZrO <sub>2</sub> )	ISO 6474
Stem Components	Wrought Ti-6Al-4V ELI Forged Ti-6Al-4V ELI	ASTM F136 ASTM F620
Acetabular Cup - Insert - Shell - Porous Coating	Wrought Ti-6Al-4V UHMWPE (HC) CP Ti (beads)	ASTM F1472 ASTM F648 ASTM F67

**Table 5.2:** BIOLOX<sup>®</sup> *delta* femoral heads component sizing.

Size [mm]	Offsets [mm]
28	-3.5, 0, +3.5
32	-4.0, 0, +4.0, +7.0
36	-4.0, 0, +4.0, +8.0

**Table 5.3:** The trial heads are the only instruments associated with the addition of the Biolox delta heads, these are considered class I manual surgical instruments as identified below. The materials from which they are manufactured have all been used extensively in similar devices and are safe for patient contact.

Instrument Type	Material	Standard	Product Code
Trial Spacer	Acetal Copolymer; 17-4 SS	ASTM D6778; ASTM A564	HWT

**Drawings**

Refer to Attachment I for drawings and dimensions of the smallest and largest sizes of each BIOLOX<sup>®</sup> *delta* component.

**Catalog Numbers**

Refer to Attachment II for a listing of catalog numbers of all BIOLOX<sup>®</sup> *delta* components.

**Product Specific Standards**

Refer to Attachment III for a list of standards to which Consensus Orthopedics claims compliance (either fully or partially) for this submission. Standards pertain to the general system requirements, materials, biocompatibility, sterility, packaging, labeling, and testing of BIOLOX<sup>®</sup> *delta* femoral heads.

## 6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The Biolox delta ceramic heads for use with the stems (TaperSet, CHS, and UniSyn) and acetabular cup (CS2) manufactured by Consensus Orthopedics, Inc. are substantially equivalent to the Biolox delta heads approved for use with the Excia and Metha stems from Aesculap Implant Systems. Additionally the Excia and Metha hip systems were cleared for use with the Consensus CS2 acetabular cup system. Refer to Attachment IV for predicate device information and labeling.

The same 12/14 femoral stem trunnion is used in all of the Consensus systems and is substantially equivalent to the 12/14 stem used by Aesculap. The following table details the comparison:

	<b>Consensus BIOLOX® <i>delta</i> Femoral Head Head (subject device)</b>	<b>Consensus Zirconia Femoral Head (K953792, K030151)</b>	<b>Aesculap BIOLOX® <i>delta</i> Ceramic Femoral Head (K082991)</b>	<b>Aesculap Excia and Metha Hip Systems w/ Consensus Acetabular Cup (K081973)</b>
<b>Intended Use</b>	Per compatible THA system	Per compatible THA system	Per compatible THA system	Per compatible THA system
Modular Head, primary and revision THA	Yes, cementless	Yes, cementless	Yes, cementless	Yes, cementless
<b>Compatible Components</b>	UniSyn Hip (K003649), Consensus Hip (K935193), TaperSet Hip (K102399), Consensus Acetabular Cup (K020153)	Consensus Hip (K935193), UniSyn Hip (K003649) TaperSet Hip (K102399)	Excia (K042344), Metha (K071916)	Excia (K042344), Metha (K071916), Consensus Acetabular Cup (K020153)
<b>Design</b>				
Taper Design	12/14	12/14	12/14	12/14
Head Diameters	28-36mm	28-36mm*	28-36mm	28-36mm
Head Size & Offsets	28: -3.5, +0, +3.5 32: -4, +0, +4, +7 36: -4, +0, +4, +8	28: -3.5, +0, +5 32: -3.5, +0, +5 36: *(CoCr only)	28: -3.5, +0, +3.5 32: -4, +0, +4, +7 36: -4, +0, +4, +8	N/A
<b>Materials</b>	<b>BIOLOX® <i>delta</i></b>	<b>Zirconia</b>	<b>BIOLOX® <i>delta</i></b>	<b>CoCr</b>
Head	72-75% Al <sub>2</sub> O <sub>3</sub> 24-26% ZrO <sub>3</sub>	ISO 13356	72-75% Al <sub>2</sub> O <sub>3</sub> 24-26% ZrO <sub>3</sub>	ASTM F1537
Stem Trunnion	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V	Ti-6Al-4V
<b>Packaging and Sterilization</b>				
Packaging	Peelable Tyvek® pouches (1073B Tyvek® Raw/48ga PTE-polyester film coated with	Peelable Tyvek® pouches (1073B Tyvek® Raw/48ga PTE-polyester film coated with low-	N/A	N/A

	low-density polyethylene), double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels.	density polyethylene), double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels.		
--	----------------------------------------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------------------	--	--

(b)(4)Trade Secret Process

**Performance Specifications and Testing:**

(b)(4)Trade Secret Process

### ***Conclusions***

Overall, ceramic femoral head components are widely used in total hip arthroplasty and have as good or improved performance when compared with cobalt chrome femoral heads.

### ***Bibliography***

Galvin AL, Jennings LM, Tipper JL, Ingham E, Fisher J. *Wear and creep of highly crosslinked polyethylene against cobalt chrome and ceramic femoral heads*. Proceedings of the Institution of Mechanical Engineers. Part H. Journal of engineering in medicine. 2010 Oct; 224(10):1175-83.

Galvin A, Brockett C, Williams S, Hatto P, Burton A, Isaac G, Stone M, Ingham E, Fisher J. *Comparison of wear of ultra-high molecular weight polyethylene acetabular cups against surface-engineered femoral heads*. Proceedings of the Institution of Mechanical Engineers. Part H. Journal of engineering in medicine. 2008 Oct;222(7):1073-80.

## **7. PROPOSED LABELING**

Proposed labeling including sample package labeling, package drawings, and the Instructions for Use (IFU) are enclosed (Attachments V, VI, and VII). Package labeling is provided for the smallest and largest sizes of each component.

## **8. STERILIZATION AND SHELF LIFE**

No changes have been made to the packaging method, sterilization technique or the shelf life of the BIOLOX<sup>®</sup> *delta* Femoral Head when compared with the Consensus<sup>®</sup> Hip System. All sterilization techniques are designed to achieve 10<sup>-6</sup> SAL.

## **9. BIOCOMPATIBILITY**

The BIOLOX<sup>®</sup> *delta* Femoral Head uses the same materials as the currently marketed Consensus<sup>®</sup> Hip System and the Aesculap BIOLOX<sup>®</sup> *delta* Femoral Head.

## **10. ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY**

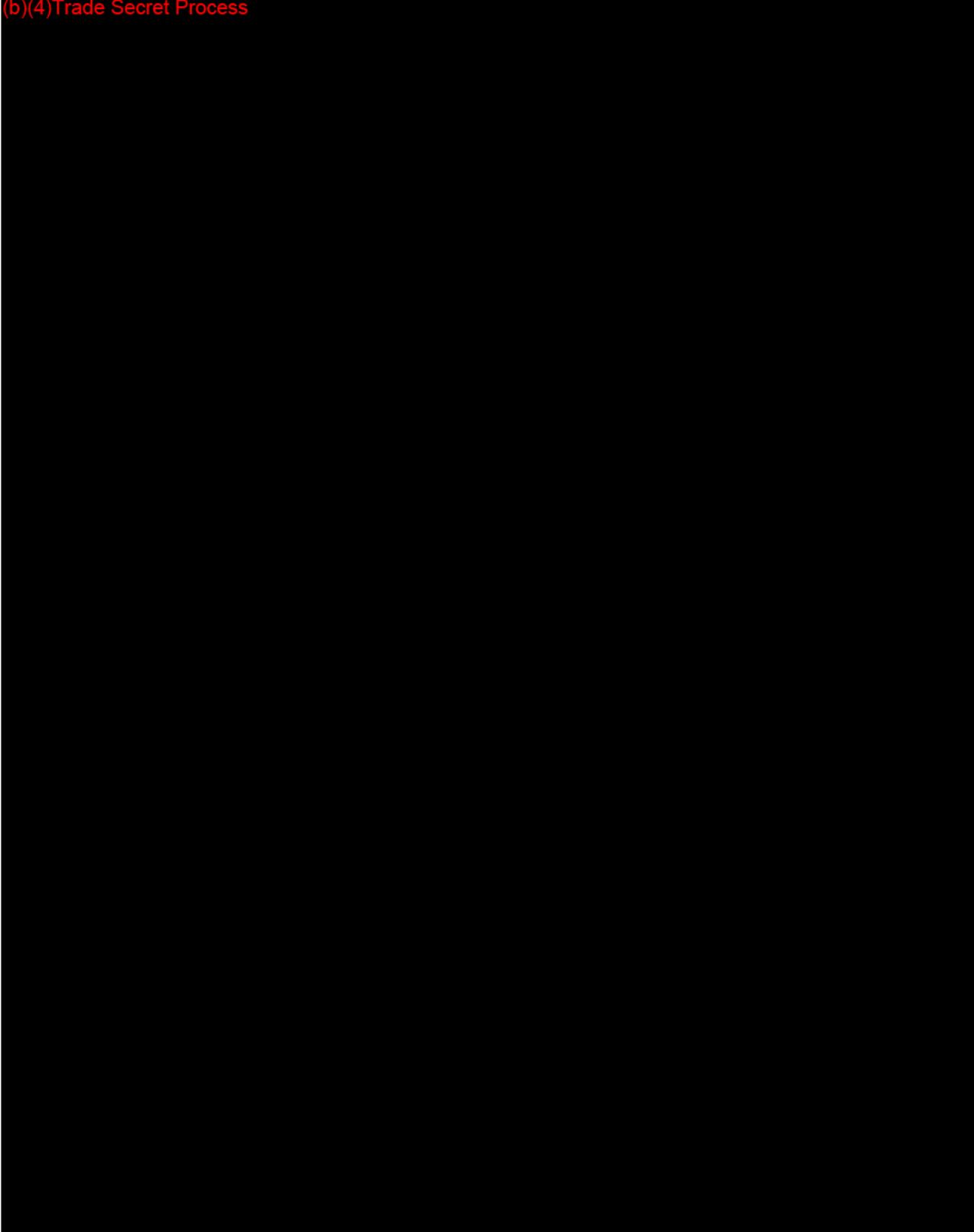
No electronic components are included in the BIOLOX<sup>®</sup> *delta* Femoral Head.

The following precautionary statement will appear in the Instructions for Use document:

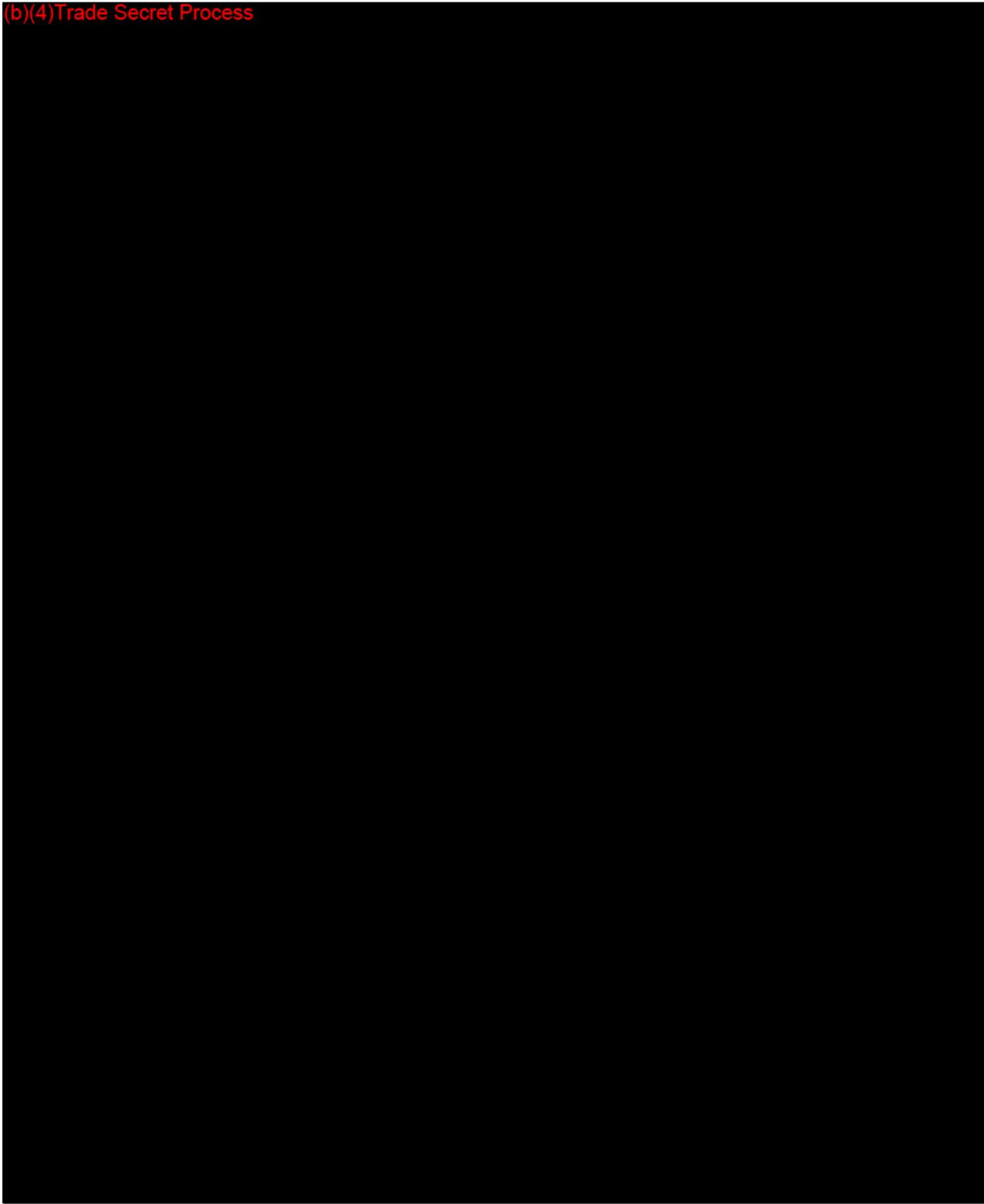
“The CONSENSUS<sup>®</sup> and the TAPERSET<sup>™</sup> hip system is MR Unsafe per ASTM F2503 as it has not been evaluated for safety in the MR environment. Patients should register their implant information with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)), or equivalent organization.”

## 11. PERFORMANCE TESTING

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



## 12. ATTACHMENTS

**Attachment I – Engineering Drawings**











**Attachment II – Product Catalog Numbers**

<b>Catalog Number</b>	<b>Name</b>	<b>Head Size (mm)</b>	<b>Offset (mm)</b>
0005-0-2801	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	28	-3.5
0005-0-2802	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	28	0
0005-0-2803	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	28	+3.5
0005-0-3201	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	32	-4
0005-0-3202	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	32	0
0005-0-3203	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	32	+4
0005-0-3204	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	32	+7
0005-0-3601	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	36	-4
0005-0-3602	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	36	0
0005-0-3603	BIOLOX <sup>®</sup> <i>delta</i> Femoral Head	36	+4
0908-2-3201	Trial, Femoral Head, BioloX Delta	32	-4
0908-2-3203	Trial, Femoral Head, BioloX Delta	32	+4
0908-2-3204	Trial, Femoral Head, BioloX Delta	32	+7
0908-2-3601	Trial, Femoral Head, BioloX Delta	36	-4
0908-2-3603	Trial, Femoral Head, BioloX Delta	36	+4
0908-2-3604	Trial, Femoral Head, BioloX Delta	36	+8

## **Attachment III – Product Specific Standards**

**Consensus Orthopedics, Inc.**  
**BIOLOX<sup>®</sup> delta Ceramic Femoral Heads**  
**510(k) Submission**

**PRODUCT SPECIFIC STANDARDS**

**General System**

- ISO 14971:2007 Medical Devices - Application of risk management to medical devices  
ISO 14630:2008 Non-active surgical implants, General requirements  
ISO 21534:2007 Non-active surgical implants - Joint replacement implants - Particular requirements  
ISO 21535:2007 Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants  
ISO 7206-1:2008(E) Implants for surgery - Partial and total hip joint prostheses - Part 1: Classification and designation of dimensions

**Materials**

***Femoral Head***

- ISO 6474-1:2010 Implants for surgery – Ceramic materials - Part 1: Ceramic materials based on high purity alumina

**Biocompatibility**

- ISO 10993-1:2003&2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and testing  
ISO 10993-7:2008 Biological Evaluation of Medical Devices - Part 7: Ethylene oxide sterilization residuals

**Sterility**

- ISO 11135-1:2007 Medical devices - Validation and routine control of ethylene oxide sterilization  
ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods -- Part 1: Determination of a population of microorganisms on products  
ISO 11737-2:1998&2009 Sterilization of medical devices – Microbiological methods – Part 2: Test of sterility performed in the validation of a sterilization process

**Packaging / Labeling**

- ISO 11607-1:2006 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

**Testing**

***Stem***

- ISO 7206-10:2003 Implants for surgery - Partial and total hip joint prostheses - Part 10: Determination of resistance to static load of modular femoral heads

**Attachment IV – Predicate Device Information and Labeling**

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Device Classification Name	<u>Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</u>
510(K) Number	K953792
Device Name	CONSENSUS ZIRCONIA HEAD SIZE -3.5, 0, +5
Applicant	U.S. MEDICAL PRODUCTS, INC. 12201 Technology Blvd., #100 Austin, TX 78727
Contact	William N Thompson
Regulation Number	<u>888.3353</u>
Classification Product Code	<u>LZO</u>
Date Received	08/14/1995
Decision Date	11/06/1995
Decision	Substantially Equivalent For Some Indications (SN)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Type	Traditional
Reviewed By Third Party	No
Expedited Review	

**ATTACHMENT 8**

**Summary of Safety and Effectiveness  
510(k) SUMMARY**

**US MEDICAL PRODUCTS, INC.  
CONSENSUS® ZIRCONIA FEMORAL HEAD**

---

US Medical Products, Inc.  
12201 Technology Blvd.  
Suite 100  
Austin, Texas 78727

William N. Thompson, Director  
Quality Assurance and Regulatory Affairs  
Voice (512) 257-4835  
Fax (512) 257-8300  
Date of Preparation: 5 August 1995

**Trade Name:** Consensus® Zirconia Femoral Head

**Common Name:** Hip replacement prosthesis, zirconia ceramic femoral head

**Classification Name:** Class II device, under the following classification:

Prosthesis, Hip, Semi-Constrained Metal/Ceramic/Polymer, Cemented or  
Non-Porous Cemented, Un-cemented under classification 21 CFR 888.3350

**Substantial Equivalence:** equivalent zirconia head components are as follows:

Exactech Ziramic™ zirconia femoral head      K914574      SE 01-13-93

**Device Description:** The Consensus® zirconia femoral head is intended for use with the Consensus® Total Hip System as an alternative to the Consensus® CoCrMo alloy femoral head components or the Consensus® BioloX® ceramic femoral head components. It is a single use device. The Consensus® zirconia femoral head is designed for use with the following Consensus® Total Hip System components:

Femoral stem, Nonporous CoCr	K922561	SE 07-21-93
Femoral Stem, HA/Ti	K945354	SE 07-18-94
Femoral Stem, Porous Ti	K935193	SE 08-18-94
Uncemented Acetabular Component	K922561	SE 07-21-93
Cemented Acetabular Component	K922561	SE 07-21-93
Cancellous Bone Screw	K922561	SE 07-21-93
Femoral stem, Nonporous Ti	K933499	SE 05-18-94

The Consensus® zirconia femoral head will be provided sterile and will be available in 28mm diameter, with a 12/14 taper, in three neck lengths. The design is a spherical head on a straight cylindrical neck, which allows for use on the left or right femoral stem and acetabular components. The material will be zirconia ceramic.

**Intended Use:** The CONSENSUS® zirconia femoral head is indicated for use in:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis and avascular necrosis with a non-acute fracture of the femoral neck.
2. Osteoarthrosis involving femoral and acetabular articular surfaces.
3. Avascular osteonecrosis and/or non-union of acute femoral neck fractures.
4. Fracture-dislocation of the hip.
5. Replacement of unsatisfactory cemented or press fit hip components if sufficient bone stock exists.

**Summary of Technological Characteristics:** The Consensus® zirconia femoral head is designed to articulate with the various Consensus® Hip femoral stem components. The Consensus® zirconia femoral head will be provided sterile and will be available in 28mm diameter, with a 12/14 taper, in three neck lengths. The design is a spherical head on a straight cylindrical neck, which allows for use on the left or right femoral stem and acetabular components. The material will be zirconia ceramic.

**Performance Data:** The Consensus® zirconia femoral head device performs with substantial equivalence to predicate devices.

**Clinical Data:** None Required

**Conclusions from Non-clinical and Clinical Data:** The Consensus® zirconia ceramic femoral head is substantially equivalent to predicate devices.

**Other Necessary Information:** None Required



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV - 6 1995

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. William N. Thompson  
Director, Quality Assurance and  
Regulatory Affairs  
U.S. Medical Products, Inc.  
12201 Technology Boulevard, Suite 100  
Austin, Texas 78727

Re: K953792  
Consensus® Zirconia Femoral Head  
Regulatory Class: II  
Product Code: LZ0  
Dated: August 5, 1995  
Received: August 14, 1995

Dear Mr. Thompson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the following limitations:

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



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.

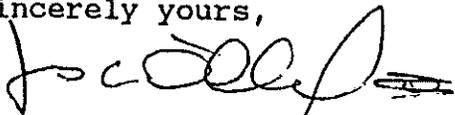
If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through

Page 2 - Mr. William N. Thompson

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

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

  
Fu Kimber C. Richter, M.D.  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

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<b>Device Classification Name</b>	<u>Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented</u>
<b>510(K) Number</b>	K100933
<b>Device Name</b>	CONSENSUS CS2 PLUS ACETABULAR INSERT CONSENSUS ORTHOPEDICS, INC
<b>Applicant</b>	1115 Winfield Way Suite 100 Eldorado Hills, CA 95762 962
<b>Contact</b>	Luke Rose
<b>Regulation Number</b>	<u>888.3358</u>
<b>Classification Product Code</b>	<u>LPH</u>
<b>Subsequent Product Code</b>	<u>LZO</u>
<b>Date Received</b>	04/05/2010
<b>Decision Date</b>	10/06/2010
<b>Decision</b>	Substantially Equivalent (SE)
<b>Classification Advisory Committee</b>	Orthopedic
<b>Review Advisory Committee</b>	Orthopedic
<b>Summary</b>	<u>Summary</u>
<b>Type</b>	Special
<b>Reviewed By Third Party</b>	No
<b>Expedited Review</b>	No

K100933

OCT 6 2010

**9. 510(K) SUMMARY**

**Sponsor Name:** Consensus Orthopedics, Inc.  
1115 Windfield Way, Suite 100  
El Dorado Hills, CA 95762

**510(k) Contact:** Matthew M. Hull, RAC  
Phone: (916) 355-7156  
Fax: (916) 355-7190  
mhull@consensusortho.com

**Date Prepared:** 1 October 2010

**Trade Name:** CS2™ Plus Acetabular Insert

**Common Name:** Cross Linked Polyethylene, Lateralized, Acetabular Insert

**Classification Name:** Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis (21 CFR 888.3358, Product Code LPH)  
  
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21 CFR 888.3353, Product Code LZO)

**Regulatory Class:** Class II

**Device Classification Panel:** Orthopedic Devices

**Predicate Device Identification:**

The intended use, materials, and design features of the subject CS2™ Plus acetabular insert are substantially equivalent to those of predicate devices manufactured by Consensus Orthopedics and competitors (Table 9.1). The safety and effectiveness of the CS2™ Plus insert are adequately supported by the substantial equivalence information and materials data provided within this Special 510(k) submission.

*Table 9.1:* Predicate device summary table.

510(k) Number	Trade Name	510(k) holder	510(k) Clearance Date
K922561	Consensus™ Total Hip System	Consensus Orthopedics, Inc.	07/21/1993
K990135	Trilogy Acetabular System Longevity Crosslinked Polyethylene	Zimmer, Inc.	07/12/1999
K994415	Marathon Cross-linked Polyethylene Acetabular Cup Liners	DePuy Orthopaedics, Inc.	02/03/2000
K001534	Pinnacle Acetabular Cup System	DePuy Orthopaedics, Inc.	06/12/2000

K100933

K010171	Duraloc Acetabular Cup System, 36mm Marathon +4 Polyethylene Liner	DePuy Orthopaedics, Inc.	04/06/2001
K021466	Consensus Acetabular Insert, Cross-Linked Polyethylene (CS2™)	Consensus Orthopedics, Inc.	07/24/2002
K061253	Reflection 3 Acetabular System	Smith & Nephew	05/31/2006
K070061	36mm CoCr Femoral Head and 36mm Acetabular Insert (CS2™)	Consensus Orthopedics, Inc.	01/31/2007

**Indications for use with the CONSENSUS® Hip System or UNISYN™ Hip System:**

- A) Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B) Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C) Proximal femoral fractures.
- D) Avascular necrosis of the femoral head.
- E) Non-union of proximal femoral neck fractures.
- F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities

Acetabular components are indicated for cemented and cementless use.

Consensus femoral stems are indicated for cemented and cementless use.

UniSyn femoral stems are indicated for cementless use only.

HA coated implants are indicated for cementless use only.

**Device Description:**

The Consensus® Hip System (CHS) currently offers a semi-constrained metal-backed acetabular component comprising a porous coated shell manufactured from Titanium alloy (ASTM F620 or F136) (K922561, K020153, K060635) and a mating insert manufactured from ultra-high molecular weight polyethylene (UHMWPE) (K922561) (ASTM F648) or highly crosslinked UHMWPE (ASTM F648) (K021466, K070061). The shell is designed for uncemented press-fit or cemented use to the prepared acetabulum, and is designed to mate with the insert via secure insert/shell locking mechanism. The previously cleared inserts are designed to articulate with the CHS femoral heads.

The CS2™ Plus acetabular insert adds a lateralized configuration to the current line of CHS crosslinked UHMWPE acetabular inserts (i.e. CS2™ inserts) (K021466, K070061). The design intent is to allow the surgeon more intraoperative flexibility to medialize the acetabular cup or lateralize the head center, while maintaining substantial insert wall thickness.

**Comparison of Technological Characteristics:**

The following features are common for the CS2™ Plus insert and the previously cleared CS2™ insert:

K100933

- Manufactured from DePuy Marathon® crosslinked UHMWPE (ASTM F648, (K994415).
- Compatible with previously cleared CHS acetabular shells (K922561, K020153, K060635), CHS femoral stems (K922561, K933499, K935453, K935193), CHS femoral heads (K953792, K960156, K030151, K070061), and UniSyn™ Hip System components (K003649, K062383) of the appropriate size.
- Identical articular surfaces designed to mate with 28mm, 32mm, and 36mm diameter femoral heads.
- 28mm ID inserts accommodate the same number of shell sizes.
- Neutral and hooded configurations.
  - Hooded configurations feature an identical Titanium X-ray marker (ASTM F136).
  - 28mm and 32mm inserts offer neutral or 20° hooded configurations.
- Minimum wall thickness at dome apex greater than 5mm.
- Identical insert/shell locking mechanism.
- Identical minimum intended range of motion.

The following features are unique to the CS2™ Plus insert in comparison to the previously cleared CS2™ insert:

- The CS2™ Plus insert is designed to position the femoral head center 5mm more laterally than that of the CS2™ insert.
- 32mm CS2™ Plus insert will accommodate two additional shell sizes (48 and 50mm OD), which are currently only compatible with 28mm CS2™ inserts.
- 36mm CS2™ Plus insert will accommodate two additional shell sizes (52 and 54mm OD), which are currently only compatible with 28mm and 32mm CS2™ inserts.
- Will not accommodate 22mm heads.
- 36mm CS2™ Plus inserts offer neutral or 10° hooded configurations, whereas the 36mm CS2™ inserts offer neutral, 10°, or 20° hooded configurations.
- The CS2™ Plus insert will have an increased wall thickness at the apex of the dome and beneath the external snap feature due to the 5mm lateral offset.
- When mated with the acetabular shell, the CS2™ Plus insert will extend further outside the shell by 5mm due to the 5mm lateral offset of the head center.

#### Summary of Nonclinical Testing and Evaluation:

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). The risk analysis was performed according to the requirements of ISO 14971:2007 "Medical Devices – Application of risk management to medical devices". Records of the risk analysis process are retained in the design history file.

Based upon the fact that the new CS2 Plus Acetabular Inserts represent a line extension of the current CS2 inserts the following preclinical testing/evaluation was performed:

- 1) Torsion testing of insert/shell locking mechanism (CS2 Plus & CS2)
- 2) Lever out testing (CS2 Plus & CS2)
- 3) Range of motion study (CS2 Plus & CS2)

K100933

- 4) CAD verification study of locking mechanism (CS2 Plus & CS2)
- 5) Push out testing (CS2)

The results of the above testing verify that the new device is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

Consensus Orthopedics, Inc.  
% Mr. Matthew M. Hull, RAC  
Director QS & RA  
1115 Windfield Way Suite 100  
El Dorado Hills, California 95762

991 2010

Re: K100933

Trade/Device Name: CONSENSUS<sup>®</sup> Hip System: CS2<sup>™</sup> Plus Acetabular Insert  
Regulation Number: 21 CFR 888.3358  
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis

Regulatory Class: Class II  
Product Code: LPH, LZO  
Dated: September 10, 2010  
Received: September 15, 2010

Dear Mr. Hull:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical

Page 2 – Mr. Matthew M. Hull, RAC

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.

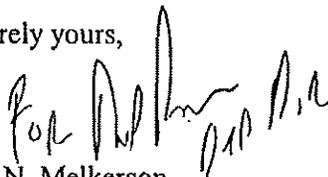
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



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

Enclosure

## Indications for Use

510(k) Number: K100933

Device Name: CONSENSUS® Hip System: CS2™ Plus Acetabular Insert

Indications for use with the CONSENSUS® Hip System or UNISYN™ Hip System

- A) Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B) Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C) Proximal femoral fractures.
- D) Avascular necrosis of the femoral head.
- E) Non-union of proximal femoral neck fractures.
- F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities

Acetabular components are indicated for cemented and cementless use.

Consensus femoral stems are indicated for cemented and cementless use.

UniSyn femoral stems are indicated for cementless use only.

HA coated implants are indicated for cementless use only.

Prescription Use  X   
(21 CFR Part 801 Subpart D)

AND/OR

Over the Counter Use        
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number  K100933

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Device Classification Name	<u>Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented</u>
510(K) Number	K102399
Device Name	CONSENSUS TAPERSET HIP SYSTEM CONSENSUS ORTHOPEDICS, INC
Applicant	1115 Winfield Way Suite 100 El Dorado Hills, CA 95762 962
Contact	Matthew Hull
Regulation Number	<u>888.3358</u>
Classification Product Code	<u>LPH</u>
Subsequent Product Codes	<u>KWL</u> <u>KWY</u> <u>LZO</u>
Date Received	08/24/2010
Decision Date	12/02/2010
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Summary	<u>Summary</u>
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

K102399

## 2. 510(k) SUMMARY

**Sponsor Name:** Consensus Orthopedics, Inc.  
1115 Windfield Way, Suite 100  
El Dorado Hills, CA 95762

**510(k) Contact:** Matthew M. Hull, RAC  
Phone: (916) 355-7156/ Fax: (916) 355-7190  
mhull@consensusortho.com

**Date Prepared:** 29 November, 2010

**Trade Name:** TaperSet™ Hip System

**Common Name:** Porous-coated hip prosthesis for cementless use

**Classification Name:** Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis is a Class II device per 21 CFR 888.3358 (Product Code LPH).

DEC 2 2010

### Device Description:

The TaperSet Hip System (THS) is a monolithic, titanium alloy tapered hip stem design with a proximal, plasma sprayed, porous CPTi coating. The stem has a dual wedge geometry and is available in both standard and 7mm lateral offsets in sizes designated as 7.5mm to 24mm. The stems feature a neck shaft angle of 135° and a 12/14 Morse taper trunnion. The TaperSet Hip System is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System. The stem is compatible with previously cleared CoCr heads, zirconia heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups.

### Indications for Use:

The TaperSet™ Hip System is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System.

The indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The TaperSet™ hip stem is indicated for cementless use.

**Substantial Equivalence:*****Technological Characteristics/Substantial Equivalence:***

The TaperSet Hip System is similar to the predicate systems in basic design and indications. The monolithic stem with porous CPTi coating is considered to have the same type of technological characteristics as the Biomet K043537 stem with differences in the stem geometry and exterior coating. The subject stem is compatible with previously cleared CoCr heads, zirconia heads, unipolar heads, bipolar heads, UHMWPE inserts and acetabular cups. Based on the material, characterization data, geometry and mechanical testing, the TaperSet Hip is substantially equivalent to legally marketed predicates.

***Legally Marketed Devices to which Substantial Equivalence is claimed:***

K043537 (Biomet) Taperloc® 12/14 Taper Femoral components  
 K921301 (Biomet) TAPERLOC FEMORAL STEM AND UNIVERSAL ACETABULAR COM  
 K030151 (Hayes Medical, Inc.) CONSENSUS HIP SYSTEM, UNISYN HIP SYSTEM  
 K935193 (U.S. Medical Products) Consensus<sup>®</sup> Hip System – Porous Coated Titanium Femoral Stem  
 K935453 (U.S. Medical Products) CONSENSUS(TM) HIP SYSTEM-HA COATED TITANIUM FEMORAL STEM  
 K933499 (U.S. Medical Products) CONSENSUS HIP SYSTEM- NON-POROUS TITANIUM FEMORAL STEM  
 K922561 (U.S. Medical Products) CONSENSUS(TM) TOTAL HIP SYSTEM  
 K922560 (U.S. Medical Products) CONSENSUS(TM) BIPOLAR SYSTEM  
 K070061 (Hayes Medical, Inc.) Consensus Hip System 36 mm CoCr Femoral Head  
 K953792 (U.S. Medical Products) CONSENSUS ZIRCONIA HEAD SIZE -3.5, 0, +5  
 K955386 (U.S. Medical Products) CONSENSUS ZIRCONIA FEMORAL HEAD  
 K960339 (U.S. Medical Products) CONSENSUS 22MM COCRMO FEMORAL HEAD  
 K960156 (U.S. Medical Products) CONSENSUS 32MM COCRMO FEMORAL HEAD  
 K960151 (U.S. Medical Products) CONSENSUS 26MM COCRMO FEMORAL HEAD  
 K060635 (Hayes Medical, Inc.) Consensus Total Hip System, Acetabular Cup  
 K030205 (Hayes Medical, Inc.) CONSENSUS UNIPOLAR HEAD, COCR  
 K021466 (Hayes Medical, Inc.) CONSENSUS ACETABULAR INSERT, CROSS-LINKED POLYETHYLENE  
 K020153 (Hayes Medical, Inc.) CONSENSUS ACETABULAR SHELL, TI COATED  
 K953198 (Hayes Medical, Inc.) CORTICELLOUS BONE SCREW  
 K100933 (Consensus) Consensus Acetabular insert, CS2 Plus

**Non-Clinical Performance Data:**

Non-clinical testing and analysis were provided, including bench testing and coating characterization. Bench testing included distal fatigue testing and proximal fatigue testing of the worst case stem consistent with the "Guidance for Industry and FDA Staff Non-clinical Information for Femoral Stem Prostheses." Range of motion analysis was also performed. The CPTi plasma sprayed titanium coating underwent characterization per FDA's "Guidance Document For Testing Orthopedic Implants With Modified Metallic Surfaces Apposing Bone or Bone Cement" and "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements." The CPTi plasma sprayed coating characterization meets the definition of porosity per 21 CFR

888.3358. Modular connection analyses including fretting and corrosion of metallic femoral heads in addition to ceramic head compatibility were also performed.

All of the observed results indicate that the TaperSet Hip System is substantially equivalent to devices currently marketed. Therefore, the device is as safe, as effective, and performs at least as safely and effectively as legally marketed predicates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Consensus Orthopedics, Inc.  
% Matthew M. Hull, RAC  
Director QS & RA  
1115 Windfield Way, Suite 100  
El Dorado Hills, California 95762

DEC 2 2010

Re: K102399

Trade/Device Name: TaperSet™ Hip System  
Regulation Number: 21 CFR 888.3358  
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated  
uncemented prosthesis  
Regulatory Class: Class II  
Product Code: LPH, LZO, KWL, KWY  
Dated: November 10, 2010  
Received: November 10, 2010

Dear Mr. Hull:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

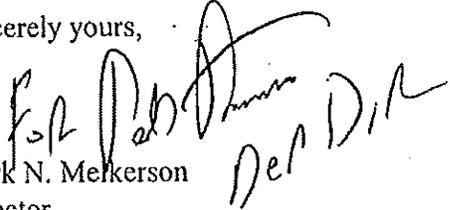
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

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

Enclosure

**I. INDICATIONS FOR USE STATEMENT**

510(k) Number: K102399

Device Name: TaperSet™ Hip System

**Indications for Use:**

The TaperSet™ Hip System is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System.

The indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities

The TaperSet™ hip stem is indicated for cementless use.

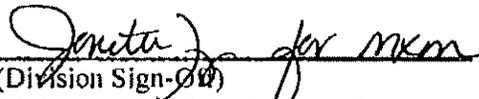
Prescription Use  X   
(21 CFR Part 801 Subpart D)

AND/OR

Over the Counter Use        
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number  K102399

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Device Classification Name	<a href="#">Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</a>
510(K) Number	K030151
Device Name	CONSENSUS HIP SYSTEM, UNISYN HIP SYSTEM
Applicant	HAYES MEDICAL, INC. 1115 Windfield Way, Suite 100 El Dorado Hills, CA 95762 962
Contact	William J Griffin
Regulation Number	<a href="#">888.3353</a>
Classification Product Code	<a href="#">LZO</a>
Date Received	01/15/2003
Decision Date	04/10/2003
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Statement	<a href="#">Statement</a>
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 10 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. William J. Griffin  
QS & RA Manager  
Hayes Medical, Inc.  
1115 Windfield Way, Suite 100  
El Dorado Hills, CA 95762

Re: K030151  
Trade/Device Name: 32 mm Zirconia Ceramic Femoral Head for Consensus®  
or UniSyn® System  
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: January 8, 2003  
Received: January 15, 2003

Dear Mr. Griffin:

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

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

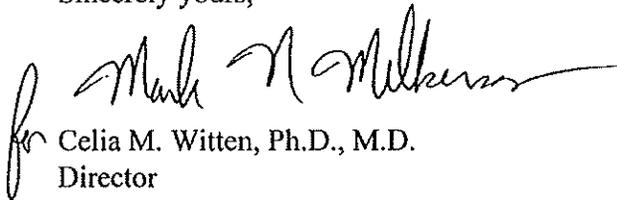
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 2 - Mr. William J. Griffin

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 (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a long horizontal flourish extending to the right.

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

Director

Division of General, Restorative and  
Neurological Devices

Office of Device Evaluation

Center for Devices and  
Radiological Health

Enclosure

K030151

### Section 8 Statement of Indications for Use

The 32 mm ceramic femoral head is design for use with the *Consensus*<sup>®</sup> or *UniSyn*<sup>®</sup> Hip Systems, and is not intended for substitution with components of other systems. The indications for use are:

*With Consensus*<sup>®</sup> System:

1. Primary intervention of rheumatoid arthritis, osteoarthritis, post traumatic arthritis or degenerative arthritis, and avascular necrosis with a non-acute fracture of the femoral neck.
2. Osteoarthrosis involving femoral and acetabular articular surfaces.
3. Avascular osteonecrosis and/or non-union of acute femoral neck fractures.
4. Fracture or dislocation of the hip.
5. Replacement of unsatisfactory cemented or press fit hip components if sufficient bone stock exists.

*With UniSyn*<sup>®</sup> System:

1. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
2. Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.
3. Proximal femoral fractures.
4. Avascular necrosis of the femoral head.
5. Non-union of proximal femoral neck fractures.
6. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.
7. Indications for the use of the UniSyn Hip System must be carefully considered with respect to the patient's entire evaluation and alternative procedures. Patient selection is dependent on age, general health, available bone stock and quality, and any prior surgery or anticipated future surgery. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Total joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding activity and joint loading are assured. This includes all patients who may or may not have multiple joint involvement, for whom restoration of joint mobility leads to an expectation of greater mobility and an improvement in the quality of life.



(Division Signature)  
Division of General, Regenerative  
and Neurological Devices

510(k) Number K030151

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Device Classification Name	<a href="#">Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</a>
510(K) Number	K082991
Device Name	BIOLOX DELTA CERAMIC FEMORAL HEAD
Applicant	AESCULAP IMPLANT SYSTEMS, INC. 3773 Corporate Pwky. Center Valley, PA 18034
Contact	Kathy A Racosky
Regulation Number	<a href="#">888.3353</a>
Classification Product Code	<a href="#">LZO</a>
Subsequent Product Codes	<a href="#">KWY</a> <a href="#">LWJ</a> <a href="#">MEH</a>
Date Received	10/07/2008
Decision Date	11/20/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Summary	<a href="#">Summary</a>
Type	Special
Reviewed By Third Party	No
Expedited Review	No

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](mailto: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  $\mu$ -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.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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<sup>®</sup> 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, MEII, 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.

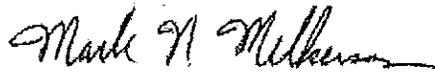
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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

Page 1 of 1

**A. INDICATIONS FOR USE STATEMENT**510(k) Number: K082991 (pg 11)

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

**Indications for Use:**

The Excla 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 Excla 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  $\mu$ -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

  
 (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)

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Device Classification Name	<a href="#">Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented</a>
510(K) Number	K081973
Device Name	METHA SHORT STEM HIP SYSTEM; MODULAR HIP SYSTEM; EXCIA HIP SYSTEM
Applicant	AESCALAP IMPLANT SYSTEMS, INC. 3773 Corporate Pwky. Center Valley, PA 18034
Contact	Matthew M Hull
Regulation Number	<a href="#">888.3353</a>
Classification Product Code	<a href="#">LZO</a>
Subsequent Product Code	<a href="#">LPH</a>
Date Received	07/10/2008
Decision Date	08/07/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Summary	<a href="#">Summary</a>
Type	Special
Reviewed By Third Party	No
Expedited Review	No

**B. 510(k) SUMMARY (as required by 21 CFR 807.92) K081973 (pg 1/2)****Consensus Acetabular Cups in Aesculap Hip Systems**  
8 July 2008

AUG - 7 2008

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

**CONTACT:** Matthew M. Hull  
800-258-1946 (phone)  
610-791-6882 (fax)  
matt.hull@ Aesculap.com (e-mail)

**TRADE NAME:** Excia and Metha Hip Systems (Consensus Acetabular Cup)

**COMMON NAME:** Total Hip System

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

**REGULATION NUMBER:** 888.3353/ 888.3358

**PRODUCT CODE:** LZO/ LPH

**SUBSTANTIAL EQUIVALENCE**

Aesculap®, Inc. believes that the Consensus Acetabular Cup is a line extension of Aesculap's Excia (K042344 – K062684) and Metha (K071916 & K080584) Hip Systems that were previously cleared for use with acetabular cups. The Consensus Acetabular Cup components have been cleared in K020153 – K070061 for use with the Consensus and Unisyn hip systems from Hayes Medical.

**DEVICE DESCRIPTION**

The Consensus Acetabular Cup from Hayes Medical is a Titanium alloy shell with a highly cross linked polyethylene insert. The Consensus acetabular cups are available in 28mm, 32mm, and 36mm ID's, a variety of sizes, and in either standard or hooded versions. The shells are available with or without screws. The Aesculap Excia hip systems also comes in 28mm – 36 mm ID's, it is available in both cemented and uncemented variants, and a wide range of sizes. Aesculap's Metha hip system also comes in 28 – 36 mm ID's but is for uncemented use, and also comes in a variety of sizes. The PlasmaCup acetabular cup from Aesculap is cleared for use with both the Excia and Metha systems.

KOB1973 (pg 2/2)

**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  $\mu$  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

**Indications for use of the CONSENSUS® HIP SYSTEM-PRIMARY HIP:**

- A) Significantly impaired joints resulting from rheumatoid, osteo, and posttraumatic arthritis.
- B) Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C) Proximal femoral fractures.
- D) Avascular necrosis of the femoral head.
- E) Non-union of proximal femoral neck fractures.
- F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Acetabular components are indicated for cemented and cementless use.

**TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))**

There are no changes to the Hayes Consensus acetabular cup nor to the Aesculap Excia and Metha hip systems. The inner dimensions of the Aesculap PlasmaCup acetabular cup inserts are identical to those of the Hayes Consensus acetabular cups. The difference is that the Consensus inserts are highly crosslinked polyethylene (UHMWPE) and the Aesculap PlasmaCup inserts are regular polyethylene (UHMWPE).

**PERFORMANCE DATA**

Based upon the engineering evaluation of the dimensions of these components no additional performance data was required.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Aesculap Implant Systems, Inc.  
% Mr. Matthew M. Hull, RAC  
Regulatory Affairs Manager  
3773 Corporate Parkway  
Center Valley, Pennsylvania 18034

AUG - 7 2008

Re: K081973  
Trade/Device Name: Consensus Acetabular Cups for use with the Aesculap Excia and Metha Hip Systems  
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, LPH  
Dated: July 9, 2008  
Received: July 10, 2008

Dear Mr. Hull:

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

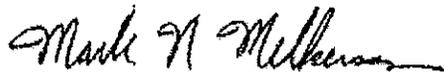
Page 2 – Mr. Matthew M. Hull, RAC

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

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

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at 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: K081973 (pg 1/1)

**Device Name:** Consensus Acetabular Cups for use with the Aesculap Excia and Metha Hip Systems

**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  $\mu$  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

**Indications for use of the CONSENSUS® HIP SYSTEM-PRIMARY HIP:**

- A) Significantly impaired joints resulting from rheumatoid, osteo, and posttraumatic arthritis.
- B) Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C) Proximal femoral fractures.
- D) Avascular necrosis of the femoral head.
- E) Non-union of proximal femoral neck fractures.
- F) Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Acetabular components are indicated for cemented and cementless use.

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)

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

510(k) Number K081973 002

**EXCIA HIP SYSTEM  
PACKAGE INSERT**

**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  $\mu$ -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 Plasmapac acetabular cups and inserts or the Consensus acetabular cups and inserts. The Plasmapac acetabular cup is manufactured from Titanium alloy with a Ti plasma spray coating with or without  $\mu$ -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 PlasmaCup 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;  $Al_2O_3$  (ISO 6474), Ceramic;  $Al_2O_3$ , ZrO $_2$ , 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.

The Excia implants have not been evaluated for safety and compatibility in the MR environment. The Excia implants have not been tested for heating or migration in the MR environment.

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 weightload 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 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;

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 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, demineralized 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**

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, JG598. Special attention should be given to boxlocks and moveable parts (joints). Only lubricate dry instruments and do not use mineral oil, petroleum, 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, EO or Chemical sterilization.**

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

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

#### **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.

#### **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

- 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;
- 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.

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 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**

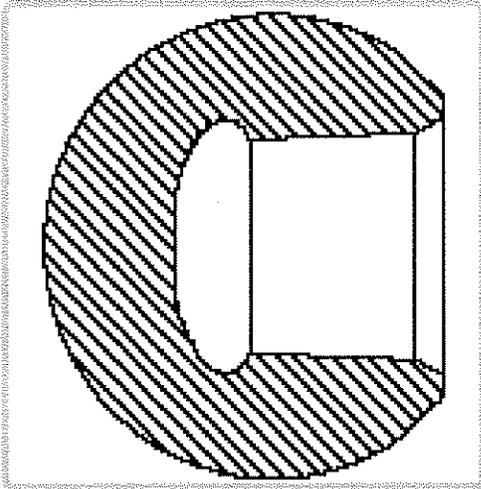
For further information regarding the Excia Hip System or a copy of the Excia Surgical Technique Manual PlasmaCup Manual, or Consensus Acetabular Cup Manual, please contact Aesculap, Inc.

**AESCLAP**<sup>®</sup>  
Implant Systems

Aesculap Implant Systems, Inc.  
3775 Corporate Parkway  
Center Valley, PA 18014

SOP-AIS-5000165 Rev. 8

**Attachment V – Package Labeling**



Label Rev:  
2-1

## Consensus® Hip System

Femoral Head, Biolox®, delta  
 Tête fémorale, Céramique Biolox®, delta  
 Femur-Kopf, Biolox®, delta  
 Testa femorale, Ceramica Biolox®, delta  
 Cabeza femoral, Cerámica Biolox®, delta  
 Femoral Kafa, Biolox®, delta

**SIZE**  
**28mm**  
**x-3.5mm**

**REF** Catalog Number **0005-0-2801**  
**LOT** **123456A1** Use by **2016-02**

GMDN: 44855

**STERILE**  
 Sterilized by Ethylene Oxide

Read Instructions  
For Use

Do Not  
Re-use

Do Not Use if  
Package is Damaged

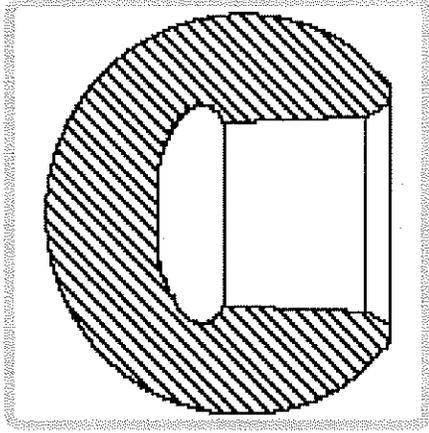
**CE**  
 0459

**Consensus**  
 Orthopedics  
 1115 Windfield Way  
 El Dorado Hills, CA 95762



# Consensus® Hip System

Femoral Head, Biolox®<sup>®</sup>, delta



NS 28mm  
S x - 3.5mm



REF 0005-0-2801

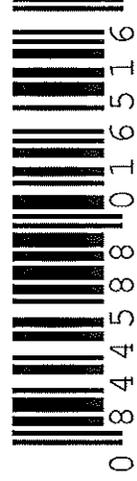
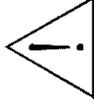
LOT 123456A1

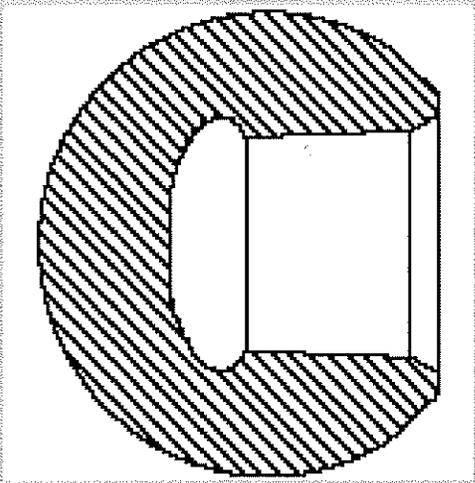
2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





# Consensus® Hip System

Femoral Head, BioloX®, delta  
Tête fémorale, Céramique BioloX®, delta  
Femur-Kopf, BioloX®, delta  
Testa femorale, Ceramica BioloX®, delta  
Cabeza femoral, Cerámica BioloX®, delta  
Femoral Kafa, BioloX®, delta

**SIZE**  
**28mm**  
**x ± 0mm**

**REF** Catalog Number **0005-0-2802**

**LOT** **123456A1** Use by **2016-02**

GMDN: **44855**

**STERILE**  
Sterilized by Ethylene Oxide

 Read Instructions  
For Use

 Do Not  
Re-use

 Do Not Use if  
Package is Damaged

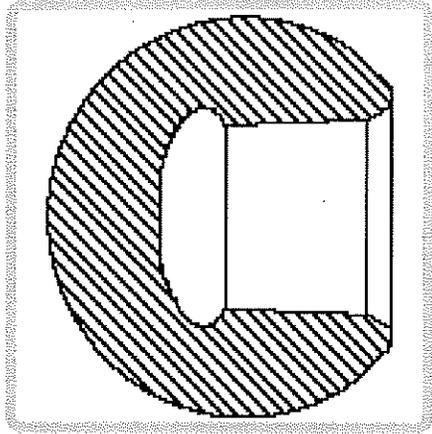
**CE**  
0459

**Consensus**  
Orthopedics  
1115 Windfield Way  
El Dorado Hills, CA 95762



# Consensus® Hip System

Femoral Head, Biolox®, delta



W 28mm  
NS x ±0mm



REF 0005-0-2802

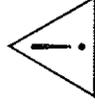
LOT 123456A1

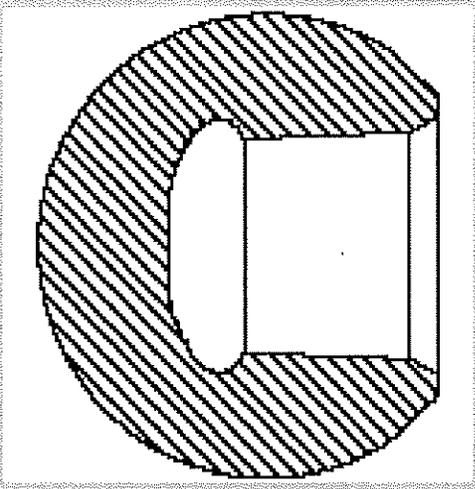
2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





# Consensus® Hip System

Femoral Head, Biolox®, delta  
Tête fémorale, Céramique Biolox®, delta  
Femur-Kopf, Biolox®, delta  
Testa femorale, Ceramica Biolox®, delta  
Cabeza femoral, Cerámica Biolox®, delta  
Femoral Kafa, Biolox®, delta

**SIZE**  
**28mm**  
**x+3.5mm**

**REF** Catalog Number **0005-0-2803**  
**LOT** **123456A1** Use by **2016-02**

GMDN: **44855**  
**STERILE** EO  
Sterilized by Ethylene Oxide



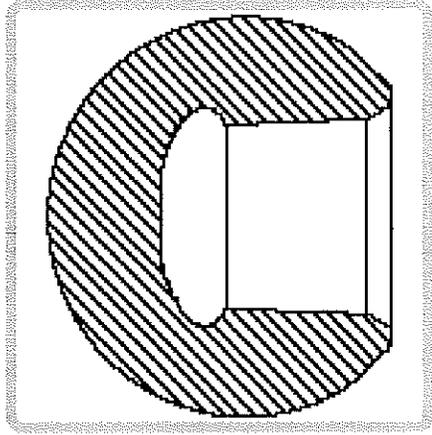
- Read Instructions For Use
- Do Not Re-use
- Do Not Use if Package is Damaged

**Consensus**  
Orthopedics  
1115 Windfield Way  
El Dorado Hills, CA 95762



# Consensus® Hip System

Femoral Head, Biolox®<sub>3</sub>, delta



NS  
28mm  
x+3.5mm



REF 0005-0-2803

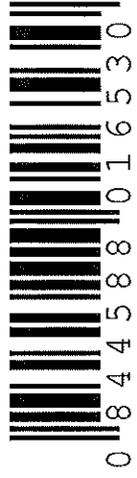
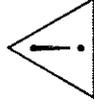
LOT 123456A1

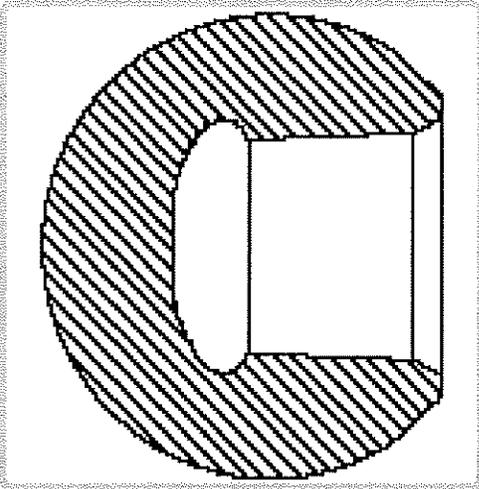
2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





**SIZE**  
**32mm**  
**x - 4mm**

**REF** Catalog Number **0005-0-3201**  
**LOT** **123456A1** Use by **2016-02**

**Consensus® Hip System**

Femoral Head, Biolox®, delta  
 Tête fémorale, Céramique Biolox®, delta  
 Femur-Kopf, Biolox®, delta  
 Testa femorale, Cerámica Biolox®, delta  
 Cabeza femoral, Cerámica Biolox®, delta  
 Femoral Kafa, Biolox®, delta

 Read Instructions  
 For Use

 Do Not  
 Re-use

 Do Not Use if  
 Package is Damaged

GMDN: **44855**

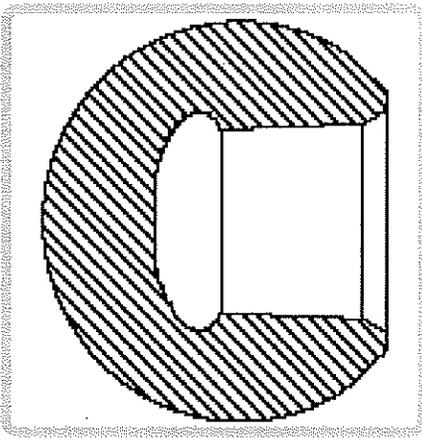
**STERILE**  
 Sterilized by Ethylene Oxide

**CE**  
 0459



# Consensus® Hip System

Femoral Head, Biolox®, delta



W 32mm  
NS x - 4mm



REF 0005-0-3201

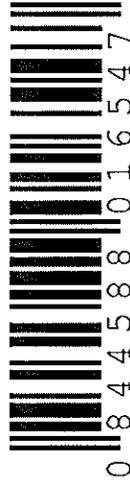
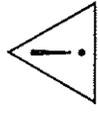
LOT 123456A1

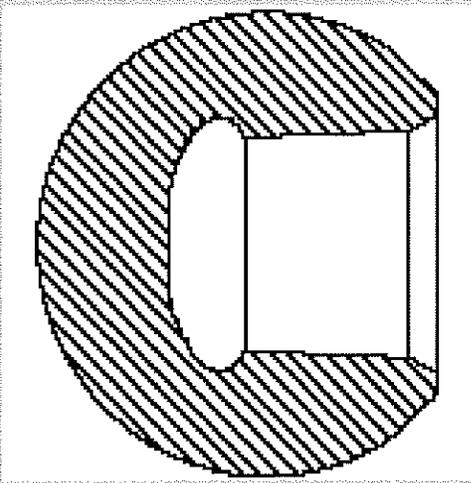
2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





**Consensus® Hip System**  
Femoral Head, BioloX®, delta  
Tête fémorale, Céramique BioloX®, delta  
Femur-Kopf, BioloX®, delta  
Testa femorale, Ceramica BioloX®, delta  
Cabeza femoral, Cerámica BioloX®, delta  
Femoral Kafa, BioloX®, delta

**SIN**  
**32mm**  
**x ± 0mm**

**REF** Catalog Number **0005-0-3202**

**LOT** **123456A1** Use by **2016-02**

GMDN: **44855**

**STERILE**  
Sterilized by Ethylene Oxide

Read Instructions For Use

Do Not Re-use

Do Not Use if Package is Damaged

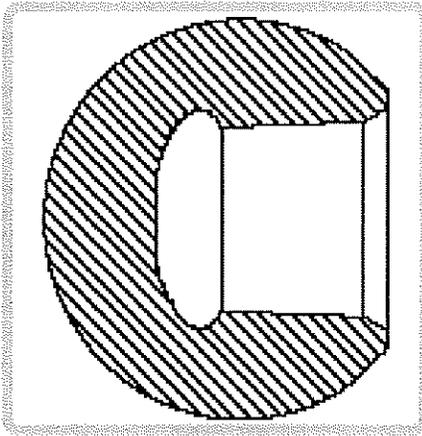
**CE**  
0459

**Consensus**  
Orthopedics  
1115 Windfield Way  
El Dorado Hills, CA 95762



# Consensus® Hip System

Femoral Head, Biolox®, delta



W 32mm  
S ±0mm



REF 0005-0-3202

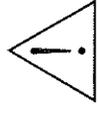
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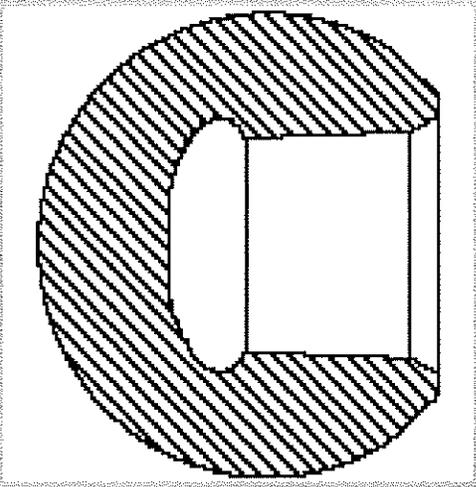
 2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





# Consensus® Hip System

Femoral Head, Biolox®, delta  
Tête fémorale, Céramique Biolox®, delta  
Femur-Kopf, Biolox®, delta  
Testa femorale, Ceramica Biolox®, delta  
Cabeza femoral, Cerámica Biolox®, delta  
Femoral Kafa, Biolox®, delta

**SIN**  
**32mm**  
**x + 4mm**

**REF** Catalog Number **0005-0-3203**

**LOT** **123456A1** Use by **2016-02**

GMDN: **44855**

**STERILE**  
Sterilized by Ethylene Oxide

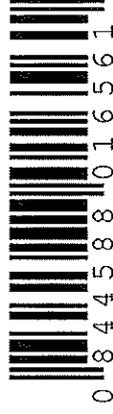
 Read Instructions  
For Use

 Do Not  
Re-use

 Do Not Use if  
Package is Damaged

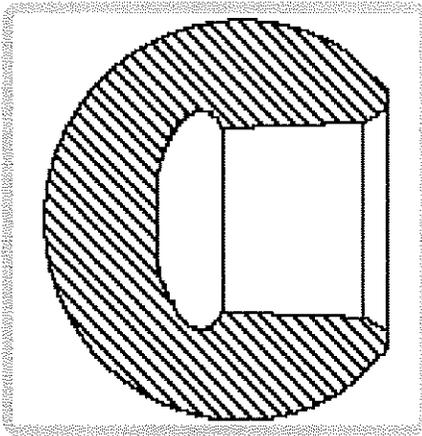
**CE**  
0459

**Consensus**  
Orthopedics  
1115 Windfield Way  
El Dorado Hills, CA 95762

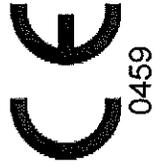


# Consensus® Hip System

Femoral Head, Biolox®, delta



W 32mm  
NS x +4mm



REF 0005-0-3203

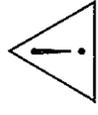
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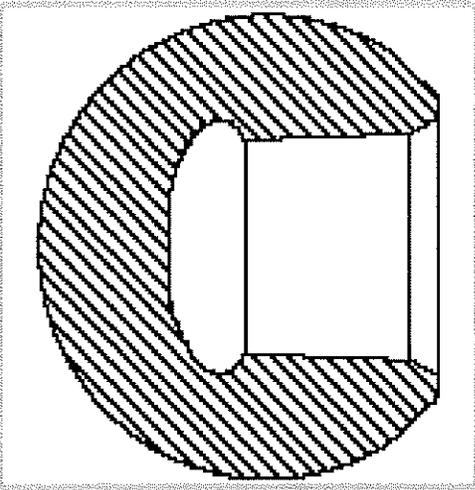
2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





# Consensus® Hip System

Femoral Head, Biolox®, delta  
Tête fémorale, Céramique Biolox®, delta  
Femur-Kopf, Biolox®, delta  
Testa femorale, Ceramica Biolox®, delta  
Cabeza femoral, Cerámica Biolox®, delta  
Femoral Kafa, Biolox®, delta

**SIZE**  
**32mm**  
**x + 7mm**

**REF** Catalog Number **0005-0-3204**

**LOT** **123456A1**  Use by **2016-02**

**GMDN: 44855**

**STERILE EO**  
Sterilized by Ethylene Oxide

**CE**  
0459

 **Read Instructions For Use**

 **Do Not Re-use**

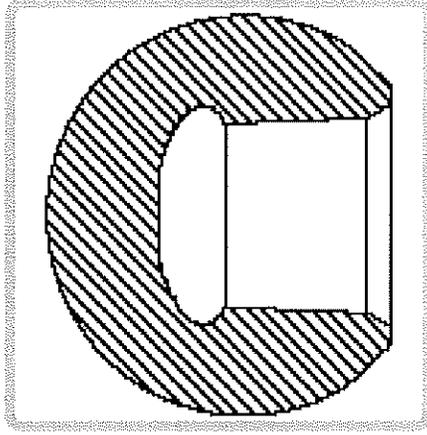
 **Do Not Use if Package is Damaged**

**Consensus**  
Orthopedics  
1115 Windfield Way  
El Dorado Hills, CA 95762



# Consensus® Hip System

Femoral Head, Biolox®, delta



UN 32mm  
NS x+7mm



REF 0005-0-3204

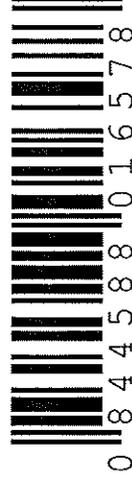
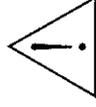
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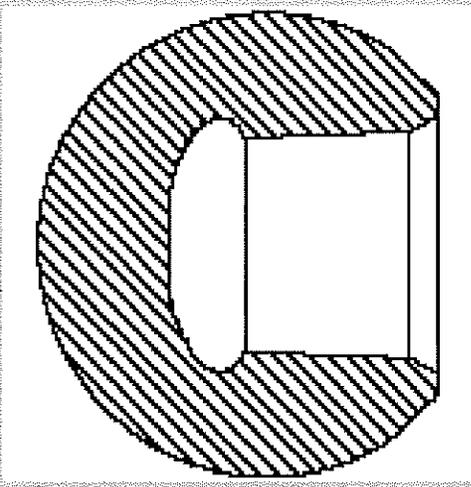
2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





# Consensus® Hip System

- Femoral Head, BioloX®, delta
- Tête fémorale, Céramique BioloX®, delta
- Femur-Kopf, BioloX®, delta
- Testa femorale, Ceramica BioloX®, delta
- Cabeza femoral, Cerámica BioloX®, delta
- Femoral Kafa, BioloX®, delta

SIZE	36mm x - 4mm
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REF	Catalog Number	0005-0-3601
LOT	Use by	123456A1 2016-02

GMDN: 44855

STERILE	EO
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Sterilized by Ethylene Oxide

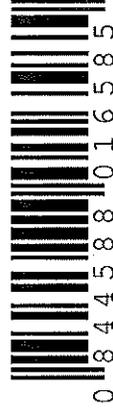
! Read Instructions For Use

⊗ Do Not Re-use

⊗ Do Not Use if Package is Damaged

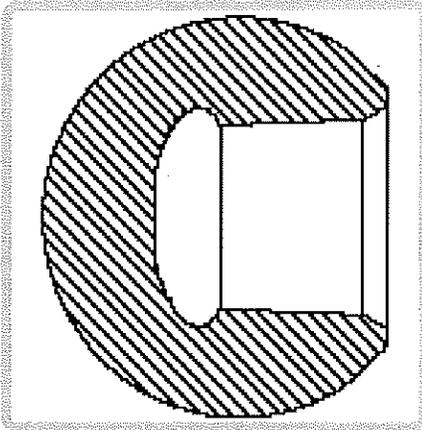
CE 0459

**Consensus**  
Orthopedics  
1115 Windfield Way  
El Dorado Hills, CA 95762

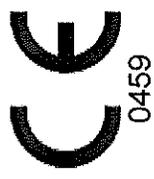


# Consensus® Hip System

Femoral Head, Biolox®, delta



UN 36mm  
NS x - 4mm



REF 0005-0-3601

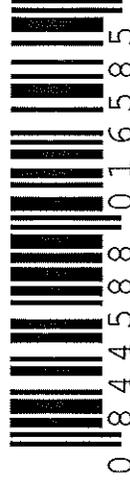
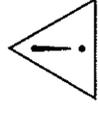
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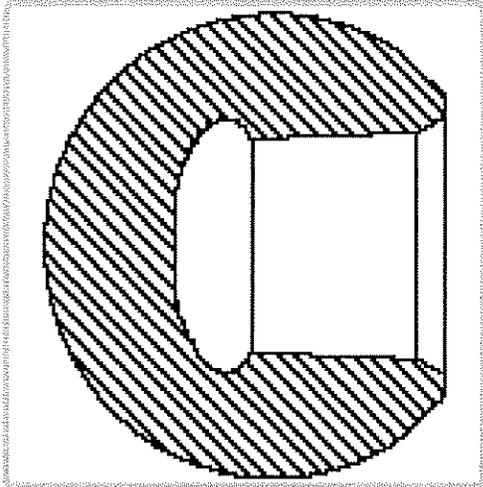
2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





# Consensus® Hip System

Femoral Head, BioloX®, delta  
 Tête fémorale, Céramique BioloX®, delta  
 Femur-Kopf, BioloX®, delta  
 Testa femorale, Ceramica BioloX®, delta  
 Cabeza femoral, Cerámica BioloX®, delta  
 Femoral Kafa, BioloX®, delta

Label Rev:  
2-1

**SIZE**  
**36mm**  
**x ± 0mm**

**REF** Catalog Number **0005-0-3602**  
**LOT** **123456A1**  Use by **2016-02**

GMDN: **44855**

**STERILE**  
 Sterilized by Ethylene Oxide

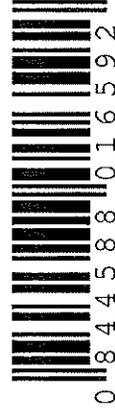
Read Instructions For Use

Do Not Re-Use

Do Not Use if Package is Damaged

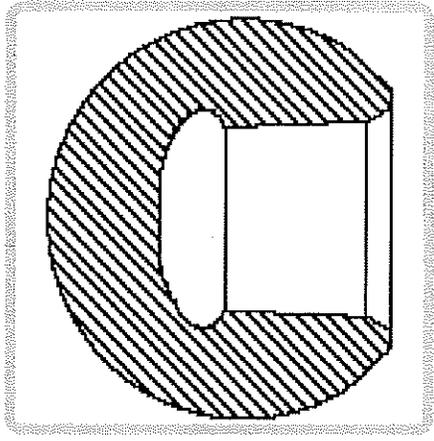
**CE**  
0459

**Consensus**  
 Orthopedics  
 1115 Windfield Way  
 El Dorado Hills, CA 95762



# Consensus® Hip System

Femoral Head, Biolox®, delta



36mm  
x ±0mm



REF 0005-0-3602

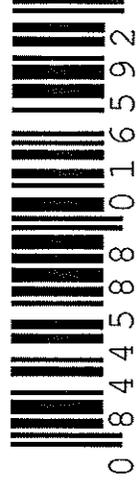
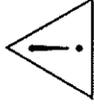
LOT 123456A1

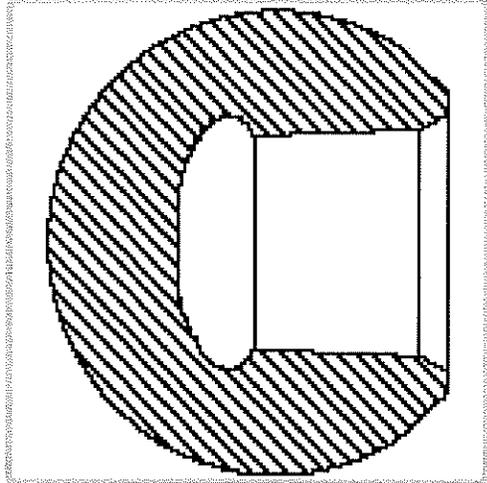
2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





**Consensus® Hip System**

Femoral Head, Biolox®, delta  
 Tête fémorale, Céramique Biolox®, delta  
 Femur-Kopf, Biolox®, delta  
 Testa femorale, Ceramica Biolox®, delta  
 Cabeza femoral, Cerámica Biolox®, delta  
 Femoral Kafa, Biolox®, delta

Label Rev:  
2-1

**SIZE**  
**36mm**  
**x + 4mm**

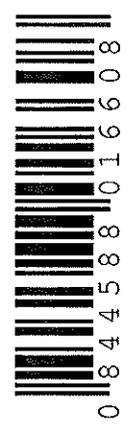
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**LOT** **123456A1** Use by **2016-02**

GMDN: **44855**  
**STERILE** EO  
 Sterilized by Ethylene Oxide

Read Instructions For Use  
 Do Not Re-use  
 Do Not Use if Package is Damaged

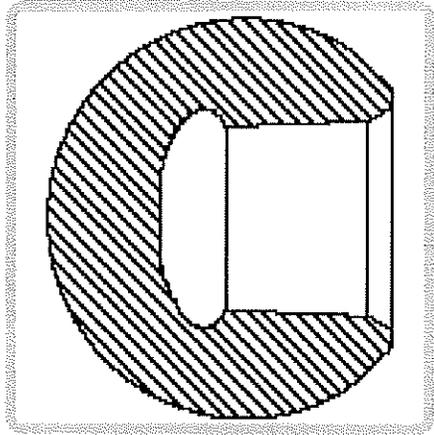
**CE**  
0459

**Consensus**  
 Orthopedics  
 1115 Windfield Way  
 El Dorado Hills, CA 95762



# Consensus® Hip System

Femoral Head, Biolox®<sub>3</sub>, delta



UNIS 36mm  
S x+4mm



REF 0005-0-3603

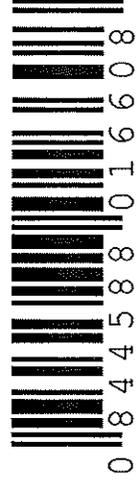
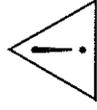
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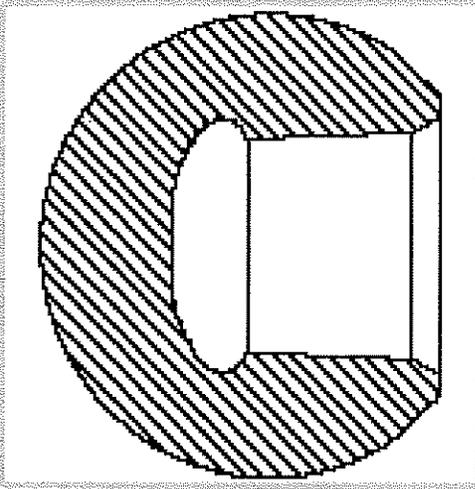
2016-02

Label Rev: 2-1 **Consensus**  
Orthopedics

GMDN: 44855

STERILE EO





# Consensus® Hip System

Femoral Head, BioloX®, delta  
 Tête fémorale, Céramique BioloX®, delta  
 Femur-Kopf, BioloX®, delta  
 Testa femorale, Ceramica BioloX®, delta  
 Cabeza femoral, Cerámica BioloX®, delta  
 Femoral Kafa, BioloX®, delta

Label Rev:  
2-1

**SIZE**  
**36mm**  
**x + 8mm**

**REF** Catalog Number **0005-0-3604**  
**LOT** **123456A1** Use by **2016-02**

GMDN: **44855**

**STERILE**  
 Sterilized by Ethylene Oxide

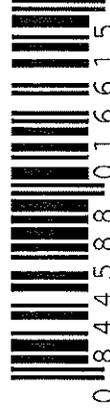
⚠ Read Instructions For Use

⊘ Do Not Re-use

⊘ Do Not Use if Package is Damaged

**Consensus**  
 Orthopedics

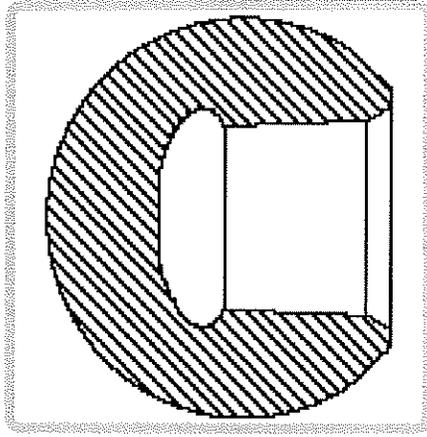
1115 Windfield Way  
 El Dorado Hills, CA 95762



**CE**  
 0459

# Consensus® Hip System

Femoral Head, Biolox®<sub>3</sub>, delta



SIZE  
36mm  
x+8mm



REF 0005-0-3604

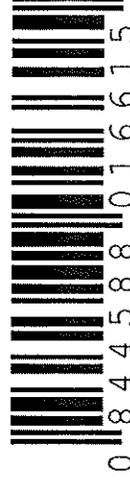
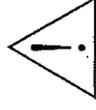
LOT 123456A1

2016-02

Label Rev: 2-1  
**Consensus**  
Orthopedics

GMDN: 44855

STERILE EO



## **Attachment VI – Packaging & Sterilization**





































**Attachment VII – Instructions for Use (IFU), Surgical Technique, and Brochure**

# CONSENSUS ORTHOPEDICS INC.

## CONSENSUS HIP SYSTEMS

### Instructions for Use (IFU)

**IMPORTANT INFORMATION FOR SURGEON: PLEASE READ PRIOR TO IMPLANTING THIS DEVICE IN A CLINICAL SETTING. THE SURGEON SHOULD BE FAMILIAR WITH THE SURGICAL TECHNIQUE.**

#### DESCRIPTION

The CONSENSUS ORTHOPEDICS, INC. TAPERSET™ HIP SYSTEM – PRIMARY HIP and the CONSENSUS® HIP SYSTEM – PRIMARY HIP are comprised of a femoral stem component, femoral head component, acetabular component and cancellous bone screws, and for cemented applications includes distal centralizers.

The femoral stem component of the CONSENSUS® HIP SYSTEM is manufactured from forged cobalt chrome alloy (CoCrMo, ASTM F799) for cemented applications, or forged titanium alloy (Ti 6Al-4V ELI, ASTM F620) for uncemented applications.

The femoral stem component of the TAPERSET™ HIP SYSTEM is manufactured from wrought Titanium alloy (Ti-6Al-4V ELI, ASTM F136). The proximal portion of the femoral stem component is plasma sprayed with commercially pure Titanium (C. P. Ti, ASTM F1580). The femoral stem is available in both standard and 7mm lateralized options.

The CONSENSUS® femoral head components is manufactured from either Cobalt Chrome alloy (CoCrMo, ASTM F799 or ASTM F1537) or Biolox *delta* Ceramic (Al<sub>2</sub>O<sub>3</sub>, ZrO<sub>2</sub>, ISO 6474). All femoral heads are highly polished and available in multiple neck lengths and head diameters. Cobalt Chrome femoral heads are designed for use with all CONSENSUS® and TAPERSET™ femoral stems, and Biolox *delta* Ceramic femoral heads are designed for use with titanium alloy CONSENSUS® and TAPERSET™ femoral stems.

The CONSENSUS® acetabular component consists of a shell and a mating insert. The acetabular component is designed for cemented or uncemented use. The acetabular shell is manufactured from Titanium alloy (Ti-6Al-4V ELI, ASTM F620 or ASTM F136), with a porous coating of commercially pure Titanium beads (C.P. Ti ASTM F-67). The acetabular shells are available in four different configurations. These are (1) Hemispherical with screw holes, (2) Hemispherical without screw holes, (3) Flared rim with screw holes and (4) Flared rim without screw holes. The component has matching circumferential scallops on the shell and insert that rotationally secure the insert in the shell and allow for dialing the insert in a desired orientation. The shells with screw holes have three anatomically placed holes, which accommodate optional cancellous bone screws to augment initial fixation. An optional CONSENSUS® apical dome hole plug and cement pod spacer are available. The acetabular insert is manufactured from either ultra-high molecular weight Polyethylene (UHMWPE, ASTM F648) or highly cross linked

Polyethylene (UHMWPE, ASTM F648), and features a Titanium alloy X-ray marker (Ti-6Al-4V ELI, ASTM F136).

The cancellous bone screws are manufactured from wrought Titanium alloy (Ti 6Al-4V ELI, ASTM F136). The cancellous bone screws are 6.5mm diameter and have a low profile head with a hex drive recess.

The CONSENSUS BIPOLAR and UNIPOLAR are intended for cementless use and are designed for use with CONSENSUS® and TAPERSET™ femoral stem components. The CONSENSUS BIPOLAR consists of a bipolar femoral head component with preassembled locking ring and bipolar insert component. The CONSENSUS UNIPOLAR consists of only a unipolar femoral head component. The bipolar femoral head component is manufactured from Cobalt Chrome alloy (CoCrMo, ASTM F75, ASTM F799, or ASTM F1537). The bipolar head has a highly polished spherical outer surface with a cylindrical bored internal diameter which accepts the polyethylene bipolar insert. The bipolar head comes with a polyethylene locking ring preassembled in a circumferential groove on the internal diameter. The bipolar insert component and locking ring are manufactured from ultra-high molecular weight polyethylene (UHMWPE, ASTM F648). The bipolar insert and locking ring are designed for use with the appropriate size bipolar head component. The unipolar femoral heads are manufactured from cobalt chrome alloy (CoCrMo, ASTM F75 or ASTM F1537).

The CONSENSUS ALL-POLY ACETABULAR CUP is designed for use with CONSENSUS® and TAPERSET™ femoral stem components. The CONSENSUS ALL-POLY ACETABULAR CUP is a one piece acetabular component designed for cemented use only, manufactured from ultra-high molecular weight Polyethylene (UHMWPE, ASTM F648), and like the acetabular insert, features a titanium alloy X-ray marker (Ti 6Al-4V ELI, ASTM F136).

The proximal spacer, distal centralizer, apical dome hole plug and cement pod spacer are manufactured from polymethylmethacrylate (PMMA, ASTM F451). The proximal spacer and distal centralizer are designed for use with the CoCr femoral stem component for cemented applications.

#### **HOW PRODUCT IS SUPPLIED**

Each component of the CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM is supplied STERILE, is contained in individual boxes or packages designed to maintain sterility, and is available in a wide range of sizes. Please refer to the current price list, surgical technique or catalog for the catalog numbers and sizes available.

#### **INDICATIONS FOR USE OF THE CONSENSUS® HIP SYSTEM-PRIMARY HIP:**

The CONSENSUS® HIP SYSTEM is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the CONSENSUS® HIP SYSTEM.

The indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.

- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The CONSENSUS® hip stem is indicated for cemented or cementless use.

**INDICATIONS FOR USE OF THE TAPERSET™ HIP SYSTEM-PRIMARY HIP**

The TaperSet™ Hip System is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System.

The indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The TaperSet™ hip stem is indicated for cementless use.

**INDICATIONS FOR USE OF THE CONSENSUS® BIPOLAR OR UNIPOLAR:**

- A. Primary replacement of the femoral head and neck with very little if any acetabular degradation noted.
- B. Rheumatoid, osteo, and post traumatic arthritis.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-unions of proximal femoral neck fractures.
- F. Revision of failed total hip arthroplasty.
- G. Treatment of malunion or nonunion acetabular fractures.

The CONSENSUS BIPOLAR OR UNIPOLAR are intended for cementless use.

**INTENDED PERFORMANCE**

All components of the CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM are intended to perform in a safe and effective manner in restoring hip function within the intended use of the product.

- H. The CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM range of motion complies with ISO 21535, except that the 28/+10mm CoCr femoral head used with the 20 degree hooded acetabular insert limits flexion/extension to 98 degrees in both the CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM.
- I. The CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM are designed to transmit load to the femur during daily activities including, but not limited to walking, stair climbing, and chair ascent.
- J. The femoral and acetabular components are designed to minimize stress shielding at the bone-implant interface.
- K. The matching articulating surfaces at the acetabular-femoral articulation are intended to minimize wear over time.
- L. The high polish finish of the articulating surface of the CoCr and BioloX *delta* Ceramic femoral heads is intended to minimize wear of the acetabular insert.
- M. The high polish finish of the unipolar and bipolar heads is intended to minimize wear of the natural acetabular cartilage.
- N. The proximal fixation surfaces of nonporous femoral stems are grit blasted to enhance adhesion at the implant-cement interface.
- O. The proximal fixation surfaces of porous CONSENSUS® and TAPERSET™ stems and the external fixation surfaces of acetabular components are porous coated to enhance adhesion at the implant-bone interface.

#### **CONTRAINDICATIONS**

- A. Any joint with active or suspected latent infection.
- B. Neuromuscular disorders or mental conditions whereby the risks associated with these conditions are outweighed by the benefits to be derived.
- C. Any condition of the bone stock in which sufficient support and fixation of the implant is in question.
- D. Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
- E. Any pathological conditions of the joint that would interfere in achieving appropriate range of motion, adequate head stability, and a well seated and supported prosthetic combination.
- F. Ligamentous or severe muscle laxity or inadequate soft tissue coverage to allow for the normal healing process and for proper hip mechanics to be reestablished.

#### **WARNINGS**

- A. All CONSENSUS® HIP SYSTEM and TAPERSET™ HIP SYSTEM components are sold sterile. If packages appear damaged or tampered with, they should be returned to the supplier.
- B. Do not implant any device that has been used, even if it appears undamaged.
- C. Machined taper surfaces of the femoral stem and head must be clean and dry at the time of assembly to ensure proper seating of the implant.

- D. Care must be taken to properly impact the femoral head to prevent any discrepancy in neck length, disassociation, or dislocation.
- E. Do not bend or contour an implant, as this may reduce its fatigue strength and may cause immediate or eventual failure under load.
- F. Never tamper with implants. Tampering may have a detrimental affect on the performance of the implant.
- G. The surgeon and O.R. staff must be extremely careful to protect all components from being marred, nicked, or notched as a result of contact with metal or any abrasive objects. This is particularly important for polished bearing areas and machined taper surfaces.
- H. The BioloX *delta* Ceramic Femoral Head is to be used ONLY with CONSENSUS ORTHOPEDICS, INC. titanium hip stems with a 12/14 taper trunnion.
- I. CONSENSUS® and TAPERSET™ femoral stems may ONLY be used in conjunction with CONSENSUS metal femoral heads or with BioloX *delta* Ceramic femoral heads.
- J. CONSENSUS femoral heads may ONLY be used in conjunction with CONSENSUS acetabular components.
- K. CONSENSUS® and TAPERSET™ hip products should not be used in conjunction with the 28/+10mm femoral head and the 20° hooded insert.

#### **PRECAUTIONS**

- A. Before any implant is used, the surgeon should be completely familiar with all aspects of the surgical procedure and the limitations of the device.
- B. It cannot be expected that joint replacements will withstand the same activity levels as normal healthy bone.
- C. Excessive physical activity may result in premature failure of the implant system due to loosening, component fracture, and/or wear. Activities which place unreasonable amounts of stress on the joint should be avoided. Patients should be instructed on the limitations of the prosthesis and how to modify their activities accordingly.
- D. Obese patients may place severe loading on the affected extremity which can be expected to accelerate joint failure. If appropriate, patients should be advised to follow a weight reduction or maintenance program.
- E. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Total joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding the activity and joint loading are assured.
- F. Proper selection of fixation type and placement of the femoral stem and acetabular component are critical factors in the prevention of unusual stress conditions and their potentially harmful affects on the life expectancy of the implant.

#### **ADVERSE EFFECTS**

- A. All prosthetic replacements have the potential for adverse effects, including infection, loosening, fracture, breakage, bending of the components, component disassembly, or positional changes of the components.
- B. Sensitivity reactions to component materials could occur, and should be ruled out preoperatively.
- C. Total joint replacement surgery is associated with serious complications including, but not limited to: nerve injury, direct arterial injury, false aneurysm, spontaneous vascular occlusion, deep vein thrombosis, ectopic ossification, non-union, dislocation, disassociation, superficial and deep infection, aseptic loosening, component failure, cement breakdown, and third party wear associated with polymethylmethacrylate or UHMWPE.
- D. Acetabular pain due to loosening of the implant, and/or localized pressure associated with incongruencies of the fit, or tissue inflammation of unknown etiology.
- E. Reoperation may be necessary to correct adverse effects.
- F. On rare occasions, complications may require arthrodesis, Girdlestone procedure or amputation of the limb.
- G. Other complications generally associated with surgery, drugs, blood use, or ancillary devices used.

#### **INFORMATION**

Surgical techniques may be obtained from a CONSENSUS ORTHOPEDICS representative or the company directly.

#### **STERILIZATION AND HANDLING**

All components have been sterilized through an Ethylene Oxide sterilization process. Do not use any component if the package has been breached.

USE CAUTION IN HANDLING PLASMA SPRAYED or POROUS COATED COMPONENTS TO PREVENT CONTAMINATION OF THE COATING OR ENTRAPMENT OF DEBRIS IN THE COATING.

COMPONENTS THAT ARE MANUFACTURED FROM ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE), POLYMETHYL-METHACRYLATE (PMMA) OR CERAMIC SHOULD NOT BE AUTOCLAVED.

#### **CERAMIC FEMORAL HEAD INSTRUCTIONS FOR USE**

##### **PREPARATORY PHASE**

- A. Use ceramic heads only on stems with tapers approved for ceramic heads.
- B. A ceramic head impacted once, and then removed, must not be mounted onto another stem.
- C. Never place a ceramic femoral head onto a stem taper that has previously been in use with a head of any type. A metal head must be used as a replacement for any type of head that has been removed from a stem taper.
- D. Never use a ceramic head which has fallen to the floor.
- E. Avoid thermal shocks to ceramic heads. Do not quench the ceramic components in cold liquids.

## **DURING OPERATION**

- A. Keep metal instruments clear of taper. Taper surface of CONSENSUS™ stem must not be scratched or damaged.
- B. Clean and dry taper of femoral stem and ceramic head before attaching the ceramic head.
- C. Use only plastic impactor to fasten ceramic heads. Never use a metal impaction instrument.

## **REPLACEMENT OF FRACTURED CERAMIC HEAD**

In the case of a fractured ceramic head, remove all ceramic particles from the wound. If you wish to replace the fractured ceramic head with another ceramic head, the polyethylene insert and femoral stem must be changed. If the stem taper is undamaged, a metal head may be used with the existing stem in lieu of a ceramic head.

**WARNING:** Single Use Only: This product is intended for single use only. Do not attempt to re-use, even if the device appears to be undamaged. Risks include device damage leading to poor performance or failure, patient cross-contamination, inadequate sterilization and general liability.

**CAUTION:** Disposal of single-use implant device - This device should be regarded as bio-contaminated and handled accordingly. Plastic or metal implants should be terminally sterilized and disposed of following existing hospital policies and procedures.

**CAUTION:** The CONSENSUS® and the TAPERSET™ hip system is MR Unsafe per ASTM F2503 as it has not been evaluated for safety in the MR environment. Patients should register their implant information with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)), or equivalent organization.

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

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# CONSENSUS ORTHOPEDICS INC.

## UNISYN™ HIP SYSTEM

### Instructions for Use (IFU)

**IMPORTANT INFORMATION FOR SURGEON: PLEASE READ PRIOR TO IMPLANTING THIS DEVICE IN A CLINICAL SETTING. THE SURGEON SHOULD BE FAMILIAR WITH THE SURGICAL TECHNIQUE.**

#### DESCRIPTION

The CONSENSUS ORTHOPEDICS, INC. UNISYN™ HIP SYSTEM - PRIMARY/REVISION Hip is comprised of four modular components – a neck segment, a body segment, a stem, and a locking nut. The modular neck segment is manufactured from titanium alloy (Ti-6Al-4V, ASTM F620). It attaches to the body segment by means of a locking taper and flexible collet junction. Multiple neck options are provided to allow horizontal and vertical offset adjustment. The neck segment utilizes a Morse taper as a means for attaching a modular femoral head. The body segment is manufactured from titanium alloy (Ti 6Al 4V, ASTM F136 or ASTM F1472). Plasma sprayed necks and bodies are coated with commercially pure titanium (C. P. Ti, ASTM F1580). Body segments are also available with hydroxylapatite (HA) coating (empirical formula  $\text{Ca}_5(\text{PO}_4)_3\text{OH}$ , ASTM F1185). The stem components are manufactured from (Ti 6Al-4V, ASTM F1472). The stem is attached to the neck segment by means of a locking taper. The stem is then secured to the neck via a locking nut (Ti 6Al-4V, ASTM F136). The locking nut has a Spiralock® thread to resist loosening. The nut is applied to the stem after the stem has been preloaded and assembled. The UniSyn Hip System was designed for uncemented use, however, if it is necessary to cement a Unisyn hip we recommended the addition of cement to appropriately stabilize the chosen implant. The design details of all taper connections are proprietary to CONSENSUS ORTHOPEDICS, INC.

The UNISYN™ HIP SYSTEM may only be used in conjunction with CONSENSUS® ceramic and metal femoral heads, the CONSENSUS® ACETABULAR CUP, the CS2™ ACETABULAR CUP, CONSENSUS® low profile cancellous bone screws, CONSENSUS® BIPOLAR heads, CONSENSUS® UNIPOLAR heads, and the CONSENSUS® ALL-POLY ACETABULAR CUP. The UNISYN™ HIP SYSTEM is designed to allow full interchangeability between all UNISYN™ components of any size configuration for maximum intraoperative flexibility. CONSENSUS ORTHOPEDICS advises to use the 30 and 45mm locking nut with the 30 to 36mm and 45 to 55mm vertical offset neck sizes respectively. All UNISYN™ component configurations may be used with all CONSENSUS® femoral head and acetabular component configurations.

For a complete description of the CONSENSUS® HIP SYSTEM components for use with the UNISYN™ HIP SYSTEM, refer to the IFU included with the appropriate product package.

UNISYN™ stems used with roughened and plasma coated bodies are intended for cemented or uncemented use. UNISYN™ stems used with plasma/HA or HA coated bodies are intended for uncemented use only.

#### **HOW PRODUCT IS SUPPLIED**

Each component of the UNISYN™ HIP SYSTEM is supplied STERILE, is contained in individual boxes or packages designed to maintain sterility, and is available in a wide range of sizes. Please refer to the current price list, surgical technique or catalog for the catalog numbers and sizes available.

#### **INDICATIONS AND USAGE**

Indications for the use of the UNISYN™ HIP SYSTEM must be carefully considered with respect to the patient's entire evaluation and alternative procedures. The selection of the UNISYN™ HIP SYSTEM is based on the judgment of the surgeon as to the needs of the patient and the expected post-operative conditions. Patient selection is dependent on age, general health, available bone stock and quality, and any prior surgery or anticipated future surgery.

#### **Indications for use of the UNISYN™ HIP SYSTEM**

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

#### **INTENDED PERFORMANCE**

All components of the UNISYN™ HIP SYSTEM are intended to perform in a safe and effective manner in restoring hip function within the intended use of the product.

- A. The UniSyn® HIP SYSTEM range of motion complies with ISO 21535, except that the Consensus® Hip System 28mm/+10 CoCr femoral head used with the 20 degree hooded acetabular insert limits flexion/extension to 98 degrees.
- B. The UNISYN™ HIP SYSTEM is designed to transmit load to the femur during daily activities including, but not limited to walking, stair climbing, and chair ascent.
- C. The taper and collet connections between modular components of the UNISYN™ HIP SYSTEM are designed to minimize micromotion and fretting, and maximize total contact area for added torsional strength and fatigue resistance.
- D. The UNISYN™ HIP SYSTEM is designed to minimize stress shielding at the implant-bone interface.

- E. The fixation surfaces of nonporous (roughened) UNISYN™ body segments are grit blasted to enhance adhesion at the implant-bone interface.
- F. The fixation surfaces of plasma coated UNISYN™ body segments are plasma sprayed to enhance adhesion at the implant-bone interface.
- G. The fixation surfaces of plasma/HA and HA coated UNISYN™ body segments are HA coated to enhance adhesion at the implant-bone interface.

#### **CONTRAINDICATIONS**

- A. Any joint with active or suspected latent infection.
- B. Neuromuscular disorders or mental conditions whereby the risks associated with these conditions are outweighed by the benefits to be derived.
- C. Any condition of the bone stock in which sufficient support and fixation of the implant is in question.
- D. Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
- E. Any pathological conditions of the joint that would interfere in achieving appropriate range of motion, adequate head stability, and a well seated and supported prosthetic combination.
- F. Ligamentous or severe muscle laxity or inadequate soft tissue coverage to allow for the normal healing process and for proper hip mechanics to be reestablished.

#### **WARNINGS**

- A. All UNISYN™ HIP SYSTEM components are sold sterile. If packages appear damaged or tampered with, they should be returned to the supplier.
- B. Do not implant any device that has been used, even if it appears undamaged.
- C. Machined taper surfaces of the femoral stem and head must be clean and dry at the time of assembly to ensure proper seating of the implant.
- D. Care must be taken to properly impact the femoral head to prevent any discrepancy in neck length, disassociation, or dislocation.
- E. Do not bend or contour an implant, as this may reduce its fatigue strength and may cause immediate or eventual failure under load.
- F. Never tamper with implants. Tampering may have a detrimental affect on the performance of the implant. Handling of the HA treated regions must be avoided as it potentially could result in the compromise of the treatment effectiveness.
- G. The surgeon and O.R. staff must be extremely careful to protect all components from being marred, nicked, or notched as a result of contact with metal or any abrasive objects. This is particularly important for polished bearing areas and machined taper surfaces.
- H. UNISYN™ products may ONLY be used in conjunction with Consensus Orthopedics CONSENSUS® ceramic and metal femoral heads.
- I. Do not use bone cement with HA coated implants.
- J. UNISYN™ products should not be used in conjunction with the 28/+10mm femoral head and the 20° hooded insert.

## PRECAUTIONS

- A. Before any implant is used, the surgeon should be completely familiar with all aspects of the surgical procedure and the limitations of the device.
- B. It cannot be expected that joint replacements will withstand the same activity levels as normal healthy bone.
- C. Excessive physical activity may result in premature failure of the implant system due to loosening, component fracture, and/or wear. Activities which place unreasonable amounts of stress on the joint should be avoided. Patients should be instructed on the limitations of the prosthesis and how to modify their activities accordingly.
- D. Obese patients may place severe loading on the affected extremity which can be expected to accelerate joint failure. If appropriate, patients should be advised to follow a weight reduction or maintenance program.
- E. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Total joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding the activity and joint loading are assured.
- F. Instruct patients on the limitations of the prosthesis and how to modify their activities accordingly.
- G. Proper selection of fixation type and placement of the femoral stem and acetabular component are critical factors in the prevention of unusual stress conditions and their potentially harmful effects on the life expectancy of the implant.

## ADVERSE EFFECTS

- A. All prosthetic replacements have the potential for adverse effects, including infection, loosening, fracture, breakage, bending of the components, component disassembly, or positional changes of the components.
- B. Sensitivity reactions to component materials could occur, and should be ruled out preoperatively.
- C. Total joint replacement surgery is associated with serious complications including, but not limited to: nerve injury, direct arterial injury, false aneurysm, spontaneous vascular occlusion, deep vein thrombosis, ectopic ossification, non-union, dislocation, disassociation, superficial and deep infection, aseptic loosening, component failure, cement breakdown, and third party wear associated with polymethylmethacrylate or UHMWPE.
- D. Acetabular pain due to loosening of the implant, and/or localized pressure associated with incongruencies of the fit, or tissue inflammation of unknown etiology.
- E. Reoperation may be necessary to correct adverse effects.
- F. On rare occasions, complications may require arthrodesis, Girdlestone procedure or amputation of the limb.
- G. Other complications generally associated with surgery, drugs, blood use, or ancillary devices used.

## **INFORMATION**

Surgical techniques may be obtained from a CONSENSUS ORTHOPEDICS representative or the company directly.

## **STERILIZATION AND HANDLING**

All components have been sterilized through an ethylene oxide sterilization process. Do not use any component if the package has been breached.

USE CAUTION IN HANDLING PLASMA SPRAYED or HA COATED COMPONENTS TO PREVENT CONTAMINATION OF THE COATING OR ENTRAPMENT OF DEBRIS IN THE COATING.

COMPONENTS THAT ARE MANUFACTURED FROM ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE), POLYMETHYL-METHACRYLATE (PMMA) OR CERAMIC SHOULD NOT BE AUTOCLAVED.

## **CERAMIC FEMORAL HEAD INSTRUCTIONS FOR USE**

### **PREPARATORY PHASE**

- A. Use ceramic heads only on stems with tapers approved for ceramic heads.
- B. A ceramic head impacted once, and then removed, must not be mounted onto another stem.
- C. Never place a ceramic femoral head onto a stem taper that has previously been in use with a head of any type. A metal head must be used as a replacement for any type of head that has been removed from a stem taper.
- D. Never use a ceramic head which has fallen to the floor.
- E. Avoid thermal shocks to ceramic heads. Do not quench the ceramic components in cold liquids.

### **DURING OPERATION**

- A. Keep metal instruments clear of taper. Taper surface of UNISYN™ stem, body, and neck must not be scratched or damaged.
- B. Clean and dry taper of UNISYN™ neck and ceramic head before attaching the ceramic head.
- C. Use only plastic impactor to fasten ceramic heads. Never use a metal impaction instrument.

### **REPLACEMENT OF FRACTURED CERAMIC HEAD**

In the case of a fractured ceramic head, remove all ceramic particles from the wound. If you wish to replace the fractured ceramic head with another ceramic head, the polyethylene insert and UNISYN™ neck component must be changed. If the neck taper is undamaged, a metal head may be used with the existing stem in lieu of a ceramic head.

**WARNING:** Single Use Only: This product is intended for single use only. Do not attempt to re-use, even if the device appears to be undamaged. Risks include device damage leading to poor performance or failure, patient cross-contamination, inadequate sterilization and general liability.

**CAUTION:** Disposal of single-use implant device - This device should be regarded as bio-contaminated and handled accordingly. Plastic or metal implants should be terminally sterilized and disposed of following existing hospital policies and procedures.

**CAUTION:** The CONSENSUS® and the TAPERSET™ hip system is MR Unsafe per ASTM F2503 as it has not been evaluated for safety in the MR environment. Patients should register their implant information with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)), or equivalent organization.

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

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### ***Introduction***

The Consensus<sup>®</sup> Hip System was developed from well established and clinically proven design principles. With consistent application of those principles and a logical system of instrumentation, the Consensus<sup>®</sup> Hip System offers the surgeon a variety of implant options, providing excellent performance for a wide spectrum of patient indications.



### ***Femoral Heads***

Femoral heads are available in cobalt chrome or BIOLOX<sup>®</sup> delta ceramic. They are ultra-precision manufactured to high sphericity and surface finish to minimize wear.

### ***Acetabular Inserts***

The acetabular insert is offered in a neutral design as well as a 20° hooded design. The hooded acetabular insert provides additional coverage to increase the stability of the reconstructed hip. Inserts are available in Ultra High Molecular Weight and Highly Cross-Linked Polyethylene.

### ***Acetabular Shells***

The Consensus<sup>®</sup> Acetabular Shell offers a metal backed and an all polyethylene acetabular component. Metal backed components are intended for cementless use, or for cemented use at the discretion of the surgeon. All polyethylene acetabular components are intended for cemented use only. The CS2<sup>™</sup> Cup is available in either a hemispherical or flared rim design. Screw holes are provided as an option for enhanced component fixation.

*Note: Please refer to surgical techniques specific to Consensus<sup>®</sup> Acetabular Shell and CS2<sup>™</sup> Cup for information on acetabular preparation.*

## ***Introduction***

The TaperSet Total Hip System was designed to provide surgeons with a proven hip system based upon the experience and success of the Mueller flat tapered stems of the past 30 years. The TaperSet Total Hip System incorporates the following design features:



- Dual taper wedge geometry providing excellent stability in both mediolateral and anteroposterior planes.
- 135° neck angle allows for restoration of joint mechanics.
- Neck geometry allowing for a maximum range of motion.
- 10 Standard and 10 High-Offset options to restore biomechanics without lengthening the leg.
- Proximal circumferential porous plasma spray coating provides for biological fixation at the implant-bone interface
- Ti-6Al-4V alloy has proven biocompatibility without excessive stiffness.
- Instrumentation designed for accuracy and simplicity.
- 12/14 Neck Taper – Compatible with Consensus Femoral Heads.
- Bone conserving design.

## ***Indications for Use:***

The TaperSet™ Hip System is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System.

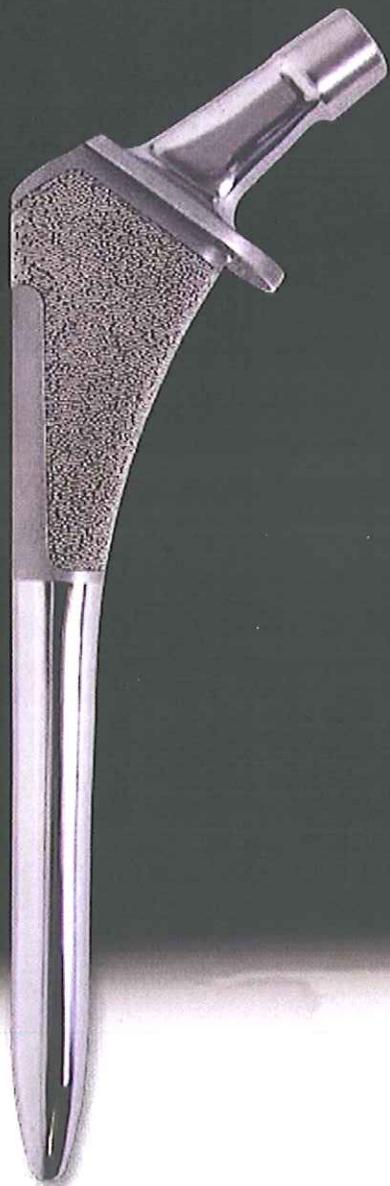
The **Consensus® Hip System** was developed from **well established** and **clinically proven** design principles. With consistent application of those principles and a **logical system of instruments**, the **Consensus® Hip System** offers the surgeon a **variety of implant options**, providing **excellent performance** for a wide spectrum of patients.

#### Shells

- Available without screw holes or with a superior cluster of three screw holes to enhance fixation
- Commercially pure titanium beaded porous coating
- Available in diameters from 42mm to 68mm
- Hemispherical or flared rim geometries

#### Inserts

- 36mm ID inserts for 52-68mm shells
- 32mm ID inserts for 48-68mm shells
- 28mm ID inserts for 46-68mm shells
- Available in 20° hooded and neutral options
- High density or highly cross-linked polyethylene



#### Heads

- 36mm BIOLOX® *delta* available in -4, 0, +4, and +8mm offsets
- 32mm BIOLOX® *delta* available in -4, 0, +4, and +7mm offsets
- 28mm BIOLOX® *delta* available in -3.5, 0, +3.5 offsets
- 36mm CoCr available in -5, 0, +5, and +10mm offsets
- 32mm CoCr available in -5, 0, +5, and +10mm offsets
- 28mm CoCr available in -5, 0, +5, and +10mm offsets

#### Stems

- 128° neck angle allows for restoration of lateral offset while maintaining proper leg length
- Press-fit stem geometry provides a 1mm press-fit in the metaphysis and line-to-line slip-fit in the diaphysis to promote loading of the proximal femur and provide initial stability and fixation of the implant
- Stems are forged from either Ti-6Al-4V or CoCr for improved strength and biocompatibility
- Full radius porous-coated collar loads medial calcar to preserve proximal bone
- Polished neck and distal bullet

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The **TaperSet Hip System** was developed from **well-established** and **proven** design principles. With consistent application of those principles and a **logical system of instruments**, the **Consensus<sup>®</sup> Hip System** offers the surgeon a **variety of implant options**, providing **excellent performance** for a wide spectrum of patients.

### Stems

- Standard and lateral offset options to restore biomechanics without lengthening the leg
- Proximal circumferential porous plasma spray coating provides for biological fixation at the implant-bone interface
- Dual taper wedge geometry provides excellent stability in both mediolateral and anteroposterior planes
- Ti-6Al-4V alloy has proven biocompatibility without excessive stiffness
- 135° neck angle allows for restoration of joint mechanics
- Bone conserving design



### Heads

- 36mm BIOLOX<sup>®</sup> *delta* available in -4, 0, +4, and +8mm offsets
- 32mm BIOLOX<sup>®</sup> *delta* available in -4, 0, +4, and +7mm offsets
- 28mm BIOLOX<sup>®</sup> *delta* available in -3.5, 0, +3.5 offsets
- 36mm CoCr available in -5, 0, +5, and +10mm offsets
- 32mm CoCr available in -5, 0, +5, and +10mm offsets
- 28mm CoCr available in -5, 0, +5, and +10mm offsets

### Inserts

- 36mm ID inserts for 52-68mm shells
- 32mm ID inserts for 48-68mm shells
- 28mm ID inserts for 46-68mm shells
- Available in 20° hooded and neutral options
- High density or highly cross-linked polyethylene

### Shells

- Available without screw holes or with a superior cluster of three screw holes to enhance fixation
- Commercially pure titanium beaded porous coating
- Available in diameters from 42mm to 68mm
- Hemispherical or flared rim geometries



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www.consensusortho.com

# UniSyn™ Hip System



*59 Head Centers*

*Infinite Version Control*

**Attachment VIII – Master File Reference Letter and Material Info**













































**Attachment IX – Mechanical Test Reports**

















































COVER SHEET MEMORANDUM

From: Reviewer Name Michael Kasser  
Subject: 510(k) Number K110542  
To: The Record

- Please list CTS decision code SE
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist [http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0\\_5631/Screening%20Checklist%207%202%2007.doc](http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc))
  - Hold (Additional Information or Telephone Hold).
  - Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	Y	
510(k) Summary /510(k) Statement	Attach Summary	Y	
Truthful and Accurate Statement.	Must be present for a Final Decision	Y	
Is the device Class III? If yes, does firm include Class III Summary?	Must be present for a Final Decision		N
Does firm reference standards? (If yes, please attach form from <a href="http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf">http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf</a> )		Y	
Is this a combination product? (Please specify category <u>N</u> , see <a href="http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC">http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC</a> )			N
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, <a href="http://www.fda.gov/cdrh/ode/guidance/1216.html">http://www.fda.gov/cdrh/ode/guidance/1216.html</a> )			N
Is this device intended for pediatric use only?			N
Is this a prescription device? (If both prescription & OTC, check both boxes.)		Y	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			N
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)			N
Does this device include an Animal Tissue Source?			N
All Pediatric Patients age <=21			N
Neonate/Newborn (Birth to 28 days)			N
Infant (29 days -< 2 years old)			N
Child (2 years -< 12 years old)			N
Adolescent (12 years -< 18 years old)			N
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.)			N

Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		N
Nanotechnology		N
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, <a href="http://www.fda.gov/cdrh/comp/guidance/169.html">http://www.fda.gov/cdrh/comp/guidance/169.html</a> )	Contact OC.	N

Regulation Number 888 3358 Class\* II Product Code LPH

(\*If unclassified, see 510(k) Staff)

Additional Product Codes: LZO

Review: \_\_\_\_\_ (Branch Chief) 0JDB (Branch Code) 4/1/2011 (Date)

Final Review: \_\_\_\_\_ (Division Director) [Signature] (Date) 4/1/11





Food and Drug Administration  
Office of Device Evaluation  
9200 Corporate Boulevard  
Rockville, MD 20850

Premarket Notification [510(k)] Review  
Traditional

K110542

Date: 4/11/11

To: The Record

Office: ODE

From: Michael Kasser, Materials Engineer, PhD, OJDB

Division: DSORD

510(k) Holder: Consensus Orthopedics, Inc.

Device Name: Consensus Biolox Delta Ceramic Femoral Heads

Contact: Matthew Hull, RAC

Phone: (916) 355-7156

Fax: (916) 355-7190

Email: mhull@consensusortho.com

*Agree PAK 4/11/11*

I. Purpose and Submission Summary:

(b)(4) Trade Secret Process

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: <b>Prescription</b> or OTC)	X		
Truthful and Accuracy Statement	X		
<b>510(k) Summary</b> or 510(k) Statement	X		
Standards Form (ISO 6474, 14971, 14630, 21534, 21535, 7206-1,10 10993-1,7, 11135-1, 11137-1,2, 11607)	X		

*Reviewer Comment: The 510(k) Summary is adequate.*

III. Device Description

(b)(4) Trade Secret Process

K935193 Consensus Hip System - Porous Coated Titanium Femoral Stem  
 K935453 CONSENSUS HIP SYSTEM-HA COATED TITANIUM FEMORAL STEM  
 K933499 CONSENSUS HIP SYSTEM- NON-POROUS TITANIUM FEMORAL STEM  
 K030151 CONSENSUS HIP SYSTEM, UNISYN HIP SYSTEM  
 K102399 TaperSet Hip System

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See the predicate device section for description of compatible components

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?	X		
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?		X	

#### IV. Indications for Use

The Consensus hip systems are designed for total or partial hip arthroplasty and are only intended to be used with compatible Consensus components per the appropriate system specific indications.

The general indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

Consensus hip system implants are intended for uncemented or cemented use per the system specific indications.

(b)(4) Trade Secret Process

#### V. Predicate Device Comparison

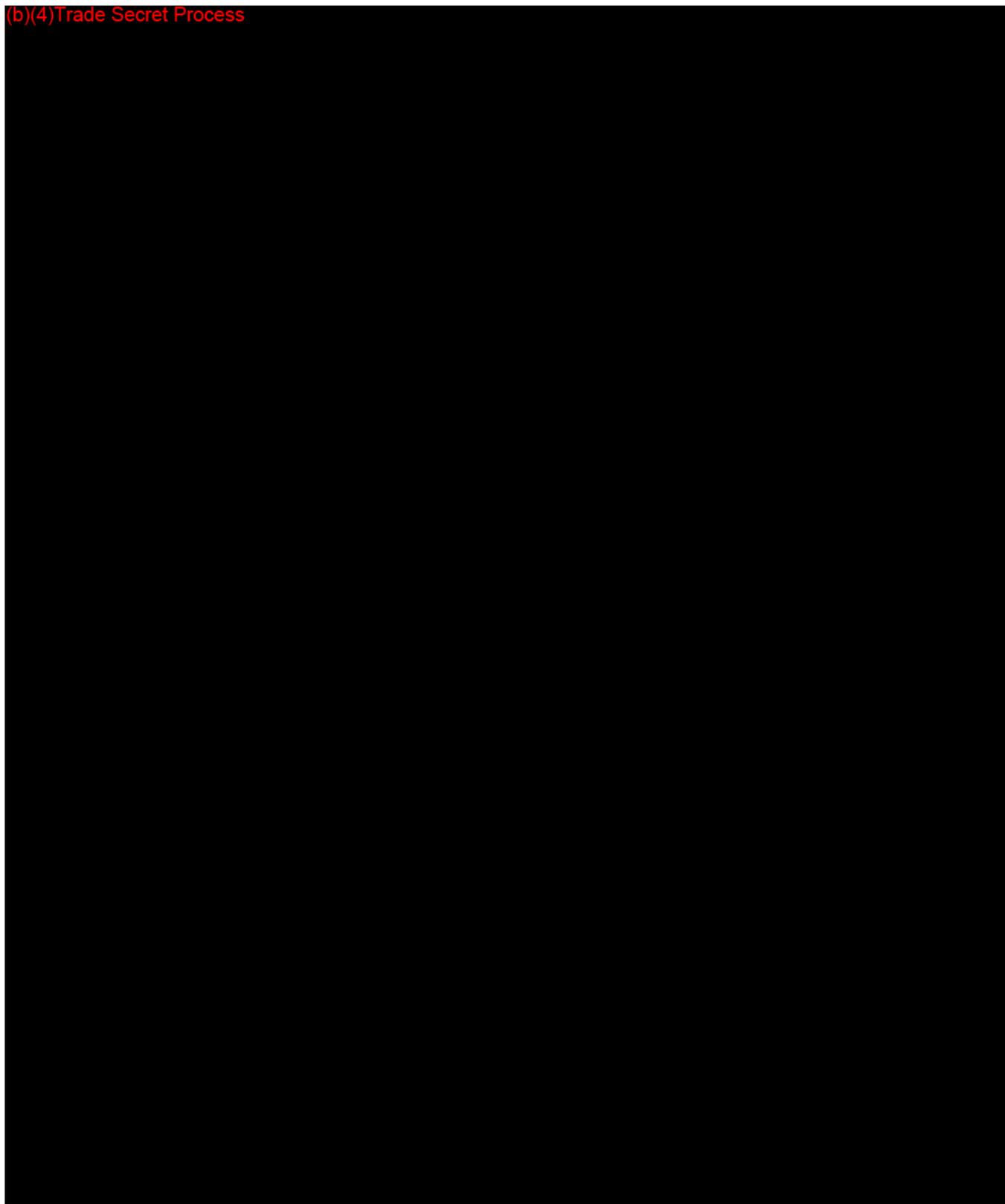
Systems:

K922561 CONSENSUS TOTAL HIP SYSTEM  
 K003649 UNISYN HIP SYSTEM  
 K102399 Consensus TaperSet Hip System  
 K081973 Aesculap Consensus Acetabular Cups for use with Aesculap Excia and Metha Hip Systems  
 K082991 Aesculap BioloX Delta Ceramic Femoral Head

**Description of Predicates:**

K922561, K933499, K935193, K935453, K953792, K955386, K960339, K960156, K960151, K070061, K020153, K021466, K030151, K060635, K100933 CONSENSUS TOTAL HIP SYSTEM

(b)(4)Trade Secret Process



**VI. Labeling**

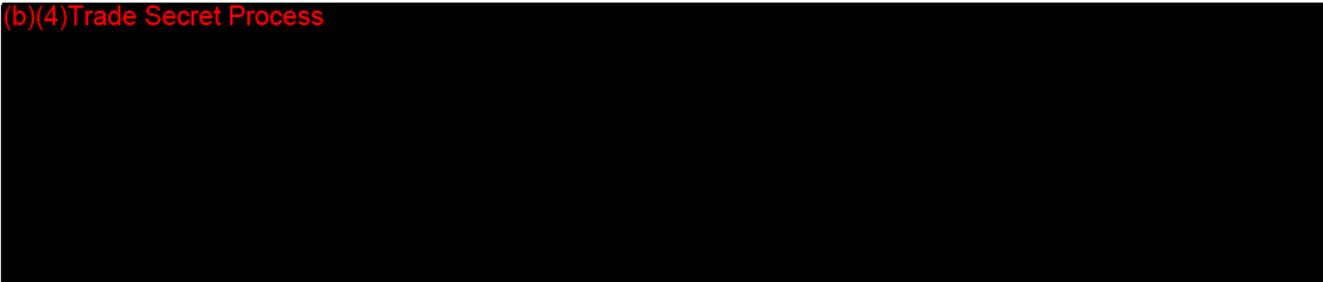
**Package Label:**

(b)(4)Trade Secret Process



**Package Insert:**

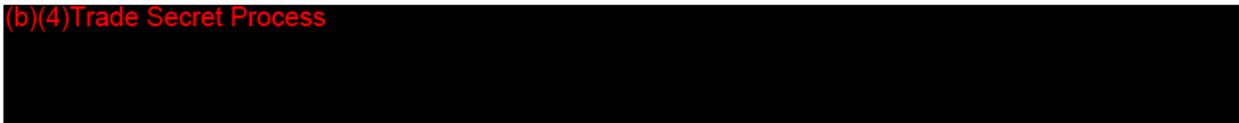
(b)(4)Trade Secret Process



**Surgical Procedure:**

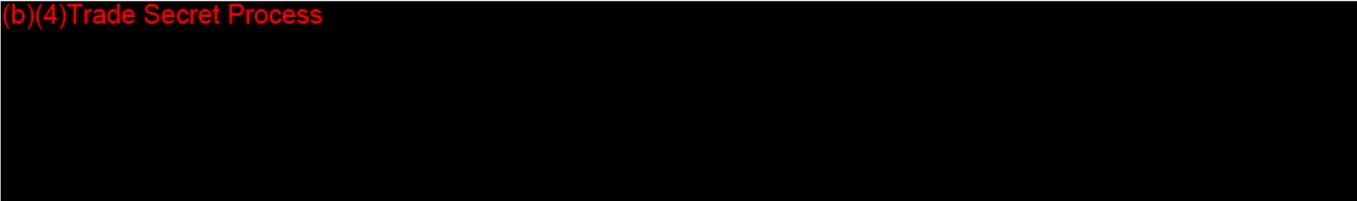
Provided.

(b)(4)Trade Secret Process



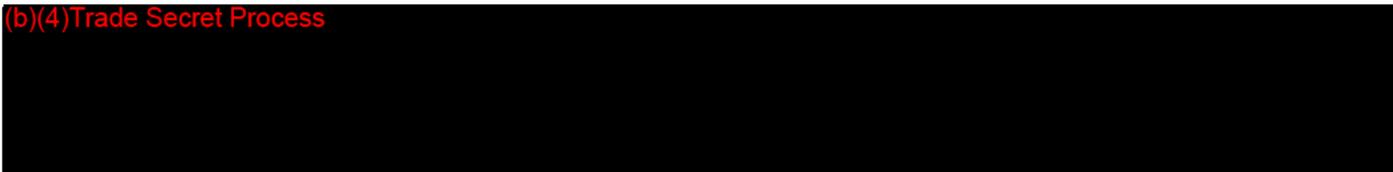
**VII. Sterilization/Shelf Life/Reuse**

(b)(4)Trade Secret Process



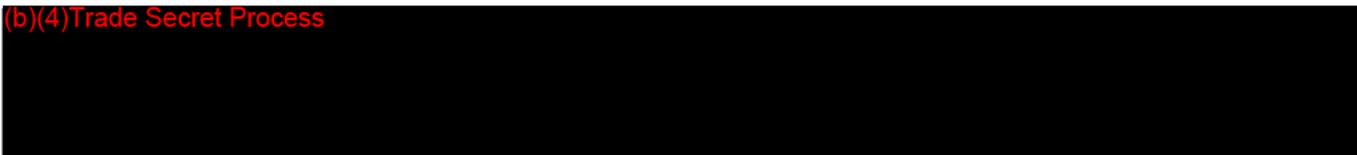
**Packaging/Shelf Life:**

(b)(4)Trade Secret Process



**VIII. Biocompatibility**

(b)(4)Trade Secret Process



**IX. Software**

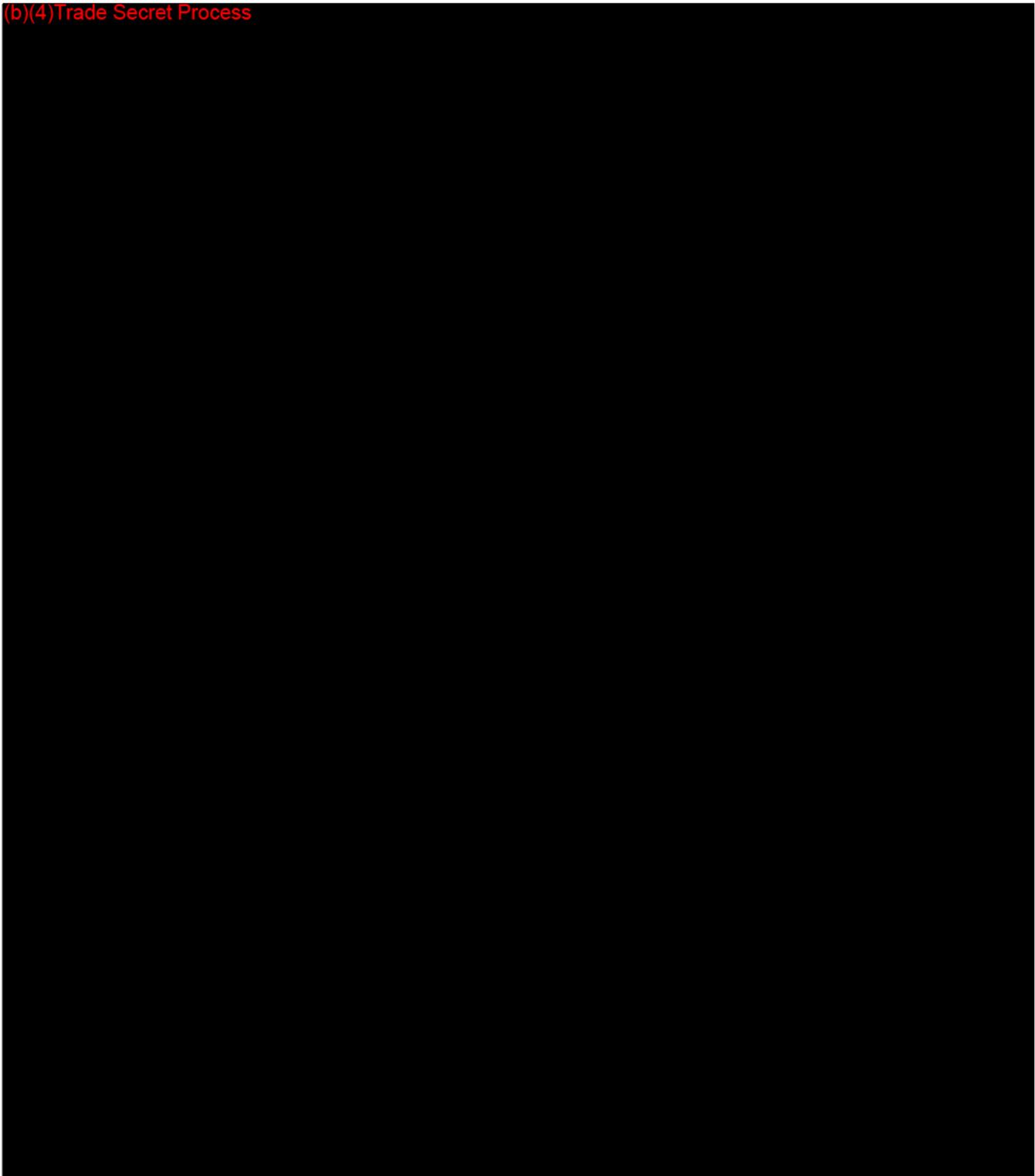
N/A

**X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety**

N/A

**XI. Performance Testing – Bench**

(b)(4)Trade Secret Process



**XII. Performance Testing – Animal**

Not performed.

**XIII. Performance Testing – Clinical**

Not performed.

**XIV. Substantial Equivalence Discussion**

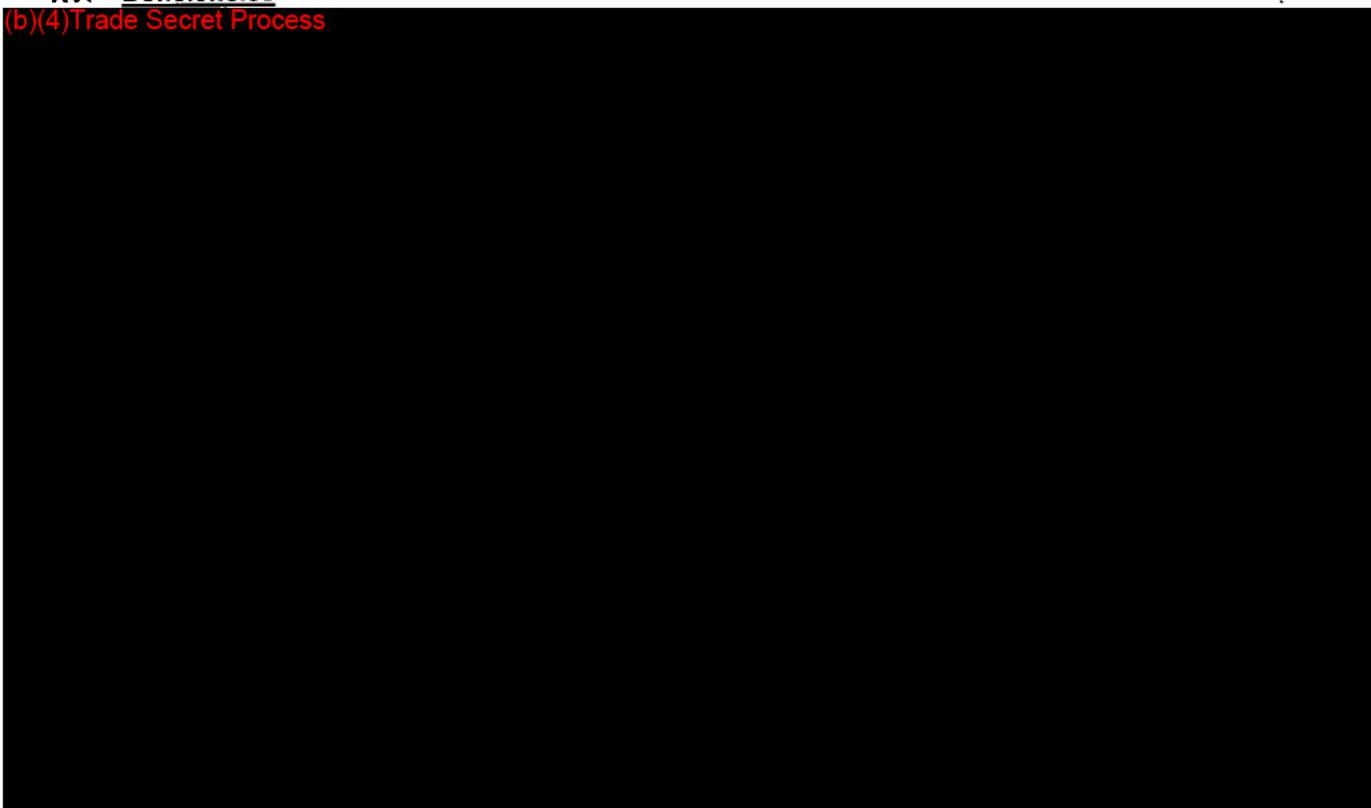
	Yes	No	
1. Same Indication Statement?	X		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
3. Same Technological Characteristics?	X		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 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?	X		Final Decision: SE

(b)(4)Trade Secret Process



**XV. Deficiencies**

(b)(4)Trade Secret Process





**XVI. Contact History**

See CTS for contact history.

**XVII. Recommendation: SE**

Regulation Number: 21 CFR 888.3358

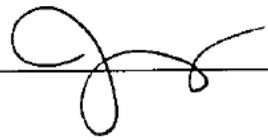
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH

  
\_\_\_\_\_

Reviewer

  
\_\_\_\_\_

Branch Chief

4/1/11  
\_\_\_\_\_  
Date

4/1/2011  
\_\_\_\_\_  
Date

**Kasser, Michael**

---

**From:** Matt Hull [mhull@consensusortho.com]  
**Sent:** Thursday, March 31, 2011 3:42 PM  
**To:** Kasser, Michael  
**Cc:** Justin Creel  
**Subject:** RE: K110542 Consensus BioloX Delta Ceramic Femoral Heads  
**Follow Up Flag:** Follow up  
**Flag Status:** Red  
**Attachments:** K110542 Response Document.pdf

Michael,

Attached please find our response to your e-mail below from 28 March. If you have any additional questions please feel free to call or e-mail me. Thanks.

Matt



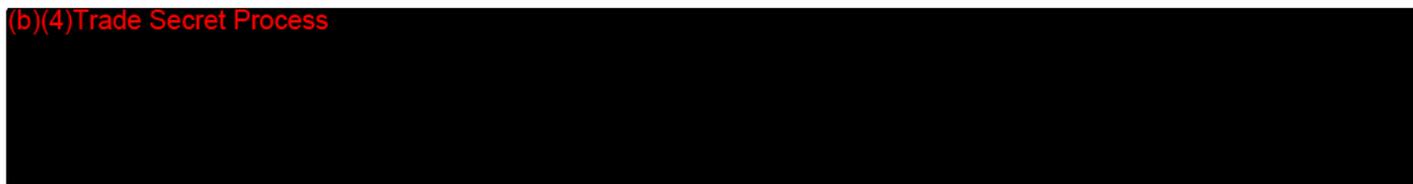
Matt Hull  
Director of QS & RA  
1115 Windfield Way, Suite 100  
El Dorado Hills, CA 95762  
P:916-355-7156 F:916-355-7190  
[www.consensusortho.com](http://www.consensusortho.com)

---

**From:** Kasser, Michael [mailto:Michael.Kasser@fda.hhs.gov]  
**Sent:** Wednesday, March 30, 2011 1:13 PM  
**To:** Matt Hull  
**Subject:** RE: K110542 Consensus BioloX Delta Ceramic Femoral Heads

Matt,

(b)(4)Trade Secret Process

A large black rectangular redaction box covers the majority of the page content below the signature of Michael Kasser.

Thanks,

Michael Kasser, PhD

---

**From:** Matt Hull [mailto:mhull@consensusortho.com]

**Sent:** Monday, March 28, 2011 2:45 PM  
**To:** Kasser, Michael  
**Subject:** RE: K110542 Consensus BioloX Delta Ceramic Femoral Heads

Dear Dr. Kasser,

(b)(4)Trade Secret Process



Matt

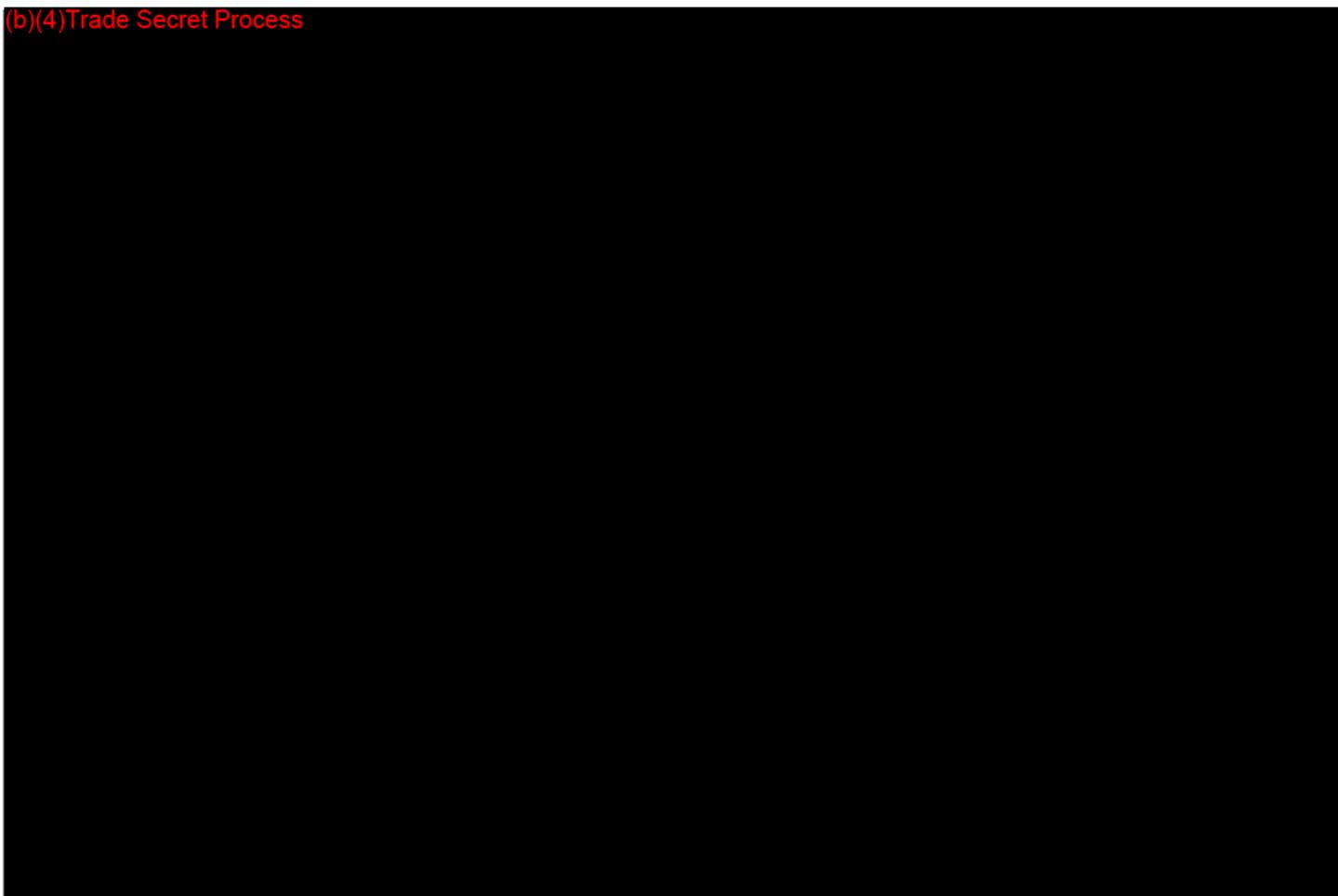
---

**From:** Kasser, Michael [mailto:Michael.Kasser@fda.hhs.gov]  
**Sent:** Monday, March 28, 2011 9:52 AM  
**To:** Matt Hull  
**Subject:** K110542 Consensus BioloX Delta Ceramic Femoral Heads

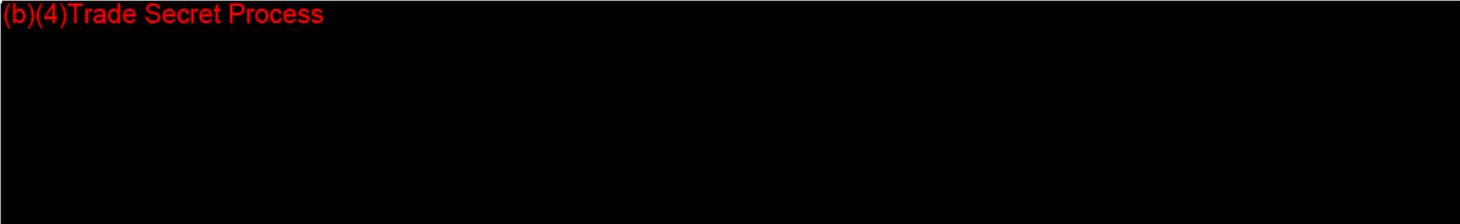
Dear Mr. Hull,

I am the FDA reviewer assigned to review 510(k) K110542 Consensus BioloX Delta Ceramic Femoral Heads. Upon reviewing your submission, I noted several deficiencies that need to be addressed before I can determine substantial equivalence.

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



Sincerely,

Michael Kasser, PhD  
Materials Engineer  
CDRH/ODE/DSORD/OJDB  
(301) 796 6946  
michael.kasser@fda.hhs.gov



31 March 2011

1115 Windfield Way, Ste 100  
Attn: Matthew M. Hull, RAC  
El Dorado Hills, CA 95762  
[mhull@consensusortho.com](mailto:mhull@consensusortho.com)  
(916) 355-7156

FDA, CDRH  
Document Mail Center- WO66-G609  
Attn: Dr. Michael Kasser, ODE  
10903 New Hampshire Ave.  
Silver Spring, MD 20993-0002

RE: K110542, Consensus Biolox *delta* Ceramic Femoral Heads

Dear Dr. Kasser,

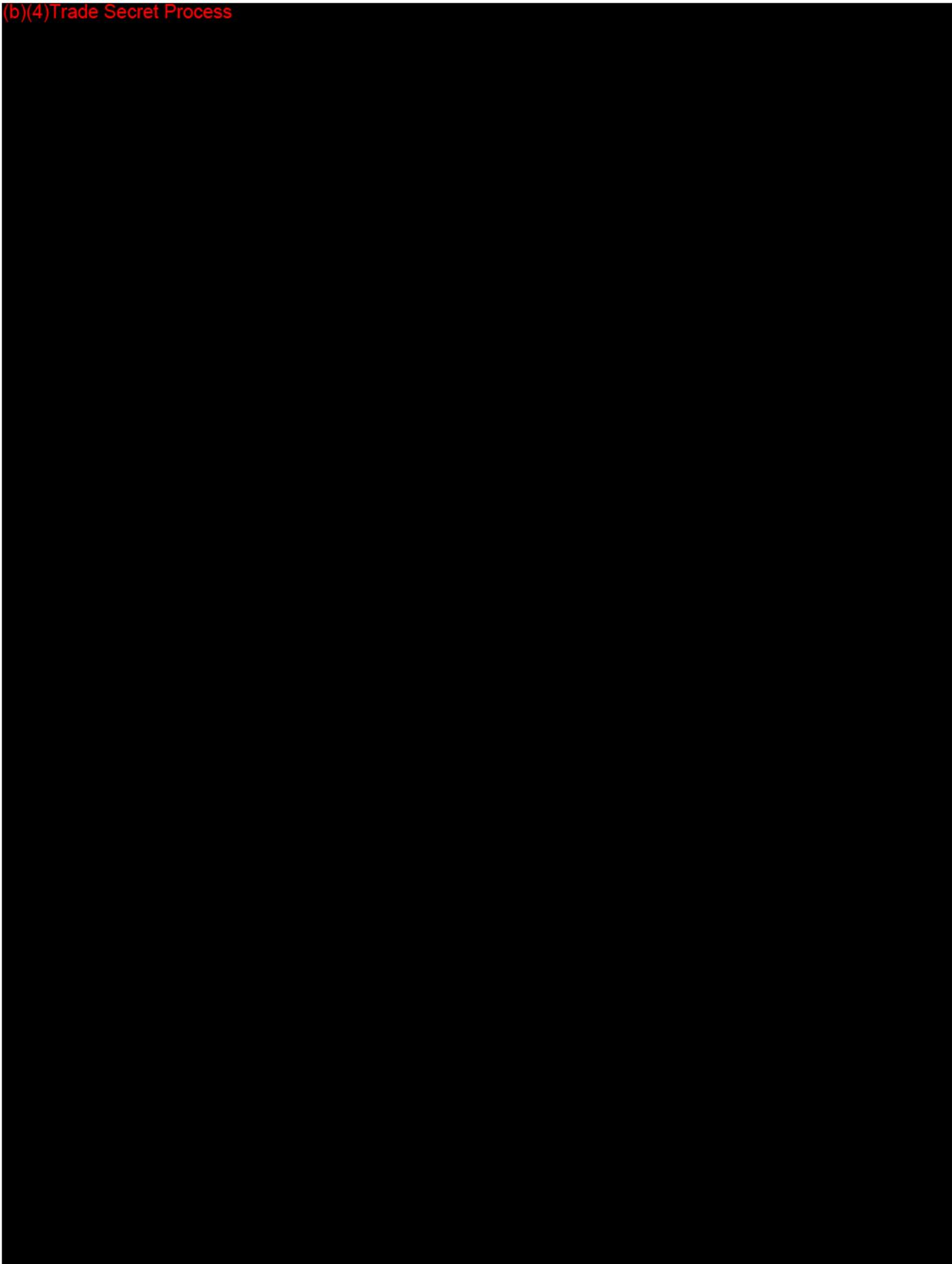
I am responding to your e-mail of 28 March 2011 regarding your request for additional information in support of our 510(k), K1110542 for the Consensus Biolox *delta* Ceramic Femoral Heads. I have included your original questions/comments in the following document, followed by our responses in bold. If you have any further questions or need clarification please contact me via telephone or e-mail as identified above. Thank you.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Matthew M. Hull". The signature is fluid and cursive, with the first and last names being more prominent.

Matthew M. Hull, RAC  
Director QS & RA

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process



**Attachment A**  
**Consensus Taper Design Comparison**













**Attachment B  
Revised Labeling**

916 642 3554

**Kasser, Michael**

---

**From:** Matt Hull [mhull@consensusortho.com]  
**Sent:** Friday, April 01, 2011 1:57 PM  
**To:** Kasser, Michael  
**Subject:** K110542 Requested Labeling Changes  
**Attachments:** CHS IFU 040111.pdf; UNISYN IFU 040111.pdf; CHS STM page 2 revision.pdf

Michael,

[REDACTED] (b) (4)

Matt



Matt Hull  
Director of QS & RA  
1115 Windfield Way, Suite 100  
El Dorado Hills, CA 95762  
P:916-355-7156 F:916-355-7190  
[www.consensusortho.com](http://www.consensusortho.com)

# CONSENSUS ORTHOPEDICS INC.

## CONSENSUS HIP SYSTEMS

### Instructions for Use (IFU)

**IMPORTANT INFORMATION FOR SURGEON: PLEASE READ PRIOR TO IMPLANTING THIS DEVICE IN A CLINICAL SETTING. THE SURGEON SHOULD BE FAMILIAR WITH THE SURGICAL TECHNIQUE.**

#### DESCRIPTION

The CONSENSUS ORTHOPEDICS, INC. TAPERSET™ HIP SYSTEM – PRIMARY HIP and the CONSENSUS® HIP SYSTEM – PRIMARY HIP are comprised of a femoral stem component, femoral head component, acetabular component and cancellous bone screws, and for cemented applications includes distal centralizers.

The femoral stem component of the CONSENSUS® HIP SYSTEM is manufactured from forged cobalt chrome alloy (CoCrMo, ASTM F799) for cemented applications, or forged titanium alloy (Ti 6Al-4V ELI, ASTM F620) for uncemented applications.

The femoral stem component of the TAPERSET™ HIP SYSTEM is manufactured from wrought Titanium alloy (Ti-6Al-4V ELI, ASTM F136). The proximal portion of the femoral stem component is plasma sprayed with commercially pure Titanium (C. P. Ti, ASTM F1580). The femoral stem is available in both standard and 7mm lateralized options.

The CONSENSUS® femoral head components is manufactured from either Cobalt Chrome alloy (CoCrMo, ASTM F799 or ASTM F1537) or Biolox *delta* Ceramic (Al<sub>2</sub>O<sub>3</sub>, ZrO<sub>2</sub>, ISO 6474). All femoral heads are highly polished and available in multiple neck lengths and head diameters. Cobalt Chrome femoral heads are designed for use with all CONSENSUS® and TAPERSET™ femoral stems, and Biolox *delta* Ceramic femoral heads are designed for use only with titanium alloy CONSENSUS® and TAPERSET™ femoral stems.

The CONSENSUS® acetabular component consists of a shell and a mating insert. The acetabular component is designed for cemented or uncemented use. The acetabular shell is manufactured from Titanium alloy (Ti-6Al-4V ELI, ASTM F620 or ASTM F136), with a porous coating of commercially pure Titanium beads (C.P. Ti ASTM F-67). The acetabular shells are available in four different configurations. These are (1) Hemispherical with screw holes, (2) Hemispherical without screw holes, (3) Flared rim with screw holes and (4) Flared rim without screw holes. The component has matching circumferential scallops on the shell and insert that rotationally secure the insert in the shell and allow for dialing the insert in a desired orientation. The shells with screw holes have three anatomically placed holes, which accommodate optional cancellous bone screws to augment initial fixation. An optional CONSENSUS® apical dome hole plug and cement pod spacer are available. The acetabular insert is manufactured from either ultra-high molecular weight Polyethylene (UHMWPE, ASTM F648) or highly cross linked

Polyethylene (UHMWPE, ASTM F648), and features a Titanium alloy X-ray marker (Ti-6Al-4V ELI, ASTM F136).

The cancellous bone screws are manufactured from wrought Titanium alloy (Ti 6Al-4V ELI, ASTM F136). The cancellous bone screws are 6.5mm diameter and have a low profile head with a hex drive recess.

The CONSENSUS BIPOLAR and UNIPOLAR are intended for cementless use and are designed for use with CONSENSUS® and TAPERSET™ femoral stem components. The CONSENSUS BIPOLAR consists of a bipolar femoral head component with preassembled locking ring and bipolar insert component. The CONSENSUS UNIPOLAR consists of only a unipolar femoral head component. The bipolar femoral head component is manufactured from Cobalt Chrome alloy (CoCrMo, ASTM F75, ASTM F799, or ASTM F1537). The bipolar head has a highly polished spherical outer surface with a cylindrical bored internal diameter which accepts the polyethylene bipolar insert. The bipolar head comes with a polyethylene locking ring preassembled in a circumferential groove on the internal diameter. The bipolar insert component and locking ring are manufactured from ultra-high molecular weight polyethylene (UHMWPE, ASTM F648). The bipolar insert and locking ring are designed for use with the appropriate size bipolar head component. The unipolar femoral heads are manufactured from cobalt chrome alloy (CoCrMo, ASTM F75 or ASTM F1537).

The CONSENSUS ALL-POLY ACETABULAR CUP is designed for use with CONSENSUS® and TAPERSET™ femoral stem components. The CONSENSUS ALL-POLY ACETABULAR CUP is a one piece acetabular component designed for cemented use only, manufactured from ultra-high molecular weight Polyethylene (UHMWPE, ASTM F648), and like the acetabular insert, features a titanium alloy X-ray marker (Ti 6Al-4V ELI, ASTM F136).

The proximal spacer, distal centralizer, apical dome hole plug and cement pod spacer are manufactured from polymethylmethacrylate (PMMA, ASTM F451). The proximal spacer and distal centralizer are designed for use with the CoCr femoral stem component for cemented applications.

#### **HOW PRODUCT IS SUPPLIED**

Each component of the CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM is supplied STERILE, is contained in individual boxes or packages designed to maintain sterility, and is available in a wide range of sizes. Please refer to the current price list, surgical technique or catalog for the catalog numbers and sizes available.

#### **INDICATIONS FOR USE OF THE CONSENSUS® HIP SYSTEM-PRIMARY HIP:**

The CONSENSUS® HIP SYSTEM is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the CONSENSUS® HIP SYSTEM.

The indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.

- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The CONSENSUS® hip stem is indicated for cemented or cementless use.

#### **INDICATIONS FOR USE OF THE TAPERSET™ HIP SYSTEM-PRIMARY HIP**

The TaperSet™ Hip System is designed for total or partial hip arthroplasty and is intended to be used with compatible components of the Consensus Hip System.

The indications for use are:

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, cup arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, osteoporosis, pseudarthrosis conversion, and structural abnormalities.

The TaperSet™ hip stem is indicated for cementless use.

#### **INDICATIONS FOR USE OF THE CONSENSUS® BIPOLAR OR UNIPOLAR:**

- A. Primary replacement of the femoral head and neck with very little if any acetabular degradation noted.
- B. Rheumatoid, osteo, and post traumatic arthritis.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-unions of proximal femoral neck fractures.
- F. Revision of failed total hip arthroplasty.
- G. Treatment of malunion or nonunion acetabular fractures.

The CONSENSUS BIPOLAR OR UNIPOLAR are intended for cementless use.

#### **INTENDED PERFORMANCE**

All components of the CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM are intended to perform in a safe and effective manner in restoring hip function within the intended use of the product.

- H. The CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM range of motion complies with ISO 21535, except that the 28/+10mm CoCr femoral head used with the 20 degree hooded acetabular insert limits flexion/extension to 98 degrees in both the CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM.
- I. The CONSENSUS® HIP SYSTEM and the TAPERSET™ HIP SYSTEM are designed to transmit load to the femur during daily activities including, but not limited to walking, stair climbing, and chair ascent.
- J. The femoral and acetabular components are designed to minimize stress shielding at the bone-implant interface when compared with CoCr.
- K. The matching articulating surfaces at the acetabular-femoral articulation are intended to reduce wear over time when compared with point loading.
- L. The high polish finish of the articulating surface of the CoCr and BioloX *delta* Ceramic femoral heads is intended to reduce wear of the acetabular insert.
- M. The high polish finish of the unipolar and bipolar heads is intended to reduce wear of the natural acetabular cartilage.
- N. The proximal fixation surfaces of nonporous femoral stems are grit blasted to enhance adhesion at the implant-cement interface.
- O. The proximal fixation surfaces of porous CONSENSUS® and TAPERSET™ stems and the external fixation surfaces of acetabular components are porous coated to provide biological fixation at the implant-bone interface.

#### **CONTRAINDICATIONS**

- A. Any joint with active or suspected latent infection.
- B. Neuromuscular disorders or mental conditions whereby the risks associated with these conditions are outweighed by the benefits to be derived.
- C. Any condition of the bone stock in which sufficient support and fixation of the implant is in question.
- D. Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
- E. Any pathological conditions of the joint that would interfere in achieving appropriate range of motion, adequate head stability, and a well seated and supported prosthetic combination.
- F. Ligamentous or severe muscle laxity or inadequate soft tissue coverage to allow for the normal healing process and for proper hip mechanics to be reestablished.

#### **WARNINGS**

- A. All CONSENSUS® HIP SYSTEM and TAPERSET™ HIP SYSTEM components are sold sterile. If packages appear damaged or tampered with, they should be returned to the supplier.
- B. Do not implant any device that has been used, even if it appears undamaged.
- C. Machined taper surfaces of the femoral stem and head must be clean and dry at the time of assembly to ensure proper seating of the implant.

- D. Care must be taken to properly impact the femoral head to prevent any discrepancy in neck length, disassociation, or dislocation.
- E. Do not bend or contour an implant, as this may reduce its fatigue strength and may cause immediate or eventual failure under load.
- F. Never tamper with implants. Tampering may have a detrimental affect on the performance of the implant.
- G. The surgeon and O.R. staff must be extremely careful to protect all components from being marred, nicked, or notched as a result of contact with metal or any abrasive objects. This is particularly important for polished bearing areas and machined taper surfaces.
- H. The Biolox *delta* Ceramic Femoral Head is to be used ONLY with CONSENSUS ORTHOPEDICS, INC. titanium hip stems with a 12/14 taper trunnion.
- I. CONSENSUS® and TAPERSET™ femoral stems may ONLY be used in conjunction with CONSENSUS metal femoral heads or with Biolox *delta* Ceramic femoral heads.
- J. CONSENSUS femoral heads may ONLY be used in conjunction with CONSENSUS acetabular components.
- K. CONSENSUS® and TAPERSET™ hip products should not be used in conjunction with the 28/+10mm femoral head and the 20° hooded insert.

#### **PRECAUTIONS**

- A. Before any implant is used, the surgeon should be completely familiar with all aspects of the surgical procedure and the limitations of the device.
- B. It cannot be expected that joint replacements will withstand the same activity levels as normal healthy bone.
- C. Excessive physical activity may result in premature failure of the implant system due to loosening, component fracture, and/or wear. Activities which place unreasonable amounts of stress on the joint should be avoided. Patients should be instructed on the limitations of the prosthesis and how to modify their activities accordingly.
- D. Obese patients may place severe loading on the affected extremity which can be expected to accelerate joint failure. If appropriate, patients should be advised to follow a weight reduction or maintenance program.
- E. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Total joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding the activity and joint loading are assured.
- F. Proper selection of fixation type and placement of the femoral stem and acetabular component are critical factors in the prevention of unusual stress conditions and their potentially harmful affects on the life expectancy of the implant.

#### **ADVERSE EFFECTS**

- A. All prosthetic replacements have the potential for adverse effects, including infection, loosening, fracture, breakage, bending of the components, component disassembly, or positional changes of the components.
- B. Sensitivity reactions to component materials could occur, and should be ruled out preoperatively.
- C. Total joint replacement surgery is associated with serious complications including, but not limited to: nerve injury, direct arterial injury, false aneurysm, spontaneous vascular occlusion, deep vein thrombosis, ectopic ossification, non-union, dislocation, disassociation, superficial and deep infection, aseptic loosening, component failure, cement breakdown, and third party wear associated with polymethylmethacrylate or UHMWPE.
- D. Acetabular pain due to loosening of the implant, and/or localized pressure associated with incongruencies of the fit, or tissue inflammation of unknown etiology.
- E. Reoperation may be necessary to correct adverse effects.
- F. On rare occasions, complications may require arthrodesis, Girdlestone procedure or amputation of the limb.
- G. Other complications generally associated with surgery, drugs, blood use, or ancillary devices used.

## **INFORMATION**

Surgical techniques may be obtained from a CONSENSUS ORTHOPEDICS representative or the company directly.

## **STERILIZATION AND HANDLING**

All components have been sterilized through an Ethylene Oxide sterilization process. Do not use any component if the package has been breached.

USE CAUTION IN HANDLING PLASMA SPRAYED or POROUS COATED COMPONENTS TO PREVENT CONTAMINATION OF THE COATING OR ENTRAPMENT OF DEBRIS IN THE COATING.

COMPONENTS THAT ARE MANUFACTURED FROM ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE), POLYMETHYL-METHACRYLATE (PMMA) OR CERAMIC SHOULD NOT BE AUTOCLAVED.

## **CERAMIC FEMORAL HEAD INSTRUCTIONS FOR USE**

### **PREPARATORY PHASE**

- A. Use ceramic heads only on stems with tapers approved for ceramic heads.
- B. A ceramic head impacted once, and then removed, must not be mounted onto another stem.
- C. Never place a ceramic femoral head onto a stem taper that has previously been in use with a head of any type. A metal head must be used as a replacement for any type of head that has been removed from a stem taper.
- D. Never use a ceramic head which has fallen to the floor.
- E. Avoid thermal shocks to ceramic heads. Do not quench the ceramic components in cold liquids.

## **DURING OPERATION**

- A. Keep metal instruments clear of taper. Taper surface of CONSENSUS™ stem must not be scratched or damaged.
- B. Clean and dry taper of femoral stem and ceramic head before attaching the ceramic head.
- C. Use only plastic impactor to fasten ceramic heads. Never use a metal impaction instrument.

## **REPLACEMENT OF FRACTURED CERAMIC HEAD**

In the case of a fractured ceramic head, remove all ceramic particles from the wound. If you wish to replace the fractured ceramic head with another ceramic head, the polyethylene insert and femoral stem must be changed. If the stem taper is undamaged, a metal head may be used with the existing stem in lieu of a ceramic head.

**WARNING:** Single Use Only: This product is intended for single use only. Do not attempt to re-use, even if the device appears to be undamaged. Risks include device damage leading to poor performance or failure, patient cross-contamination, inadequate sterilization and general liability.

**CAUTION:** Disposal of single-use implant device - This device should be regarded as bio-contaminated and handled accordingly. Plastic or metal implants should be terminally sterilized and disposed of following existing hospital policies and procedures.

**CAUTION:** The CONSENSUS® and the TAPERSET™ hip system has not been evaluated for safety in the MR environment. Patients should register their implant information with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)), or equivalent organization.

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

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800-240-0500  
916-355-7100

# CONSENSUS ORTHOPEDICS INC.

## UNISYN™ HIP SYSTEM

### Instructions for Use (IFU)

**IMPORTANT INFORMATION FOR SURGEON: PLEASE READ PRIOR TO IMPLANTING THIS DEVICE IN A CLINICAL SETTING. THE SURGEON SHOULD BE FAMILIAR WITH THE SURGICAL TECHNIQUE.**

#### DESCRIPTION

The CONSENSUS ORTHOPEDICS, INC. UNISYN™ HIP SYSTEM - PRIMARY/REVISION Hip is comprised of four modular components – a neck segment, a body segment, a stem, and a locking nut. The modular neck segment is manufactured from titanium alloy (Ti-6Al-4V, ASTM F620). It attaches to the body segment by means of a locking taper and flexible collet junction. Multiple neck options are provided to allow horizontal and vertical offset adjustment. The neck segment utilizes a Morse taper as a means for attaching a modular femoral head. The body segment is manufactured from titanium alloy (Ti 6Al 4V, ASTM F136 or ASTM F1472). Plasma sprayed necks and bodies are coated with commercially pure titanium (C. P. Ti, ASTM F1580). Body segments are also available with hydroxylapatite (HA) coating (empirical formula  $\text{Ca}_5(\text{PO}_4)_3\text{OH}$ , ASTM F1185). The stem components are manufactured from (Ti 6Al-4V, ASTM F1472). The stem is attached to the neck segment by means of a locking taper. The stem is then secured to the neck via a locking nut (Ti 6Al-4V, ASTM F136). The locking nut has a Spiralock® thread to resist loosening. The nut is applied to the stem after the stem has been preloaded and assembled. The UniSyn Hip System was designed for uncemented use, however, if it is necessary to cement a Unisyn hip we recommended the addition of cement to appropriately stabilize the chosen implant. The design details of all taper connections are proprietary to CONSENSUS ORTHOPEDICS, INC.

The UNISYN™ HIP SYSTEM may only be used in conjunction with CONSENSUS® ceramic and metal femoral heads, the CONSENSUS® ACETABULAR CUP, the CS2™ ACETABULAR CUP, CONSENSUS® low profile cancellous bone screws, CONSENSUS® BIPOLAR heads, CONSENSUS® UNIPOLAR heads, and the CONSENSUS® ALL-POLY ACETABULAR CUP. The UNISYN™ HIP SYSTEM is designed to allow full interchangeability between all UNISYN™ components of any size configuration for maximum intraoperative flexibility. CONSENSUS ORTHOPEDICS advises to use the 30 and 45mm locking nut with the 30 to 36mm and 45 to 55mm vertical offset neck sizes respectively. All UNISYN™ component configurations may be used with all CONSENSUS® femoral head and acetabular component configurations.

For a complete description of the CONSENSUS® HIP SYSTEM components for use with the UNISYN™ HIP SYSTEM, refer to the IFU included with the appropriate product package.

UNISYN™ stems used with roughened and plasma coated bodies are intended for cemented or uncemented use. UNISYN™ stems used with plasma/HA or HA coated bodies are intended for uncemented use only.

#### **HOW PRODUCT IS SUPPLIED**

Each component of the UNISYN™ HIP SYSTEM is supplied STERILE, is contained in individual boxes or packages designed to maintain sterility, and is available in a wide range of sizes. Please refer to the current price list, surgical technique or catalog for the catalog numbers and sizes available.

#### **INDICATIONS AND USAGE**

Indications for the use of the UNISYN™ HIP SYSTEM must be carefully considered with respect to the patient's entire evaluation and alternative procedures. The selection of the UNISYN™ HIP SYSTEM is based on the judgment of the surgeon as to the needs of the patient and the expected post-operative conditions. Patient selection is dependent on age, general health, available bone stock and quality, and any prior surgery or anticipated future surgery.

#### **Indications for use of the UNISYN™ HIP SYSTEM**

- A. Significantly impaired joints resulting from rheumatoid, osteo, and post-traumatic arthritis.
- B. Revision of failed femoral head replacement, hip arthroplasty or other hip procedures.
- C. Proximal femoral fractures.
- D. Avascular necrosis of the femoral head.
- E. Non-union of proximal femoral neck fractures.
- F. Other indications such as congenital dysplasia, arthrodesis conversion, coxa magna, coxa plana, coxa vara, coxa valga, developmental conditions, metabolic and tumorous conditions, osteomalacia, pseudarthrosis conversion, and structural abnormalities.

#### **INTENDED PERFORMANCE**

All components of the UNISYN™ HIP SYSTEM are intended to perform in a safe and effective manner in restoring hip function within the intended use of the product.

- A. The UniSyn® HIP SYSTEM range of motion complies with ISO 21535, except that the Consensus® Hip System 28mm/+10 CoCr femoral head used with the 20 degree hooded acetabular insert limits flexion/extension to 98 degrees.
- B. The UNISYN™ HIP SYSTEM is designed to transmit load to the femur during daily activities including, but not limited to walking, stair climbing, and chair ascent.
- C. The taper and collet connections between modular components of the UNISYN™ HIP SYSTEM are designed to reduce micromotion and fretting, and maximize total contact area for torsional strength and fatigue resistance.
- D. The UNISYN™ HIP SYSTEM is designed to minimize stress shielding at the implant-bone interface when compared with CoCr.

- E. The fixation surfaces of nonporous (roughened) UNISYN™ body segments are grit blasted at the implant-bone interface.
- F. The fixation surfaces of plasma coated UNISYN™ body segments are plasma sprayed provide biological fixation at the implant-bone interface.
- G. The fixation surfaces of plasma/HA and HA coated UNISYN™ body segments are HA coated to provide biological fixation at the implant-bone interface.

## **CONTRAINDICATIONS**

- A. Any joint with active or suspected latent infection.
- B. Neuromuscular disorders or mental conditions whereby the risks associated with these conditions are outweighed by the benefits to be derived.
- C. Any condition of the bone stock in which sufficient support and fixation of the implant is in question.
- D. Obese or overweight patients who may place undue loads on the prosthesis which can result in failure of the device.
- E. Any pathological conditions of the joint that would interfere in achieving appropriate range of motion, adequate head stability, and a well seated and supported prosthetic combination.
- F. Ligamentous or severe muscle laxity or inadequate soft tissue coverage to allow for the normal healing process and for proper hip mechanics to be reestablished.

## **WARNINGS**

- A. All UNISYN™ HIP SYSTEM components are sold sterile. If packages appear damaged or tampered with, they should be returned to the supplier.
- B. Do not implant any device that has been used, even if it appears undamaged.
- C. Machined taper surfaces of the femoral stem and head must be clean and dry at the time of assembly to ensure proper seating of the implant.
- D. Care must be taken to properly impact the femoral head to prevent any discrepancy in neck length, disassociation, or dislocation.
- E. Do not bend or contour an implant, as this may reduce its fatigue strength and may cause immediate or eventual failure under load.
- F. Never tamper with implants. Tampering may have a detrimental affect on the performance of the implant. Handling of the HA treated regions must be avoided as it potentially could result in the compromise of the treatment effectiveness.
- G. The surgeon and O.R. staff must be extremely careful to protect all components from being marred, nicked, or notched as a result of contact with metal or any abrasive objects. This is particularly important for polished bearing areas and machined taper surfaces.
- H. UNISYN™ products may ONLY be used in conjunction with Consensus Orthopedics CONSENSUS® ceramic and metal femoral heads.
- I. Do not use bone cement with HA coated implants.
- J. UNISYN™ products should not be used in conjunction with the 28/+10mm femoral head and the 20° hooded insert.

## **PRECAUTIONS**

- A. Before any implant is used, the surgeon should be completely familiar with all aspects of the surgical procedure and the limitations of the device.
- B. It cannot be expected that joint replacements will withstand the same activity levels as normal healthy bone.
- C. Excessive physical activity may result in premature failure of the implant system due to loosening, component fracture, and/or wear. Activities which place unreasonable amounts of stress on the joint should be avoided. Patients should be instructed on the limitations of the prosthesis and how to modify their activities accordingly.
- D. Obese patients may place severe loading on the affected extremity which can be expected to accelerate joint failure. If appropriate, patients should be advised to follow a weight reduction or maintenance program.
- E. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity. Total joint replacement in younger patients should be considered only when explicit indications outweigh the associated risks of the surgery and modified demands regarding the activity and joint loading are assured.
- F. Instruct patients on the limitations of the prosthesis and how to modify their activities accordingly.
- G. Proper selection of fixation type and placement of the femoral stem and acetabular component are critical factors in the prevention of unusual stress conditions and their potentially harmful effects on the life expectancy of the implant.

## **ADVERSE EFFECTS**

- A. All prosthetic replacements have the potential for adverse effects, including infection, loosening, fracture, breakage, bending of the components, component disassembly, or positional changes of the components.
- B. Sensitivity reactions to component materials could occur, and should be ruled out preoperatively.
- C. Total joint replacement surgery is associated with serious complications including, but not limited to: nerve injury, direct arterial injury, false aneurysm, spontaneous vascular occlusion, deep vein thrombosis, ectopic ossification, non-union, dislocation, disassociation, superficial and deep infection, aseptic loosening, component failure, cement breakdown, and third party wear associated with polymethylmethacrylate or UHMWPE.
- D. Acetabular pain due to loosening of the implant, and/or localized pressure associated with incongruencies of the fit, or tissue inflammation of unknown etiology.
- E. Reoperation may be necessary to correct adverse effects.
- F. On rare occasions, complications may require arthrodesis, Girdlestone procedure or amputation of the limb.
- G. Other complications generally associated with surgery, drugs, blood use, or ancillary devices used.

## **INFORMATION**

Surgical techniques may be obtained from a CONSENSUS ORTHOPEDICS representative or the company directly.

## **STERILIZATION AND HANDLING**

- All components have been sterilized through an ethylene oxide sterilization process. Do not use any component if the package has been breached.

USE CAUTION IN HANDLING PLASMA SPRAYED or HA COATED COMPONENTS TO PREVENT CONTAMINATION OF THE COATING OR ENTRAPMENT OF DEBRIS IN THE COATING.

COMPONENTS THAT ARE MANUFACTURED FROM ULTRA-HIGH MOLECULAR WEIGHT POLYETHYLENE (UHMWPE), POLYMETHYL-METHACRYLATE (PMMA) OR CERAMIC SHOULD NOT BE AUTOCLAVED.

## **CERAMIC FEMORAL HEAD INSTRUCTIONS FOR USE**

### **PREPARATORY PHASE**

- A. Use ceramic heads only on stems with tapers approved for ceramic heads.
- B. A ceramic head impacted once, and then removed, must not be mounted onto another stem.
- C. Never place a ceramic femoral head onto a stem taper that has previously been in use with a head of any type. A metal head must be used as a replacement for any type of head that has been removed from a stem taper.
- D. Never use a ceramic head which has fallen to the floor.
- E. Avoid thermal shocks to ceramic heads. Do not quench the ceramic components in cold liquids.

### **DURING OPERATION**

- A. Keep metal instruments clear of taper. Taper surface of UNISYN™ stem, body, and neck must not be scratched or damaged.
- B. Clean and dry taper of UNISYN™ neck and ceramic head before attaching the ceramic head.
- C. Use only plastic impactor to fasten ceramic heads. Never use a metal impaction instrument.

### **REPLACEMENT OF FRACTURED CERAMIC HEAD**

In the case of a fractured ceramic head, remove all ceramic particles from the wound. If you wish to replace the fractured ceramic head with another ceramic head, the polyethylene insert and UNISYN™ neck component must be changed. If the neck taper is undamaged, a metal head may be used with the existing stem in lieu of a ceramic head.

**WARNING:** Single Use Only: This product is intended for single use only. Do not attempt to re-use, even if the device appears to be undamaged. Risks include device damage leading to poor performance or failure, patient cross-contamination, inadequate sterilization and general liability.

**CAUTION:** Disposal of single-use implant device - This device should be regarded as bio-contaminated and handled accordingly. Plastic or metal implants should be terminally sterilized and disposed of following existing hospital policies and procedures.

**CAUTION:** The CONSENSUS® and the TAPERSET™ hip system has not been evaluated for safety in the MR environment. Patients should register their implant information with the MedicAlert Foundation ([www.medicalert.org](http://www.medicalert.org)), or equivalent organization.

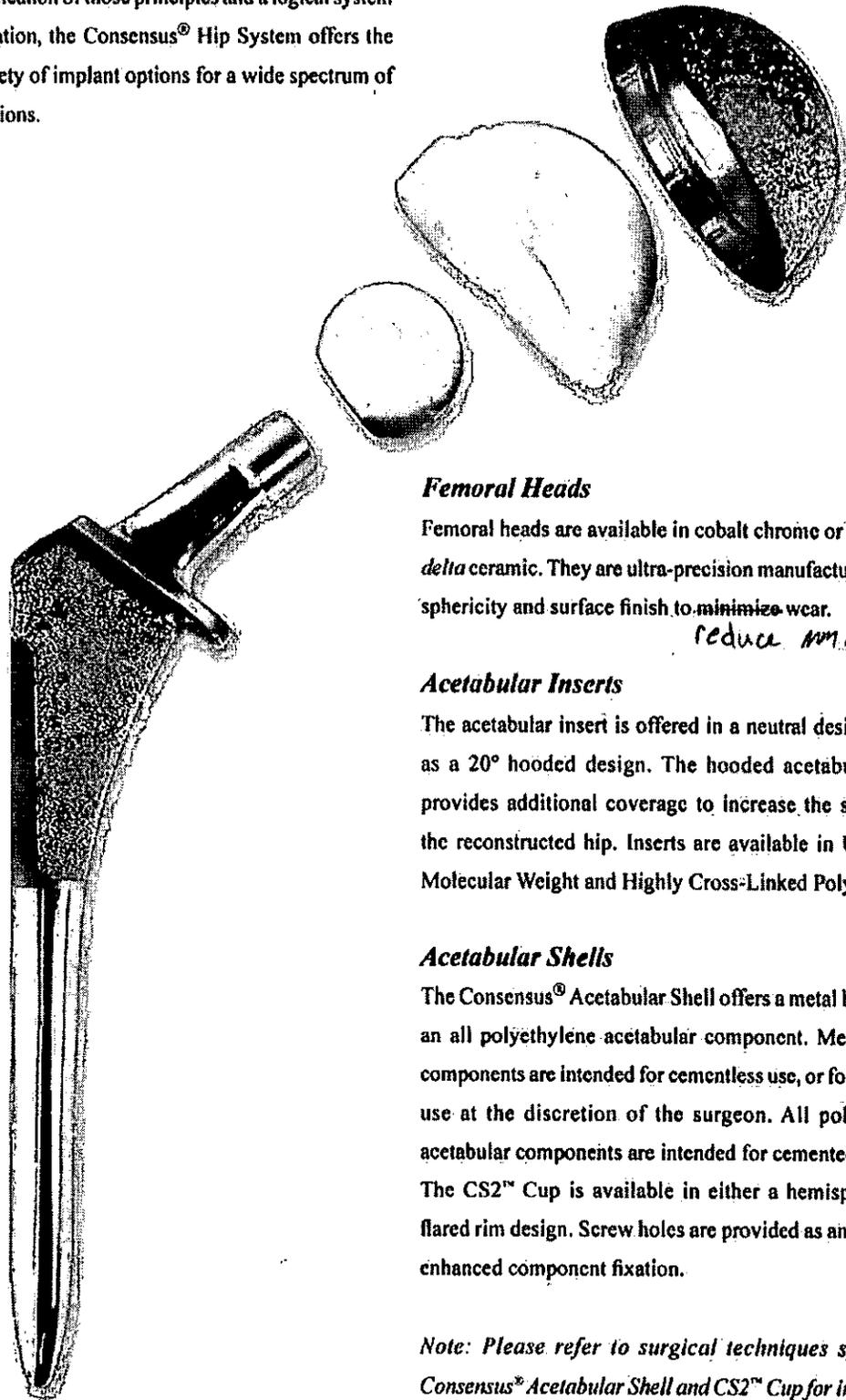
**CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.**

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CHS STM

### **Introduction**

The Consensus<sup>®</sup> Hip System was developed from well established and clinically proven design principles. With consistent application of those principles and a logical system of instrumentation, the Consensus<sup>®</sup> Hip System offers the surgeon a variety of implant options for a wide spectrum of patient indications.



### **Femoral Heads**

Femoral heads are available in cobalt chrome or BIOLOX<sup>®</sup> delta ceramic. They are ultra-precision manufactured to high sphericity and surface finish to minimize wear.

reduce mm. 4/1/11

### **Acetabular Inserts**

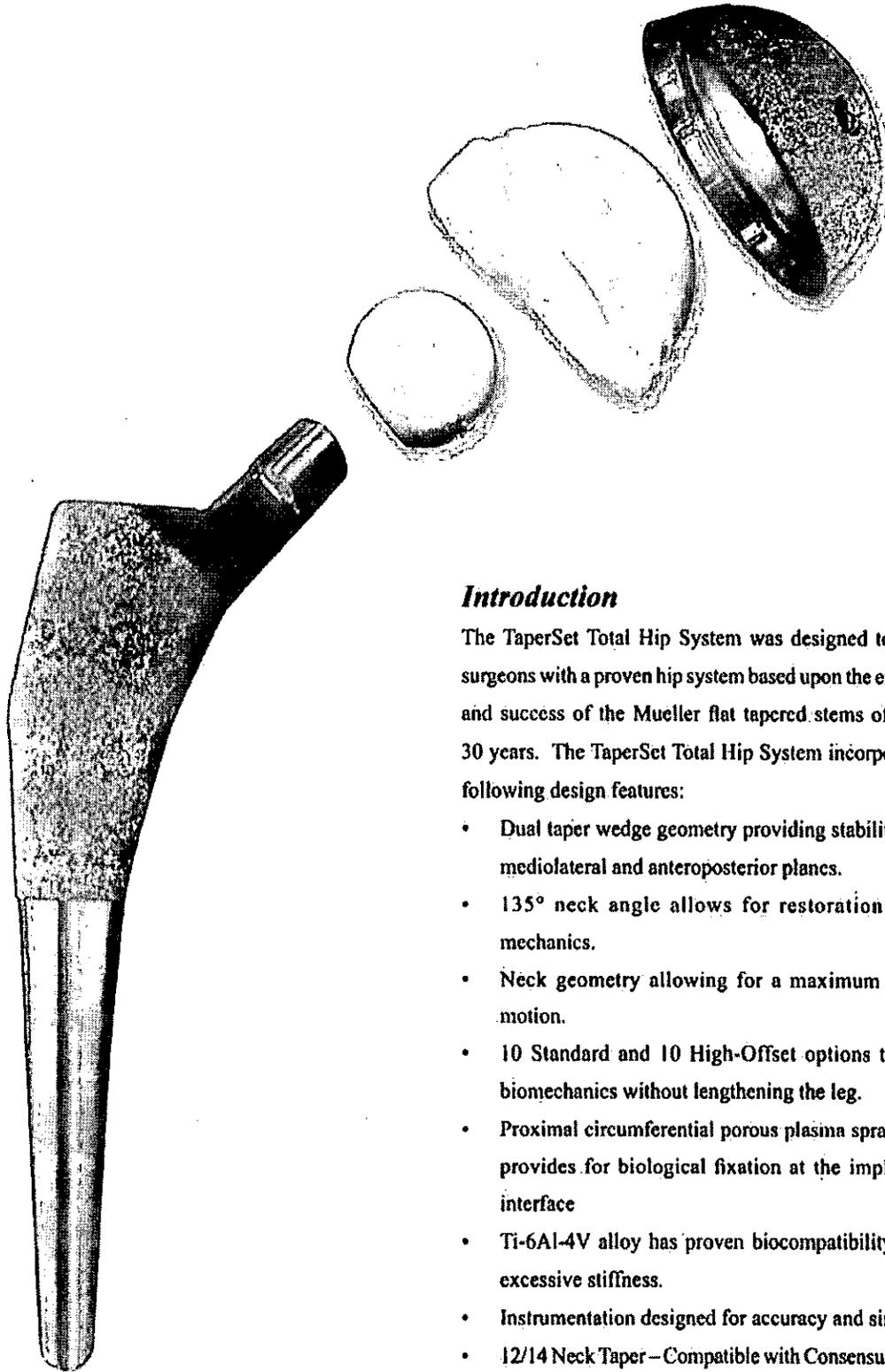
The acetabular insert is offered in a neutral design as well as a 20° hooded design. The hooded acetabular insert provides additional coverage to increase the stability of the reconstructed hip. Inserts are available in Ultra High Molecular Weight and Highly Cross-Linked Polyethylene.

### **Acetabular Shells**

The Consensus<sup>®</sup> Acetabular Shell offers a metal backed and an all polyethylene acetabular component. Metal backed components are intended for cementless use, or for cemented use at the discretion of the surgeon. All polyethylene acetabular components are intended for cemented use only. The CS2<sup>™</sup> Cup is available in either a hemispherical or flared rim design. Screw holes are provided as an option for enhanced component fixation.

*Note: Please refer to surgical techniques specific to Consensus<sup>®</sup> Acetabular Shell and CS2<sup>™</sup> Cup for information on acetabular preparation.*

THS STM



### ***Introduction***

The TaperSet Total Hip System was designed to provide surgeons with a proven hip system based upon the experience and success of the Mueller flat tapered stems of the past 30 years. The TaperSet Total Hip System incorporates the following design features:

- Dual taper wedge geometry providing stability in both mediolateral and anteroposterior planes.
- 135° neck angle allows for restoration of joint mechanics.
- Neck geometry allowing for a maximum range of motion.
- 10 Standard and 10 High-Offset options to restore biomechanics without lengthening the leg.
- Proximal circumferential porous plasma spray coating provides for biological fixation at the implant-bone interface
- Ti-6Al-4V alloy has proven biocompatibility without excessive stiffness.
- Instrumentation designed for accuracy and simplicity.
- 12/14 Neck Taper – Compatible with Consensus Femoral Heads.

The **Consensus® Hip System** was developed from **well established and clinically proven design principles**. With consistent application of those principles and a **logical system of instruments**, the **Consensus® Hip System** offers the surgeon a **variety of implant options** for a wide spectrum of patients.

#### Shells

- Available without screw holes or with a superior cluster of three screw holes to enhance fixation
- Commercially pure titanium beaded porous coating
- Available in diameters from 42mm to 68mm
- Hemispherical or flared rim geometries

#### Inserts

- 36mm ID inserts for 52-68mm shells
- 32mm ID inserts for 48-68mm shells
- 28mm ID inserts for 46-68mm shells
- Available in 20° hooded and neutral options
- Highly cross-linked or standard UHMWPE

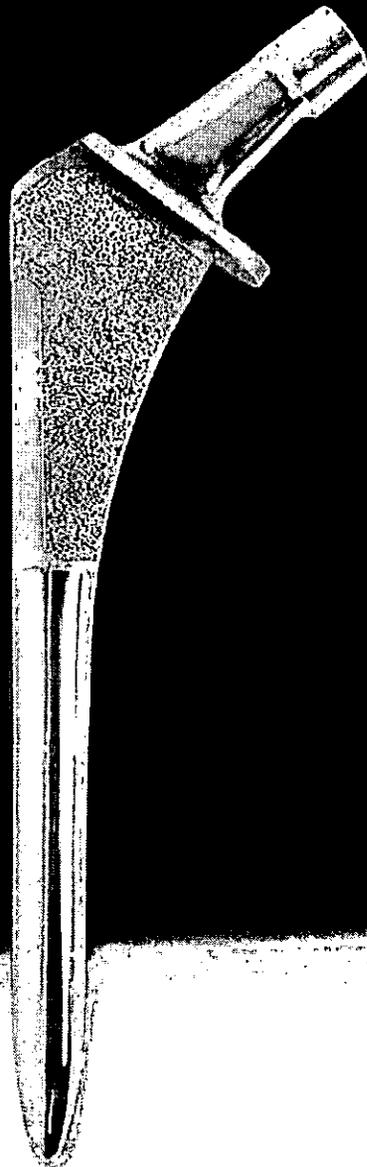


#### Heads

- 36mm BIOLOX® *della* available in -4, 0, +4, and +8mm offsets
- 32mm BIOLOX® *della* available in -4, 0, +4, and +7mm offsets
- 28mm BIOLOX® *della* available in -3.5, 0, +3.5 offsets
- 36mm CoCr available in -5, 0, +5, and +10mm offsets
- 32mm CoCr available in -5, 0, +5, and +10mm offsets
- 28mm CoCr available in -5, 0, +5, and +10mm offsets

#### Stems

- 128° neck angle allows for restoration of lateral offset while maintaining proper leg length
- Press-fit stem geometry provides a 1mm press-fit in the metaphysis and line-to-line slip-fit in the diaphysis to promote loading of the proximal femur and provide initial stability and fixation of the implant
- Stems are forged from either Ti-6Al-4V or CoCr
- Full radius porous-coated collar loads medial calcar to preserve proximal bone
- Polished neck and distal bullet



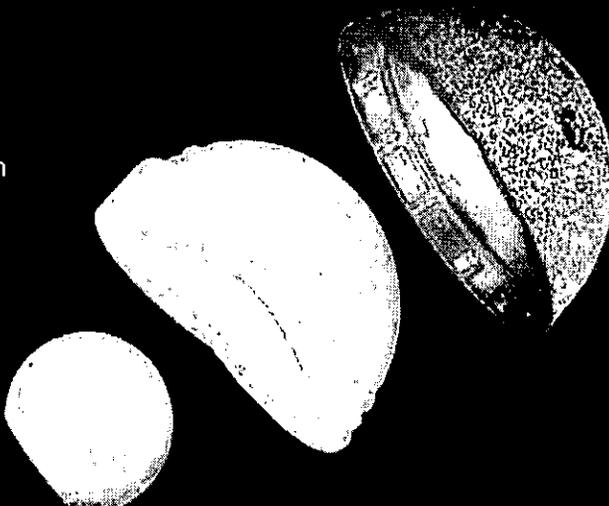
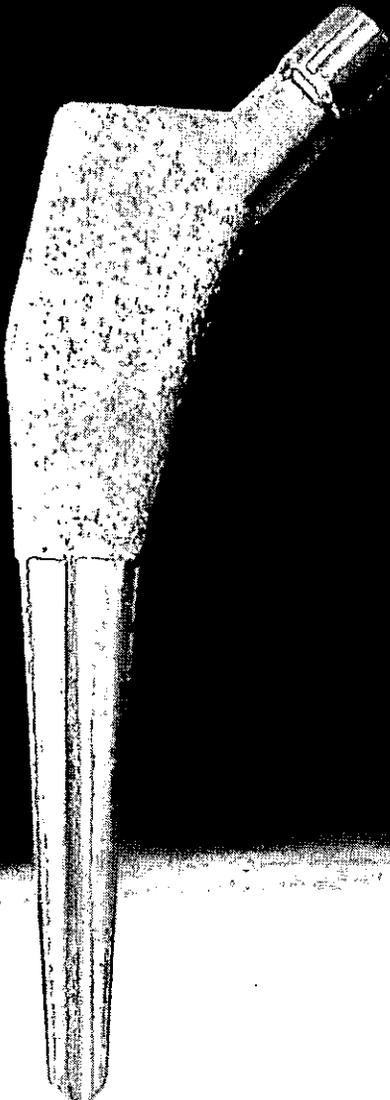
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The **TaperSet Hip System** was developed from **well-established** and **proven** design principles. With consistent application of those principles and a **logical system of instruments**, the **Consensus<sup>®</sup> Hip System** offers the surgeon a **variety of implant options** for a wide spectrum of patients.

### Stems

- Standard and lateral offset options to restore biomechanics without lengthening the leg
- Proximal circumferential porous plasma spray coating provides for biological fixation at the implant-bone interface
- Dual taper wedge geometry provides stability in both mediolateral and anteroposterior planes
- Ti-6Al-4V alloy has proven biocompatibility without excessive stiffness
- 135° neck angle allows for restoration of joint mechanics



### Heads

- 36mm CoCr available in -5, 0, +5, and +10mm offsets
- 32mm CoCr available in -5, 0, +5, and +10mm offsets
- 28mm CoCr available in -5, 0, +5, and +10mm offsets
- 36mm BIOLOX<sup>®</sup> *delta* available in -4, 0, +4, and +8mm offsets
- 32mm BIOLOX<sup>®</sup> *delta* available in -4, 0, +4, and +7mm offsets
- 28mm BIOLOX<sup>®</sup> *delta* available in -3.5, 0, +3.5 offsets

### Inserts

- 36mm ID inserts for 52-68mm shells, 10° and neutral options
- 32mm ID inserts for 48-68mm shells, 20° and neutral options
- 28mm ID inserts for 46-68mm shells, 20° and neutral options
- Highly cross-linked or standard UHMWPE

### Shells

- Available without screw holes or with a superior cluster of three screw holes to enhance fixation
- Commercially pure titanium beaded porous coating
- Available in diameters from 42mm to 68mm
- Hemispherical or flared rim geometries

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**Kasser, Michael**

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**From:** Matt Hull [mhull@consensusortho.com]  
**Sent:** Friday, April 01, 2011 11:00 AM  
**To:** Kasser, Michael  
**Cc:** Justin Creel  
**Subject:** K110542  
**Attachments:** COI Printed Box Info.pdf

Michael,

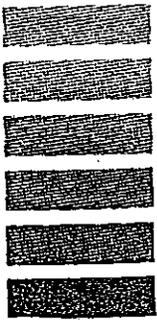
Attached is a copy of the printed portion of our box that contains the prescription device use statement as you requested.

(b)(4)Trade Secret Process - Design Test report

Matt



Matt Hull  
Director of QS & RA  
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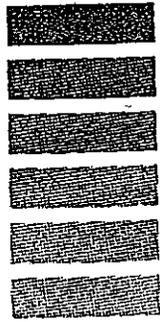


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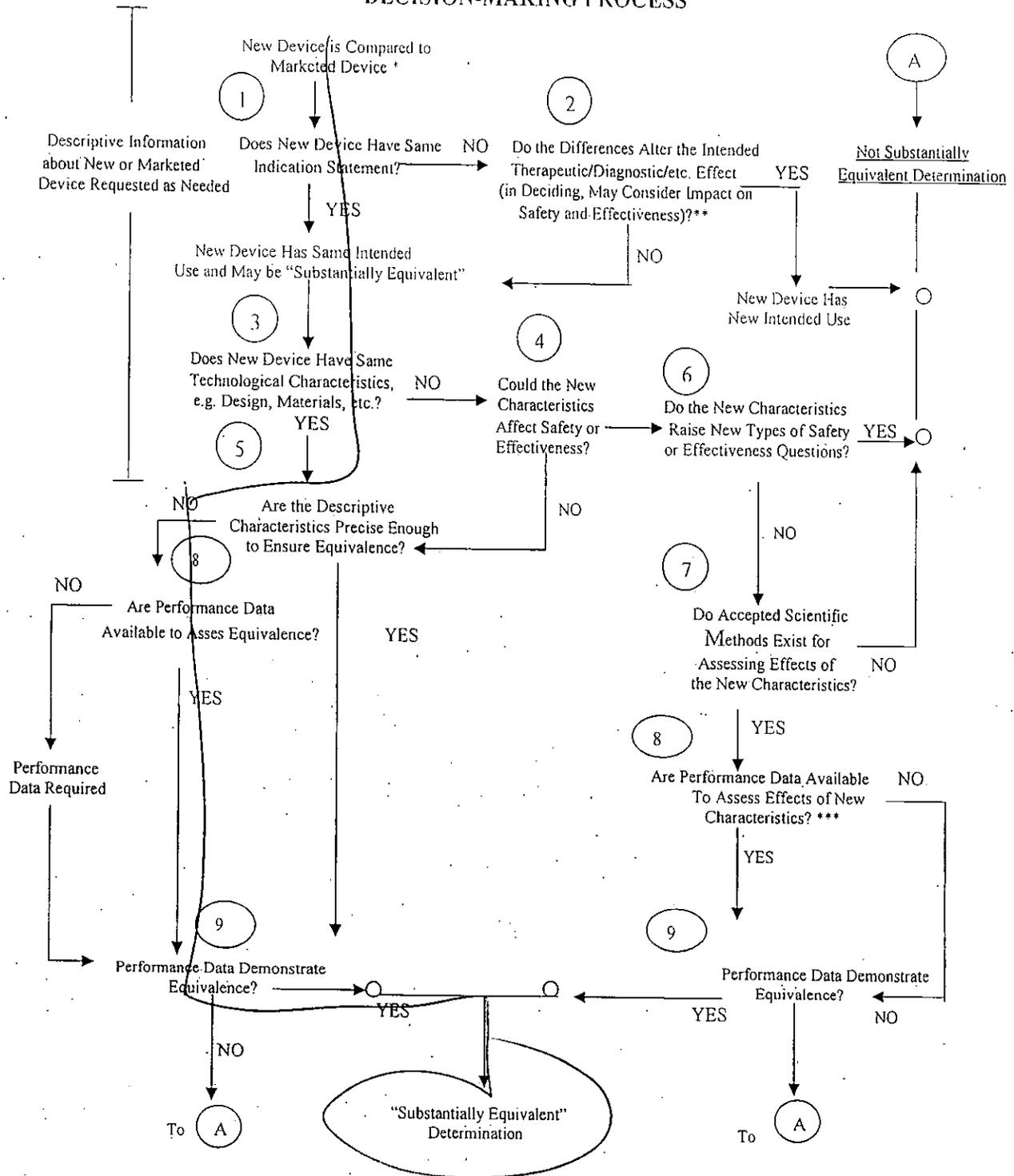
El Dorado Hills, California, U.S.A.  
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# Consensus

Orthopedics



## 510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



\* 510(k) Submissions compare new devices to marketed devices: FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

\*\* This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

\*\*\* Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.