

K101451

JUN 22 2010

APEX Modular Hip System BIOLOX® delta Femoral Head

May 24, 2010

Submitter	OMNI life science, Inc. 50 O'Connell Way E. Taunton MA 02718	Contact	Radhika Pondicherry Regulatory Affairs 774-226-1852 (508) 822-6030 (fax)
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Preparation Date 24 May2010

Device Name

Common Name Hip joint ceramic, uncemented prosthesis

Trade Name APEX Modular Hip System BIOLOX® delta Femoral Head

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

Regulatory Class Class II per 21 CFR §888.3353

Product Code LZO

Legally Marketed Predicate Device(s)

- K012918- Apex Modular™ Alumina Femoral Head, November 27, 2001
- K073150- ApeX-LNK Poly Acetabular Cup Liners- 36mm Alumina Femoral Heads, February 27, 2008
- K100555- ApeX-LNK Poly Acetabular Liners and Apex Modular Head, March 29, 2010

Device Description

The Apex Modular Hip System BIOLOX® delta Femoral Head is composed of an alumina matrix composite, the femoral heads include diameters ranging from 28mm to 40mm with various offsets.

Indications for Use

The Apex Modular™ Ceramic Femoral Heads are intended for use in combination with the Apex Modular Hip Stem as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with a polyethylene or metal-backed polyethylene acetabular cup or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Congenital dislocation
- Revision procedures where other treatments or devices have failed
- Femoral neck and trochanteric fractures of the proximal femur.

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Predicate Device Comparison

	Delta Femoral head (subject device)	Alumina Femoral head (K012918, K 073150)	Apex Modular Head (K100555)
INTENDED USE			
Modular Head, primary and revision THA	Yes, cementless	Yes, cementless	Yes, cementless
DESIGN			
Taper design	12/14	12/14	12/14
Head Diameters	28-40mm	28-36mm	40mm
Head Size & Offsets	28-+0,+3.5,-3.5	28- +0,+3.5,-3.5	
	32-+0,+4,+7,-4	32- +0,+4,-4	
	36-+0,+4,+8,-4	36-+0,+4,-4	
	40-+0,+4,+8,-4	40mm- not available in Alumina material	40mm- +0,+3.5,+7,-3.5
MATERIALS	BILOX delta	BILOX forte	CoCr Alloy
Ceramic Head	72-75 %Al ₂ O ₃ ,+ 24-26 % Z ₂ O ₃	99.7% Al ₂ O ₃	ASTM-1537
Stem Trunion	Titanium alloy CoCr alloy	Titanium alloy CoCr alloy	Titanium alloy CoCr alloy
PACKAGING AND STERILIZATION			
Packaging	Peelable Tyvek® pouches (1073B Tyvek®/2.5ml Mylar®),double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels; the inner pouch for the ceramic heads will be polyethylene with a peelable Tyvek®panel.	Peelable Tyvek® pouches (1073B Tyvek®/2.5ml Mylar®),double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels; the inner pouch for the ceramic heads will be polyethylene with a peelable Tyvek®panel.	Paper Board Box, Double Tyvek inner pouch
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide
SAL	10 ⁻⁶	10 ⁻⁶	10 ⁻⁶

Non-Clinical Test Summary

The following tests were conducted:

- Component testing of BIOLOX forte ball head 32-12/14 L on CoCr test tapers and BIOLOX delta ball heads 28-12/14 L on CoCr test tapers supplied by OMNIlife science.- CeramTec Procedure VA 02 04 4129, ISO-7606-10
- Component testing of BIOLOX delta ball heads 28-12/14 L on titanium test tapers supplied by OMNIlife science. CeramTec Procedure VA 02 04 4129, ISO-7606-10
- 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
- ETO Residuals per ANSI/AAMI/ISO 10993-7.

Clinical Test Summary

No clinical studies were performed.

Conclusions

The - APEX Modular Hip System BIOLOX® delta Femoral Head is substantially equivalent to the predicate devices.

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

JUN 22 2010

OMNI life science, Inc.
% Ms. Radhika Pondicherry
Regulatory Affairs
50 O'Connell Way
East Taunton, Massachusetts 02718

Re: K101451

Trade/Device Name: APEX Modular Hip System BIOLOX delta 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
Dated: May 24, 2010
Received: May 25, 2010

Dear Ms. Pondicherry:

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

Page 2 – Ms. Radhika Pondicherry

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,


for 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 (if known): K101451

Device Name: APEX Modular Hip System BIOLOX delta Femoral Head

The Apex Modular™ Ceramic Femoral Heads are intended for use in combination with the Apex Modular Hip Stem as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with a polyethylene or metal-backed polyethylene acetabular cup or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed
- Femoral neck and trochanteric fractures of the proximal femur.

Prescription Use X
(Part 21 CFR 801 Subpart D)

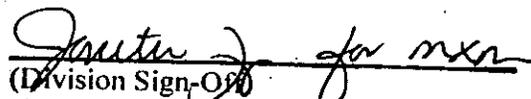
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1


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

510(k) Number K101451



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

JUN 22 2010

OMNI life science, Inc.
% Ms. Radhika Pondicherry
Regulatory Affairs
50 O'Connell Way
East Taunton, Massachusetts 02718

Re: K101451

Trade/Device Name: APEX Modular Hip System BIOLOX delta Femoral Head
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Page 2 – Ms. Radhika Pondicherry

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Sincerely yours,



for 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 (if known): K101451

Device Name: APEX Modular Hip System BIOLOX delta Femoral Head

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- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed
- Femoral neck and trochanteric fractures of the proximal femur.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Janita J. Foxman
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101451

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

May 25, 2010

OMNI LIFE SCIENCE, INC.
50 O'CONNELL WAY
EAST TAUNTON, MASSACHUSETTS 02718
UNITED STATES
ATTN: RADHIKA PONDICHERRY

510k Number: K101451

Received: 5/25/2010

Product: APEX MODULE HIP SYSTEM BIOLOX

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4)Trade Write the Payment Identification number on your check.
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A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: <http://www.fda.gov/oc/mdufma/coversheet.html>

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) OMNI LIFE SCIENCE INC 50 O'Connell Way #10 E. Taunton MA 02718 US	2. CONTACT NAME Robert Zoletti 2.1 E-MAIL ADDRESS rzoletti@omniis.com 2.2 TELEPHONE NUMBER (include Area code) 774-226-1845 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 508-8226030
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) (b)(4)Trade	

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: <http://www.fda.gov/oc/mdufma>)

<u>Select an application type:</u>		3.1 Select a center
<input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party		<input checked="" type="checkbox"/> CDRH
<input type="checkbox"/> 513(g) Request for Information		<input type="checkbox"/> CBER
<input type="checkbox"/> Biologics License Application (BLA)		3.2 Select one of the types below
<input type="checkbox"/> Premarket Approval Application (PMA)		<input checked="" type="checkbox"/> Original Application
<input type="checkbox"/> Modular PMA		<u>Supplement Types:</u>
<input type="checkbox"/> Product Development Protocol (PDP)		<input type="checkbox"/> Efficacy (BLA)
<input type="checkbox"/> Premarket Report (PMR)		<input type="checkbox"/> Panel Track (PMA, PMR, PDP)
<input type="checkbox"/> Annual Fee for Periodic Reporting (APR)		<input type="checkbox"/> Real-Time (PMA, PMR, PDP)
<input type="checkbox"/> 30-Day Notice		<input type="checkbox"/> 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

YES, I meet the small business criteria and have submitted the required qualifying documents to FDA NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number: SBD106102

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?

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.)

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 <http://www.fda.gov/cdrh/mdufma> for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

This application is the first PMA submitted by a qualified small business, including any affiliates The sole purpose of the application is to support conditions of use for a pediatric population

This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only 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).)

YES NO

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)Trade 20-May-2010

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Handwritten signature and initials.

Date of Submission 05/19/2010	User Fee Payment ID Number	FDA Submission Document Number (if known)
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SECTION A TYPE OF SUBMISSION

PMA <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	PMA & HDE Supplement <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	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input type="checkbox"/> Traditional <input checked="" type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <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):
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <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 OMNI life science Inc.	Establishment Registration Number (if known) 1226188		
Division Name (if applicable)	Phone Number (including area code) 774-226-1852		
Street Address 50 O'Connell Way	FAX Number (including area code) 508-822-6030		
City East Taunton	State / Province MA	ZIP/Postal Code 02718	Country USA
Contact Name Radhika Pondicherry			
Contact Title Regulatory Affairs Specialist		Contact E-mail Address rpondicherry@omnils.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
<input type="checkbox"/> 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		
<input type="checkbox"/> 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
<input checked="" type="checkbox"/> Other Reason (specify): Modification to a previously cleared device.		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	LZO	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information
 510 (k) summary attached
 510 (k) statement

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

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K012918	1 Apex Modular Alumina Femoral Head	1 OMNI life science, Inc.
2 K073150	2 ApeX-LNK Poly Acetabular Cup Liners	2 OMNI life science, Inc.
3 K100555	3 ApeX-LNK Poly™ Acetabular Cup, Apex Modular Head	3 OMNI life science, Inc.
4	4	4
5	5	5
6	6	6

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name
 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Trade or Proprietary or Model Name for This Device	Model Number
1 APEX Modular Hip System BIOLOX® delta Femoral Head	1
2	2
3	3
4	4
5	5

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

1 K073150	2 K012918	3 K100555	4	5	6
7	8	9	10	11	12

Data Included in Submission
 Laboratory Testing Animal Trials Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code LZO	C.F.R. Section (if applicable) 888.3353	Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified
Classification Panel Orthopedic (OR)		

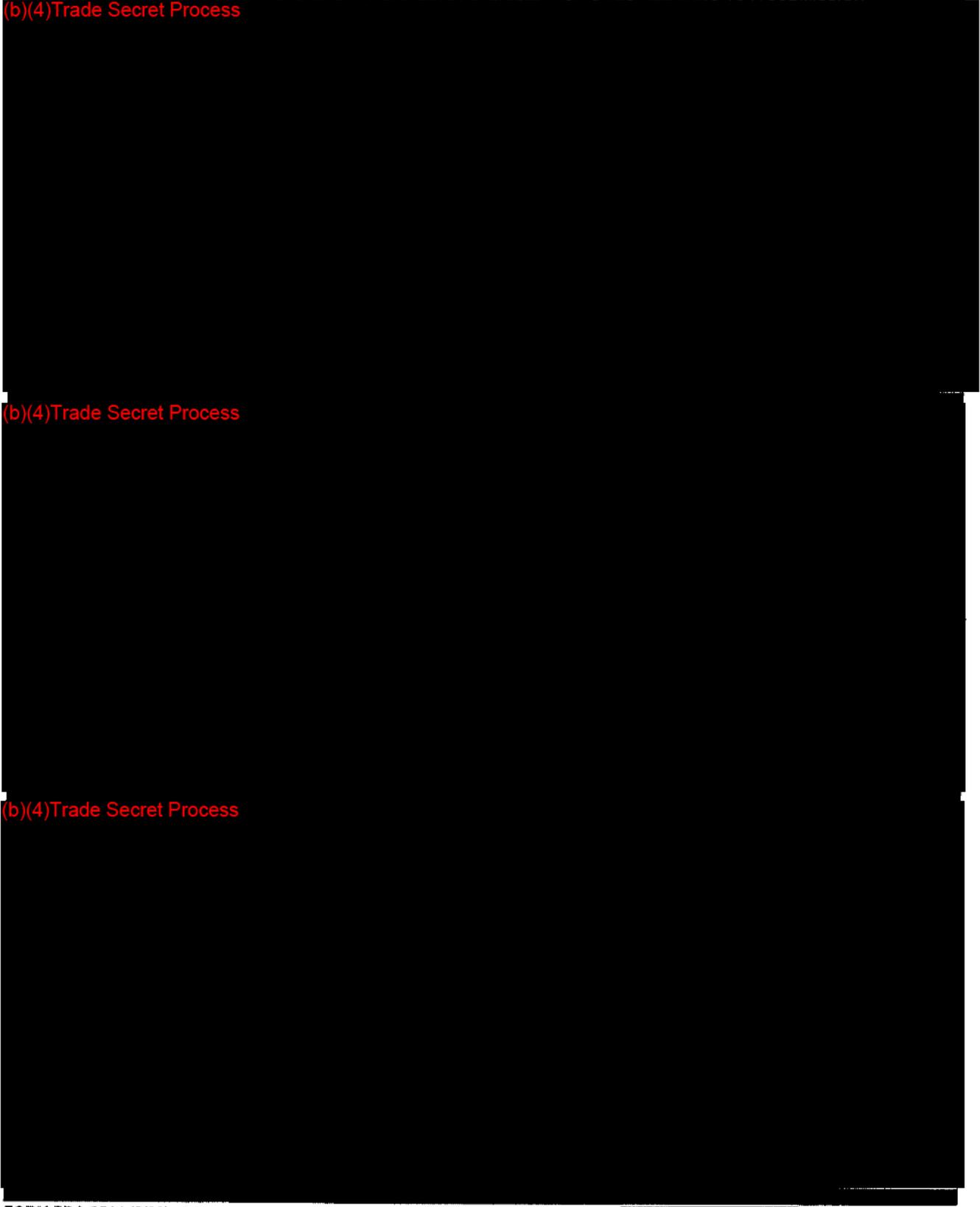
Indications (from labeling)
 The Apex Modular™ Ceramic Femoral Heads are intended for use in combination with the Apex Modular Hip Stem as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with a polyethylene or metal-backed polyethylene acetabular cup or bipolar component.

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

(b)(4)Trade Secret Process



(b)(4)Trade Secret Process

(b)(4)Trade Secret Process

SECTION I

UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	7206-10	ISO	Implants for surgery — Partial and totalhip-joint prostheses Determination of resistance to static load of modular femoral heads	2003	
2	10993-7	ISO	Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	2008	
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.



OMNI life science, Inc.
50 O'Connell Way, Suite #10
E. Taunton, MA 02767
Voice: (774)-226-1852
Fax (508) 822-6030
Email: rpondicherry@omnils.com

Special 510(k): Device Modification

May 24, 2010

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
MAY 25 2010
Received

Reference:

- Apex Modular™ Alumina Femoral Head (K012918, November 27, 2001)
- ApeX-LNK Poly Acetabular Cup Liners (36mm Alumina Femoral Heads -K073150, February 27, 2008)
- ApeX-LNK Poly™ Acetabular Cup, Apex Modular Head (40mm CoCr Femoral heads-K100555, March 29, 2010)

Dear Madam/Sir:

OMNI life science, Inc hereby submits this Special 510(k): Device Modification to request a modification for our Apex Modular™ Alumina Femoral Head. The modification is an addition of the new material, BIOLOX® delta to the product line.

We believe this modification is eligible for the Special 510 (k) process since the APEX Modular Hip System BIOLOX® delta Femoral Heads are similar in overall design, material and indications to the Apex Modular™ Alumina Femoral Head (K012918, K073150, K100555). The BIOLOX delta heads are supplied by CeramTec and the material has been used in previously cleared femoral head products.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by FDA. We have taken precautions to protect the confidentiality of our intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Two paper copies of the submission are enclosed along with a CD containing a full and true PDF copy.

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at 774-226-1852 or via email at rpondicherry@omnils.com

Sincerely,


Radhika Pondicherry
Regulatory Affairs Specialist

Special 510 (k) APEX Modular Hip System BIOLOX® delta Femoral Head

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510(k) Checklist

510(k) Number: Unknown

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

- Special 510(k) - Do Sections 1 and 2
- Abbreviated 510(k) - Do Sections 1, 3 and 4
- Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate Page #	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510] Manual.	7	
Table of Contents.	8	
Truthful and Accurate Statement.	43	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	12	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	12	
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510] Manual.	18	
Statement of Indications for Use that is on a separate page in the premarket submission.	37	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510] Manual.	14	
510(k) Summary or 510(k) Statement.	40	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	13,44	
Identification of legally marketed predicate device. *	12	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	39	
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	49	
510(k) Kit Certification ***		

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present Page #	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	12	
A description of the modified device and a comparison to the sponsor's predicate device.	13,15	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	13	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.		
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	16	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	16	
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	39	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	39	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

Items with checks in the "Present or Adequate" column do not require e additional information from the sponsor. Items with checks in the "Missing or Inadequate" column must be submitted before substantive review of the document.

Passed Screening Yes No

Reviewer: _____

Concurrence by Review Branch: _____

Date: _____

Device Trade Name

APEX Modular Hip System BIOLOX® delta Femoral Head

Common Name/Classification Name

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

Address and Registration #

OMNI life science

50 O'Connell Way, Suite 10

E. Taunton, MA 02718

Registration Number: 1226188

Contract Manufacturer

(b)(4)Trade Secret Process



Packager / Labeler

(b)(4)Trade Secret Process



Contract Sterilizer

(b)(4)Trade Secret Process



Device Class

APEX Modular Hip System BIOLOX® delta Femoral Head has been classified as Class II
21 CFR § 888.3353

Product Code: LZ0

These products are reviewed by the Orthopedic Devices panel

Predicate Device Information

K012918- Apex Modular™ Alumina Femoral Head, November 27, 2001

K073150- ApeX-LNK Poly Acetabular Cup Liners- 36mm Alumina Femoral Heads, February 27, 2008

K100555- ApeX-LNK Poly Acetabular Liners and Apex Modular Head, March 29, 2010

Labeling and Indications for use

Draft labels can be found in Attachment #1.

The IFU is in Attachment #2

No changes have been made to the indications for the APEX Modular Hip System with the addition of the BIOLOX® delta Femoral Head.

Indications for Use

The Indications for Use Statement can be found in Attachment #3.

This is the **same intended use** as previously cleared for the Apex Modular™ Alumina Femoral Head:

- K012918- Apex Modular™ Alumina Femoral Head, November 27, 2001
- K073150- ApeX-LNK Poly Acetabular Cup Liners- 36mm Alumina Femoral Heads, February 27, 2008
- K100555- ApeX-LNK Poly Acetabular Liners and Apex Modular Head, March 29, 2010

Description of the Device Modification

Material

- The predicate BIOLOX® forte material is 99.7% aluminum oxide (Al_2O_3).
- The subject BIOLOX® delta material is composed of approximately 75% aluminum oxide and 25% zirconia.

Head Design

Head Material and Offsets

The bores on the BIOLOX forte and BIOLOX delta Apex Modular Femoral Heads are the same. The bore was designed and tested for compatibility with the neck taper on the Apex Modular Hip Stem (K000788) and the Apex ARC™ Hip Stem (K090845). (Ref to Attachment # 11 for Test reports)

The femoral head design is identical to the Apex Modular Femoral Head, K012918, K073150, and K100555 other than the following modifications:

- K012918: The BIOLOX forte femoral heads, sizes 28mm to 32mm, were cleared on November 27, 2001 and are identical to the femoral head design of the Apex BIOLOX delta femoral heads. The 32mm Apex BIOLOX delta femoral head is available in an additional +7 offset.
- K073150: The 36mm Apex BIOLOX forte femoral head, cleared on February 27, 2008 has the identical head design as the subject Apex BIOLOX delta heads. The 36mm Apex BIOLOX delta femoral head is available in an additional +8 offset.
- K100555: The 40mm CoCr femoral head, cleared on March 29, 2010 has the identical head design as the subject Apex BIOLOX delta femoral heads. The 40mm Apex BIOLOX delta femoral head is available in various offsets (see Attachment 12 for product code list).

Head Size

Size: 28mm, 32mm, 36mm, 40mm with various offsets for each respective head size

BIOLOX® delta femoral heads are available in an additional, larger, 40mm size with various offsets. The 40mm Apex BIOLOX delta head is identical in design to the Apex Modular 40mm CoCr Head FDA cleared in K100555.

The BIOLOX delta 40mm head (b)(4)Trade Secret worst case scenario for burst strength of the ceramic heads. The (b)(4)Trade head remains as the worst case scenario for the delta heads (ref: Attachment # 11 Test Report- Influence of Diameter and Neck Length on burst strength of BIOLOX forte and BIOLOX delta ball heads with taper type 12/14).

See Attachment # 12 for Product Code List

FDA References

- BIOLOX® forte, BIOLOX® delta ceramic ball heads- Master Files (b) 7
- (b)(4)Trade Secret Process

The only modifications made to Apex BIOLOX delta femoral heads are:

1. BIOLOX® delta is composed of 75% Aluminum Oxide and 25% Zirconia, as compared to the predicate device Apex Modular Alumina Femoral Head (BIOLOX® forte) which is composed of 99% Aluminum Oxide.
2. 40 mm BIOLOX® delta heads with various offsets. Worst case head size for burst strength is the (b) For test reports showing the worst case scenario femoral heads compatibility with the Cobalt Chromium and Titanium stem tapers see Attachment # 12.
3. Addition of 32mm +7 and 36mm +8 femoral head offsets.

Substantial Equivalence Comparison

Equivalence

The modified APEX Modular Hip System BIOLOX® delta Femoral Head has the following similarities to the following predicate devices:

- Same operating principle(s): Modular Head, primary and revision Total Hip Arthroplasty (THA), cementless application
- Same basic design: The femoral head, mates with the APEX Modular Necks, the 40mm delta head is substantially equivalent in design to the FDA cleared Apex Modular Head-40mm - K100555.
- Same shelf life: 5 years from date of manufacture
- Packaged and sterilized using the same materials and processes: ETO, SAL 10⁻⁶

CeramTec AG manufactures the APEX Modular BIOLOX delta heads. CeramTec AG manufactured BIOLOX delta femoral heads have been cleared in the following:

- Smith & Nephew BIOLOX® Delta Ceramic Femoral Heads (K083762, March 11, 2009)
- BIOLOX® delta Ceramic Femoral Head by Zimmer Inc. (K071535, November 19, 2007)

Difference

The APEX Modular Hip System BIOLOX® delta Femoral Head is manufactured from BIOLOX® delta, the current Apex Modular Hip System ceramic head is manufactured from BIOLOX forte.

APEX Modular™ Hip System BIOLOX® delta Femoral Head, Apex Modular™ Alumina Femoral Head and Apex Modular™ Head Device Comparison

	Delta Femoral head (subject device)	Alumina Femoral head (K012918, K 073150)	Apex Modular Head (K100555)
INTENDED USE			
Modular Head, primary and revision THA	Yes, cementless	Yes, cementless	Yes, cementless
DESIGN			
Taper design	12/14	12/14	12/14
Head Diameters	28-40mm	28-36mm	40mm
Head Size and Offsets	28-+0,+3.5,-3.5	28- +0,+3.5,-3.5	
	32-+0,+4,+7,-4	32- +0,+4,-4	
	36-+0,+4,+8,-4	36-+0,+4,-4	
	40-+0,+4,+8,-4	40mm- not available in Alumina material	40mm- +0,+3.5,+7,-3.5
MATERIALS	BIOLOX delta	BIOLOX forte	CoCr Alloy
Ceramic Head	72-75 %Al ₂ O ₃ , 24-26 % Z ₂ O ₃	99.7% Al ₂ O ₃	ASTM-1537
Stem Trunion	Titanium alloy CoCr alloy	Titanium alloy CoCr alloy	Titanium alloy CoCr alloy
PACKAGING AND STERILIZATION			
Packaging	Peelable Tyvek® pouches (1073B Tyvek®/2.5ml Mylar®),double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels; the inner pouch for the ceramic heads will be polyethylene with a peelable Tyvek®panel.	Peelable Tyvek® pouches (1073B Tyvek®/2.5ml Mylar®),double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels; the inner pouch for the ceramic heads will be polyethylene with a peelable Tyvek®panel.	Paper Board Box, Double Tyvek inner pouch
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide
SAL	10 ⁻⁶	10 ⁻⁶	10 ⁻⁶

In summary, the APEX Modular Hip System BIOLOX® delta Femoral Head described in this submission is, in our opinion, substantially equivalent to the predicate device.

Compliance with Performance Standards

No Performance Standards applicable to this device have been adopted under Section 514 of the Act.

Summary of Design Control Activities

See Attachment # 10 CeramTec Authorization Letter, (b)(4)Trade Secret

(b)(4)Trade Secret Process

Device Modification	Hazard	Verification Activity	Acceptance Criteria	Results of Verification/Validation
(b)(4)Trade Secret Process				

Statement of Conformance

Design Controls & Manufacturing See Attachment #4.

Truthful and Accuracy Certification

A certification of the truthfulness and accuracy is provided in Attachment #6.

510(k) Summary

A 510(k) Summary for the APEX Modular Hip System BIOLOX delta Femoral Head is included in Attachment #5.

Labels and IFUs

The product labels are provided in Attachment #1.
The IFU is provided in Attachment #2.

Clinical Studies

No clinical studies were conducted to support this submission. See Form FDA 3674, Attachment #9.

Attachment 1

Draft labels

Pouch Label

Ref. No.: H3-52800 **PACKAGE STERILE UNLESS OPENED OR DAMAGED**
BIOLOX® delta
Femoral Head
28mm dia x +0mm (12/14M) YYYY-MM
LOT XXXXX
 OMNI life science, Inc. E. Taunton, MA 02718 USA

Patient Label

H3-52800 *XXXXX*
 Ref No.: **H3-52800** AFFIX TO PATIENT RECORD
BIOLOX® delta Femoral Head **STERILE EO**
28mm dia x +0mm (12/14M) YYYY-MM
 MAT'L: aluminum oxide-zirconium oxide composite **LOT** XXXXX
 OMNI life science, Inc. E. Taunton, MA 02718 USA www.omnils.com

Box Label

REF. NO.: H3-52800 **LOT** XXXXX
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION: **STERILE EO** QTY: 1
 YYYY-MM
BIOLOX® delta Femoral Head **USE BY**
28mm +0mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS FOR USE
OMNI life science
 E. TAUNTON, MA 02718 USA
 www.omnils.com
Rx only
 Inner unit sterile unless inner packaging is damaged or opened.
APEX MODULAR™ **28**
HIP SYSTEM
BIOLOX® delta Femoral Head
OMNI life science **SIZE:** **28**
28mm dia +0mm **Use only with the Apex Hip System**
 (12/14M)
 H3-52800 *XXXXX*

on purple LABEL STOCK

Pouch Label

Ref. No.: H3-52804 **PACKAGE STERILE UNLESS OPENED OR DAMAGED**
BIOLOX[®] delta
Femoral Head YYYY-MM
28mm dia x +3.5mm (12/14L) XXXXX
 OMNI life science, Inc. E. Taunton, MA 02718 USA

Patient Label

H3-52804 *XXXXX*
 Ref No.: **H3-52804** AFFIX TO PATIENT RECORD
BIOLOX[®] delta Femoral Head **STERILE** **EO**
28mm dia x +3.5mm (12/14L) YYYY-MM
 MATL: aluminum oxide-zirconium oxide composite **XXXXX**
 OMNI life science, Inc. E. Taunton, MA 02718 USA www.omnils.com

Box Label

REF. NO.: H3-52804 XXXXX
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION: **STERILE** **EO** QTY: 1
 YYYY-MM
BIOLOX[®] delta Femoral Head USE BY
28mm +3.5mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS FOR USE
OMNI life science
 E. TAUNTON, MA 02718 USA
 www.omnils.com
Rx only
 Inner unit sterile unless inner packaging is damaged or opened.
APEX MODULAR[™] **28**
HIP SYSTEM
BIOLOX[®] delta Femoral Head
OMNI life science SIZE:
28mm dia +3.5mm Use only with the Apex Hip System
 (12/14L)
 H3-52804 *XXXXX*

Pouch Label

Ref. No.: **H3-52899** **PACKAGE STERILE UNLESS OPENED OR DAMAGED**
BIOLOX® delta
Femoral Head
28mm dia x -3.5mm (12/14S) **YYYY-MM**
LOT XXXXX
 OMNI life science, Inc. E. Taunton, MA 02718 USA

Patient Label

"H3-52899" "XXXXX"
 Ref No.: **H3-52899** **AFFIX TO PATIENT RECORD**
BIOLOX® delta Femoral Head **STERILE** **EO**
28mm dia x -3.5mm (12/14S)
 MAT'L: aluminum oxide-zirconium oxide composite **YYYY-MM**
OMNI life science, Inc. **LOT** **XXXXX**
E. Taunton, MA 02718 USA **www.omnils.com**

Box Label

REF. NO.: **H3-52899** **LOT** XXXXX
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION: **STERILE** **EO** QTY: 1
YYYY-MM
BIOLOX® delta Femoral Head
28mm -3.5mm **USE BY**
 SINGLE USE ONLY
 SEE INSTRUCTIONS FOR USE
OMNI life science®
E. TAUNTON, MA 02718 USA
www.omnils.com
Rx only
 Inner unit sterile unless inner packaging is damaged or opened.
APEX MODULAR™
HIP SYSTEM
BIOLOX® delta Femoral Head
OMNI life science® **SIZE:**
28mm dia -3.5mm
 (12/14S)
 "H3-52899" "XXXXX"
28
 Use only with the Apex Hip System

Pouch Label

Ref. No.: **H3-53200** **PACKAGE STERILE UNLESS OPENED OR DAMAGED**
BIOLOX® delta
Femoral Head
32mm dia x +0mm (12/14M) **YYYY-MM**
XXXXX
OMNI life science, Inc. **E. Taunton, MA 02718 USA**

Patient Label

H3-53200 **XXXXX**
 Ref No.: **H3-53200** **AFFIX TO PATIENT RECORD**
BIOLOX® delta Femoral Head **STERILE EO**
32mm dia x +0mm (12/14M)
 MATL: aluminum oxide-zirconium oxide composite **YYYY-MM**
XXXXX
OMNI life science, Inc. **www.omnils.com**
E. Taunton, MA 02718 USA

Box Label

REF. NO.: H3-53200 **XXXXX**
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION
STERILE EO **QTY: 1**
YYYY-MM
BIOLOX® delta Femoral Head **USE BY**
32mm +0mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS FOR USE
OMNI life science
E. TAUNTON, MA 02718 USA
www.omnils.com
Rx only
 Inner unit sterile unless inner packaging is damaged or opened
APEX MODULAR™ HIP SYSTEM
BIOLOX® delta Femoral Head
OMNI life science **SIZE:**
32mm dia +0mm **32**
(12/14M) **delta**
 Use only with the Apex Hip System
H3-53200 **XXXXX**

Pouch Label

Ref. No.: **H3-53204** PACKAGE STERILE UNLESS
BIOLOX® delta OPENED OR DAMAGED
Femoral Head YYYY-MM
32mm dia x +4mm (12/14L) **LOT** XXXXX
OMNI life science, Inc. E. Taunton, MA 02718 USA

Patient Label

"H3-53204" "XXXXX"
 Ref No.: **H3-53204** AFFIX TO PATIENT RECORD
BIOLOX® delta Femoral Head **STERILE** **EO**
32mm dia x +4mm (12/14L) YYYY-MM
 MAT'L: aluminum oxide-zirconium
 oxide composite **LOT** XXXXX
OMNI life science, Inc. E. Taunton, MA 02718 USA www.omnils.com

Box Label

REF. NO. H3-53204 **LOT** XXXXX
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION QTY: 1
STERILE **EO** YYYY-MM
BIOLOX® delta Femoral Head USE BY
32mm +4mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS
 FOR USE **OMNI life science**
 E. TAUNTON, MA 02718 USA
 www.omnils.com
Rx only
 Inner unit sterile unless inner packaging is damaged or opened.
APEX MODULAR™
HIP SYSTEM
BIOLOX® delta Femoral Head
OMNI life science SIZE: **32**
32mm dia +4mm
 (12/14L) Use only with the
 Apex Hip System
 "H3-53204" "XXXXX"

Pouch Label

Ref. No.: **H3-53208** **PACKAGE STERILE UNLESS OPENED OR DAMAGED**
BIOLOX[®] delta
Femoral Head **YYYY-MM**
32mm dia x +7mm (12/14XL) **LOT XXXXX**
OMNI life science, Inc. **E. Taunton, MA 02718 USA**

Patient Label

H3-53208 *XXXXX*
 Ref No.: **H3-53208** **AFFIX TO PATIENT RECORD**
BIOLOX[®] delta Femoral Head **STERILE EO**
32mm dia x +7mm (12/14XL)
 MAT'L: aluminum oxide-zirconium oxide composite **YYYY-MM**
OMNI life science, Inc. **LOT XXXXX**
E. Taunton, MA 02718 USA **www.omnils.com**

Box Label

REF. NO.: H3-53208 **LOT XXXXX**
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION: **STERILE EO** **QTY: 1**
YYYY-MM
BIOLOX[®] delta Femoral Head **USE BY**
32mm +7mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS FOR USE
Rx only
 Inner unit sterile unless inner packaging is damaged or opened.
OMNI life science
E. TAUNTON, MA 02718 USA
www.omnils.com
APEX MODULAR[™] HIP SYSTEM
BIOLOX[®] delta Femoral Head
OMNI life science **SIZE:** **32**
32mm dia +7mm **BIOLOX[®] delta**
(12/14XL) **Use only with the Apex Hip System.**
 H3-53208 *XXXXX*

Pouch Label

Ref. No.: **H3-53299** **PACKAGE STERILE UNLESS OPENED OR DAMAGED**
BIOLOX® delta
Femoral Head **YYYY-MM**
32mm dia x -4mm (12/14S) **LOT XXXXX**
OMNI life science, Inc. **E. Taunton, MA 02718 USA**

Patient Label

H3-53299 **XXXXX**
 Ref No.: **H3-53299** **AFFIX TO PATIENT RECORD**
BIOLOX® delta Femoral Head **STERILE EO**
32mm dia x -4mm (12/14S) **YYYY-MM**
 MAT'L: aluminum oxide-zirconium oxide composite **LOT XXXXX**
OMNI life science, Inc. **E. Taunton, MA 02718 USA** **www.omnils.com**

Box Label

REF. NO. H3-53299 **LOT XXXXX**
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION: **STERILE EO** QTY: 1
YYYY-MM
BIOLOX® delta Femoral Head **USE BY**
32mm -4mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS FOR USE
OMNI life science
E. TAUNTON, MA 02718 USA
www.omnils.com
Rx only
 Inner unit sterile unless inner packaging is damaged or opened.
APEX MODULAR™ HIP SYSTEM **32**
BIOLOX® delta Femoral Head **BIOLOX® delta**
OMNI life science **SIZE:** **Use only with the Apex Hip System**
32mm dia -4mm (12/14S)
H3-53299 **XXXXX**

Pouch Label

Ref. No.: **H3-53600**
BIOLOX® delta
Femoral Head
36mm dia x +0mm (12/14M)

PACKAGE STERILE UNLESS
 OPENED OR DAMAGED

⌚ YYYY-MM
 LOT XXXXX

OMNI life science, Inc.
 E. Taunton, MA 02718 USA

Patient Label

 *H3-53600*
 Ref No.: **H3-53600**
BIOLOX® delta Femoral Head
36mm dia x +0mm (12/14M)

 *XXXXX*
 AFFIX TO PATIENT RECORD
 STERILE EO

⌚ YYYY-MM
 LOT XXXXX
 www.omnils.com

MATL.: aluminum oxide-zirconium
 oxide composite
 OMNI life science, Inc.
 E. Taunton, MA 02718 USA

Box Label

REF. NO.: **H3-53600** LOT XXXXX

MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION: **STERILE EO** QTY: 1
 ⌚ YYYY-MM

BIOLOX® delta Femoral Head
36mm +0mm USE BY

SINGLE USE ONLY
 SEE INSTRUCTIONS
 FOR USE

OMNI life science
 E. TAUNTON, MA 02718 USA
 www.omnils.com

⊗ ⚠ Rx only
 Inner unit sterile unless inner packaging is damaged or opened.

APEX MODULAR™
HIP SYSTEM

BIOLOX® delta Femoral Head
OMNI life science SIZE: **36**
36mm dia +0mm **BIOLOX®**
 (12/14M) **delta**
 Use only with the
 Apex Hip System

 *H3-53600*  *XXXXX*

Pouch Label

Ref. No.: **H3-53604**
BIOLOX[®] delta
Femoral Head
36mm dia x +4mm (12/14L)
 OMNI life science, Inc.
 E. Taunton, MA 02718 USA

PACKAGE STERILE UNLESS
 OPENED OR DAMAGED

⌚ YYYY-MM
 LOT XXXXX

Patient Label

 *H3-53604*
 Ref No.: **H3-53604**
BIOLOX[®] delta Femoral Head
36mm dia x +4mm (12/14L)
 MAT'L: aluminum oxide-zirconium
 oxide composite
 OMNI life science, Inc.
 E. Taunton, MA 02718 USA

 *XXXXX*
 AFFIX TO PATIENT RECORD
 STERILE EO
 ⌚ YYYY-MM
 LOT XXXXX
 www.omnisl.com

Box Label

REF. NO.: H3-53604 LOT XXXXX

MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION
 STERILE EO QTY: 1
 ⌚ YYYY-MM

BIOLOX[®] delta Femoral Head
36mm +4mm
 USE BY

SINGLE USE ONLY
 SEE INSTRUCTIONS
 FOR USE

OMNI life science
 E. TAUNTON, MA 02718 USA
 www.omnisl.com

  **Rx only**
 Inner unit sterile unless inner packaging is damaged or opened.

APEX MODULAR[™]
HIP SYSTEM
BIOLOX[®] delta Femoral Head
OMNI life science

SIZE: **36**
36mm dia +4mm
 (12/14L)
 BIOLOX[®] delta
 Use only with the
 Apex Hip System

 *H3-53604*  *XXXXX*

Pouch Label

Ref. No.: **H3-53608** PACKAGE STERILE UNLESS
BIOLOX® delta OPENED OR DAMAGED
Femoral Head YYYY-MM
36mm dia x +8mm (12/14XL) **XXXXX**
 OMNI life science, Inc. E. Taunton, MA 02718 USA

Patient Label

H3-53608 *XXXXX*
 Ref No.: **H3-53608** AFFIX TO PATIENT RECORD
BIOLOX® delta Femoral Head **STERILE** **EO**
36mm dia x +8mm (12/14XL) YYYY-MM
 MAT'L: aluminum oxide-zirconium
 oxide composite
 OMNI life science, Inc. **XXXXX**
 E. Taunton, MA 02718 USA www.omnils.com

Box Label

REF. NO.: **H3-53608** **XXXXX**
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION
STERILE **EO** QTY: 1
YYYY-MM
BIOLOX® delta Femoral Head USE BY
36mm +8mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS FOR USE
 OMNI life science
 E. TAUNTON, MA 02718 USA
 www.omnils.com
Rx only
 Inner unit sterile unless inner packaging is damaged or opened.
APEX MODULAR™
HIP SYSTEM
BIOLOX® delta Femoral Head
 OMNI life science SIZE:
36mm dia +8mm **36**
 (12/14XL) Use only with the
 Apex Hip System
 H3-53608 *XXXXX*

Pouch Label

Ref. No.: **H3-53699** PACKAGE STERILE UNLESS
BIOLOX® delta OPENED OR DAMAGED
Femoral Head YYYY-MM
36mm dia x -4mm (12/14S) **XXXXX**
 OMNI life science, Inc. E. Taunton, MA 02718 USA

Patient Label

H3-53699 *XXXXX*
 Ref No.: **H3-53699** AFFIX TO PATIENT RECORD
BIOLOX® delta Femoral Head **STERILE** **EO**
36mm dia x -4mm (12/14S) YYYY-MM
 MAT'L: aluminum oxide-zirconium **XXXXX**
 oxide composite OMNI life science, Inc.
 E. Taunton, MA 02718 USA www.omnils.com

Box Label

REF NO.: **H3-53699** **XXXXX**
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION QTY: 1
STERILE **EO** YYYY-MM
BIOLOX® delta Femoral Head USE BY
36mm -4mm
 SINGLE USE ONLY **OMNI life science**
 SEE INSTRUCTIONS E. TAUNTON, MA 02718 USA
 FOR USE www.omnils.com
Rx only
 Inner unit sterile unless inner packaging is damaged or opened.
APEX MODULAR™ **36**
HIP SYSTEM
BIOLOX® delta Femoral Head
OMNI life science SIZE:
36mm dia -4mm Use only with the
 (12/14S) Apex Hip System.
 H3-53699 *XXXXX*

Pouch Label

Ref. No.: H3-54000
BIOLOX[®] delta
Femoral Head
40mm dia x +0mm (12/14M)
 OMNI life science, Inc. E. Taunton, MA 02718 USA

PACKAGE STERILE UNLESS
 OPENED OR DAMAGED
 YYYYY-MM
 LOT XXXXX

Patient Label

H3-64000
 Ref No.: **H3-54000**
BIOLOX[®] delta Femoral Head
40mm dia x +0mm (12/14M)
 MAT'L: aluminum oxide-zirconium
 oxide composite
 OMNI life science, Inc.
 E. Taunton, MA 02718 USA

XXXXX
 AFFIX TO PATIENT RECORD
 STERILE EO
 YYYYY-MM
 LOT XXXXX
 www.omnils.com

Box Label

REF. NO.: H3-54000 LOT XXXXX

MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION
 STERILE EO QTY: 1
 YYYYY-MM

BIOLOX[®] delta Femoral Head
 40mm +0mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS
 FOR USE

OMNI life science
 E. TAUNTON, MA 02718 USA
 www.omnils.com

Rx only
 Inner unit sterile unless inner packaging is damaged or opened.

APEX MODULAR[™]
HIP SYSTEM
BIOLOX[®] delta Femoral Head
 SIZE: **40**
40mm dia +0mm
 (12/14M)

Use only with the
 Apex Hip System

H3-64000 *XXXXX*

Pouch Label

Ref. No.: H3-54004
BIOLOX[®] delta
Femoral Head
40mm dia x +4mm (12/14L)
 OMNI life science, Inc. E. Taunton, MA 02718 USA

PACKAGE STERILE UNLESS
 OPENED OR DAMAGED

⌚ YYY-MM
 LOT XXXXX

Patient Label

Ref No.: **H3-54004** AFFIX TO PATIENT RECORD
BIOLOX[®] delta Femoral Head STERILE EO
40mm dia x +4mm (12/14L)
 MATL: aluminum oxide-zirconium
 oxide composite
 OMNI life science, Inc.
 E. Taunton, MA 02718 USA

⌚ YYY-MM
 LOT XXXXX
 www.omnils.com

Box Label

REF NO: H3-54004 LOT XXXXX

MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION: STERILE EO QTY: 1
 ⌚ YYY-MM

BIOLOX[®] delta Femoral Head
40mm +4mm
 USE BY

SINGLE USE ONLY
 SEE INSTRUCTIONS
 FOR USE

OMNI life science[™]
 E. TAUNTON, MA 02718 USA
 www.omnils.com

⚠ Rx only
 Inner unit sterile unless inner packaging is damaged or opened.

APEX MODULAR[™]
HIP SYSTEM
BIOLOX[®] delta Femoral Head
OMNI life science[™] SIZE: **40**
40mm dia +4mm
 (12/14L)

Use only with the
 Apex Hip System

⌚ YYY-MM
 LOT XXXXX

Pouch Label

Ref. No.: H3-54008
BIOLOX[®] delta
Femoral Head
40mm dia x +8mm (12/14XL)
 OMNI life science, Inc. E. Taunton, MA 02718 USA

PACKAGE STERILE UNLESS
 OPENED OR DAMAGED
 YYY-MM
 LOT XXXX

Patient Label

Ref No.: **H3-54008**
BIOLOX[®] delta Femoral Head
40mm dia x +8mm (12/14XL)
 MAT'L: aluminum oxide-zirconium
 oxide composite
 OMNI life science, Inc.
 E. Taunton, MA 02718 USA

AFFIX TO PATIENT RECORD
 STERILE EO
 YYY-MM
 LOT XXXX
 www.omnils.com

Box Label

REF. NO.: H3-54008 LOT XXXX
 MATERIAL: aluminum oxide-zirconium oxide composite
 METHOD OF STERILIZATION: STERILE EO QTY: 1
 YYY-MM
BIOLOX[®] delta Femoral Head
40mm +8mm
 SINGLE USE ONLY
 SEE INSTRUCTIONS FOR USE
 OMNI life science[®]
 E. TAUNTON, MA 02718 USA
 www.omnils.com
 Rx only
 Inner unit sterile unless inner packaging is damaged or opened.

APEX MODULAR[™]
HIP SYSTEM
BIOLOX[®] delta Femoral Head
 OMNI life science SIZE: **40**
40mm dia +8mm
 (12/14XL)
 Use only with the Apex Hip System

Pouch Label

Ref. No.: H3-54099
BIOLOX® delta
Femoral Head

40mm dia x -4mm (12/14S)

OMNI life science, Inc.

**PACKAGE STERILE UNLESS
OPENED OR DAMAGED**

⌚ YYYY-MM

LOT XXXXX

E. Taunton, MA 02718 USA

Patient Label



Ref No.: **H3-54099**

BIOLOX® delta Femoral Head

40mm dia x -4mm (12/14S)

MATL: aluminum oxide-zirconium
oxide composite

OMNI life science, Inc.
E. Taunton, MA 02718 USA



AFFIX TO PATIENT RECORD

STERILE EO

⌚ YYYY-MM

LOT XXXXX

www.omniis.com

Box Label

REF. NO. H3-54099

LOT XXXXX

MATERIAL: aluminum oxide-zirconium oxide composite

METHOD OF STERILIZATION

STERILE EO

QTY: 1



YYYY-MM

BIOLOX® delta Femoral Head

40mm -4mm

USE BY

SINGLE USE ONLY

SEE INSTRUCTIONS

FOR USE

OMNI life science

E. TAUNTON, MA 02718 USA

www.omniis.com

Rx only

Inner unit sterile unless inner packaging is damaged or opened.

**APEX MODULAR™
HIP SYSTEM**

BIOLOX® delta Femoral Head

OMNI life science

SIZE:

**40mm dia -4mm
(12/14S)**

40



Use only with the
Apex Hip System



Attachment 2
Instructions for Use

OMNI life science, Inc.
50 O'Connell Way
East Taunton, MA 02718 USA
www.omnils.com
(508)824-2444

The Apex Hip System** Ceramic Heads

OUTER BOX LABEL SYMBOLS

-  EXPIRATION DATE
-  SINGLE USE ONLY
-  SEE INSTRUCTIONS FOR USE

 DO NOT USE IF PACKAGED IS DAMAGED

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

PRODUCT HANDLING

Implants are provided sterile and should always be stored unopened in their respective protective containers. Prior to use, inspect package for damage, which may compromise sterility. If packaging has been opened or damaged, contact manufacturer's representative. When unpacking the implant, verify the labeling for correct Product Code and size. When removing the implant from its packaging, the relevant aseptic instructions must be observed. Protect prosthesis from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage. Procedures for implanting and removal are available upon request.

DESCRIPTION

The Apex Hip System Ceramic Heads are modular ceramic heads for use with the Apex Hip System stems. Several offset options are available for the heads to appropriately fit the anatomy of the patient.

MATERIALS:

- BIOLOX® forte alumina ceramic (CeramTec AG), or
- BIOLOX® delta alumina matrix composite ceramic (CeramTec AG)

INDICATIONS FOR USE

The Apex Modular™ Ceramic Femoral Heads are intended for use in combination with the Apex Modular Hip Stem as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with a polyethylene or metal-backed

polyethylene acetabular cup or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

CONTRAINDICATIONS

Absolute contraindications include:

- Infection or sepsis or osteomyelitis;
 - Insufficient bone structure or quality which may affect the stability of the implant;
 - Rapid joint destruction or bone absorption;
 - Skeletal immaturity;
 - Muscular, ligamentous, neurological, vascular deficiencies or poor skin coverage, which may compromise the affected extremity;
 - Alcoholism or other addictions;
 - Sensitivity to the implant materials;
 - High levels of physical activity (e.g. competitive sports, heavy physical labor);
 - Obesity that can produce loads on the prosthesis, which can lead to failure of the fixation of the device or the device itself;
 - Use of head/neck combinations with a lateral offset greater than 47.5mm with the Size 2 or Size 3 x 9mm Apex Modular stem (both versions) is contraindicated due to the lack of fatigue strength data for these combinations.
- Relative contraindications include:
- Uncooperative patient or a patient with neurological disorders and incapable of following instruction;
 - Metabolic disorders which may impair bone formation or bone quality;
 - Distant foci of infections.

WARNINGS AND PRECAUTIONS

While total hip arthroplasty and hemi-arthroplasty components are not intended to withstand activity levels and loads of normal healthy bone, they are a means of restoring mobility and reducing pain for many patients. In using joint replacement implants, the surgeon should be aware of the following:

- The correct selection of the modular implant components is extremely important. The potential for success in joint replacement is increased by the selection of the proper size, shape and design of the implant. Joint replacement prostheses require careful seating and adequate bone support, and should be restricted to limited functional stress. The surgeon is to be thoroughly familiar with the implants, instruments, and surgical procedure prior to performing surgery.
- In selecting patients for joint replacement surgery, the following factors can be of extreme importance to the eventual success of the procedure:
 1. The patient's weight. An overweight or obese patient can produce loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when a small prosthesis must be used. Patients receiving hip joint replacements should be advised that the longevity of the implant may depend on their weight and level of activity.
 2. The patient's occupation or activity. If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation, the device or both.
 3. A condition of senility, mental illness or alcoholism. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions, leading to failure or other complications.
 4. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.
 5. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, total joint replacement can only be considered a delaying technique or temporary relief.
- The correct handling of the implant is extremely important. Care must be taken to protect mating surfaces and polished bearing surfaces from nicks and scratches which could become the focal point for failure. Do not tamper with the implant as contouring or bending of the implant may reduce its service life and may cause immediate or eventual failure under load.
- Standard cleaning procedures cannot be relied upon to remove contamination from porous coating.
- A surgical implant should not be reused. Even though a used implant may appear undamaged, it may have

small defects and internal stress patterns, which may lead to failure. Use only new prosthesis of the current design.

- Resterilization of the device is not recommended.
- Bone excision should be limited to the amount necessary to accommodate the implants. Prior to closure, the surgical site should be thoroughly cleaned of bone chips, bone cement or other detritus that may cause a third body wear problem. Range of motion should be checked for impingement or instability.

- Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load-bearing, ranges of motion, and activity levels permissible. Excessive physical activity and trauma affecting the replaced joint have been implicated in premature failure by loosening, fracture and/or wear of the prosthesis implant. Early load-bearing should be carefully controlled. The patient should be advised to report any related pain, decrease in range of motion, swelling, fever, and unusual incidences.

- The Apex Hip System has not been evaluated for safety and compatibility in the MR environment. The Apex Hip System has not been tested for heating or migration in the MR environment.

- The modular head and neck components must be firmly seated to prevent disassociation. Scratching of modular heads and tapers should be avoided. Repeated assembly and disassembly of the head or neck components could compromise a critical locking action. The head or neck components should be changed only when clinically necessary. The interfaces should be clean and free from debris prior to assembly.

ADDITIONAL CONSIDERATIONS FOR CERAMIC HEADS

The Apex Modular Alumina Femoral Heads (forte or delta) are only for use with Apex Hip System femoral stems. No other ceramic heads should be used with these hip stems. Other considerations for the ceramic heads include the following:

- The ceramic head must not be sterilized on the hip stem.
- The ceramic heads should not be resterilized.
- The stem cone and head bore should be dry and free of contamination.
- The ceramic head should not be implanted if the head, or the cone of the stem, are possibly damaged.
- The ceramic head should be placed on the stem neck gently while keeping the head and neck in alignment,

and then firmly attached by sharply hitting the head with a soft plastic hammer.

- The Apex Modular ceramic heads are contraindicated for use with anything other than an UHMWPE cup or a metal backed UHMWPE cup.

POSSIBLE ADVERSE EFFECTS

The possible adverse effects of the Apex Hip System are similar to those occurring with any hip arthroplasty and include the following:

- Dislocation or subluxation due to improper positioning or muscle and fibrous tissue laxity.

- Loosening or migration of components due to trauma and/or loss of fixation.

- Accelerated wear of the polyethylene articulating surfaces of acetabular components. Such wear may be initiated by particles of cement, metal, or other debris which can cause abrasion of the articulating surfaces. Accelerated wear shortens the useful life of the prostheses, and leads to early revision surgery to replace the worn components.

- Histiocytic granuloma formation and osteolysis around the implant due to wear debris.

- Fatigue fracture of the implant as the result of strenuous activity, improper alignment, inadequate fixation, extreme duration of service, or obesity.

- Urological complications, especially urinary retention and infection.

- Dislocation, wear, dissociation, or fracture of the acetabular cup liner due to neck-liner impingement.

- Other complications associated with general surgery, drugs or ancillary devices used, blood, etc.

Intraoperative and early postoperative complications can include:

- Damage to blood vessels;
- Temporary or permanent neuropathies;
- Traumatic arthrosis of the knee from Intraoperative positioning of the extremity;
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
- Hematoma;
- Delayed wound healing;
- Infection;
- Femoral perforation;
- Fracture of the femur while press-fitting the femoral stem component.
- Undesirable shortening or lengthening of the limb;

Late postoperative complications can include:

- Aggravated problems of the knee or ankle of the affected limb or contralateral extremity by leg length discrepancy, too much femoral medialization, or muscle deficiency;

- Femoral fracture by trauma or excessive loading, particularly in the presence of poor bone stock;

- Periparticular calcification or ossification, with or without impediment to joint mobility;

- Inadequate range of motion due to improper selection or positioning of components, by femoral impingement and periarticular calcification;

- Excessive joint pressures and pain with ambulation due to excessive scarring of the joint capsule and surrounding tissues;

- Infection;

- Trochanteric avulsion as a result of excessive muscular weakening;

- Trochanteric non-union due to inadequate reattachment and/or early weight bearing.

CAUTION

- May cause image distortions in MRI (Magnetic Resonance Imaging) and CT (Computed Tomography).
- Disposal of implants should be carried out using the hospital's standard method for non-biodegradable non-combustible medical waste.

All rights reserved. Apex Modular™ and Interface™ Acetabular System are trademarks of OMNI life science, Inc.

**U.S. Patents 6,702,854 and 7,044,975, other patents pending.
BIOLOX® is a registered trademark of CeramTec AG. Additional information about the Apex Hip System may be obtained from OMNIlife science, Inc.

Attachment 3
Indications for Use Statement

Indications for Use

510(k) Number (if known):

Device Name: APEX Modular Hip System BIOLOX delta Femoral Head

The Apex Modular™ Ceramic Femoral Heads are intended for use in combination with the Apex Modular Hip Stem as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with a polyethylene or metal-backed polyethylene acetabular cup or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed
- Femoral neck and trochanteric fractures of the proximal femur.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Attachment 4

Declaration of Conformity with Design Controls

**Verification
Activities**

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



*Radhika Pondicherry
Regulatory Affairs Specialist
OMNIlife science Inc.*

20 May 2010
20May 2010

**Manufacturing
Facility**

OMNI life science, Inc., is the specification developer and is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.



*Edward J. Cheal, Ph.D.
Vice President of Research and
Development
OMNI life science, Inc.*

5/20/10
20May 2010

Attachment 5

510(k) Summary

Submitter	OMNI life science, Inc. 50 O'Connell Way E. Taunton MA 02718	Contact	Radhika Pondicherry Regulatory Affairs 774-226-1852 (508) 822-6030 (fax)
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Preparation Date 24 May2010

Device Name

Common Name	Hip joint ceramic, uncemented prosthesis
Trade Name	APEX Modular Hip System BIOLOX® delta Femoral Head
Classification Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis

Regulatory Class Class II per 21 CFR §888.3353

Product Code LZO

Legally Marketed Predicate Device(s)

- K012918- Apex Modular™ Alumina Femoral Head, November 27, 2001
- K073150- ApeX-LNK Poly Acetabular Cup Liners- 36mm Alumina Femoral Heads, February 27, 2008
- K100555- ApeX-LNK Poly Acetabular Liners and Apex Modular Head, March 29, 2010

Device Description The Apex Modular Hip System BIOLOX® delta Femoral Head is composed of an alumina matrix composite, the femoral heads include diameters ranging from 28mm to 40mm with various offsets.

Indications for Use The Apex Modular™ Ceramic Femoral Heads are intended for use in combination with the Apex Modular Hip Stem as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with a polyethylene or metal-backed polyethylene acetabular cup or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis
- Rheumatoid arthritis
- Correction of functional deformity
- Congenital dislocation
- Revision procedures where other treatments or devices have failed
- Femoral neck and trochanteric fractures of the proximal femur.

Predicate Device Comparison

	Delta Femoral head (subject device)	Alumina Femoral head (K012918, K 073150)	Apex Modular Head (K100555)
INTENDED USE			
Modular Head, primary and revision THA	Yes, cementless	Yes, cementless	Yes, cementless
DESIGN			
Taper design	12/14	12/14	12/14
Head Diameters	28-40mm	28-36mm	40mm
Head Size & Offsets	28-+0,+3.5,-3.5	28- +0,+3.5,-3.5	
	32-+0,+4,+7,-4	32- +0,+4,-4	
	36-+0,+4,+8,-4	36-+0,+4,-4	
	40-+0,+4,+8,-4	40mm- not available in Alumina material	40mm- +0,+3.5,+7,-3.5
MATERIALS	BILOX delta	BILOX forte	CoCr Alloy
Ceramic Head	72-75 %Al ₂ O ₃ ,+24-26 % Z ₂ O ₃	99.7% Al ₂ O ₃	ASTM-1537
Stem Trunion	Titanium alloy CoCr alloy	Titanium alloy CoCr alloy	Titanium alloy CoCr alloy
PACKAGING AND STERILIZATION			
Packaging	Peelable Tyvek® pouches (1073B Tyvek®/2.5ml Mylar®),double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels; the inner pouch for the ceramic heads will be polyethylene with a peelable Tyvek®panel.	Peelable Tyvek® pouches (1073B Tyvek®/2.5ml Mylar®),double pouched, in a cardboard box, with foam inserts, and tamper resistant outer labels; the inner pouch for the ceramic heads will be polyethylene with a peelable Tyvek®panel.	Paper Board Box, Double Tyvek inner pouch
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide
SAL	10 ⁻⁶	10 ⁻⁶	10 ⁻⁶

Non-Clinical Test Summary

The following tests were conducted:

- Component testing of BIOLOX forte ball head 32-12/14 L on CoCr test tapers and BIOLOX delta ball heads 28-12/14 L on CoCr test tapers supplied by OMNIlife science.- CeramTec Procedure VA 02 04 4129, ISO-7606-10
- Component testing of BIOLOX delta ball heads 28-12/14 L on titanium test tapers supplied by OMNIlife science. CeramTec Procedure VA 02 04 4129, ISO-7606-10
- 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
- ETO Residuals per ANSI/AAMI/ISO 10993-7.

Clinical Test Summary

No clinical studies were performed.

Conclusions

The - APEX Modular Hip System BIOLOX® delta Femoral Head is substantially equivalent to the predicate devices.

Attachment 6

Certificate of Truthfulness and Accuracy

In accordance with 21 CFR 807.87 (j), I certify that, in my capacity as Regulatory Affairs Specialist for OMNI life science, Inc., I believe to the best of my knowledge, that all the data and information submitted in this premarket notification for the APEX Modular Hip System BIOLOX® delta Femoral Head are truthful and accurate and that no material fact has been omitted.

 20 May 2010

Radhika Pondicherry 20May 2010

Attachment 7
Device Drawings

Attachment 8
Financial Interest

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

- (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators	None	

- (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).
- (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME Radhika Pondicherry	TITLE Regulatory Affairs Specialist
FIRM/ORGANIZATION OMNI life science Inc	
SIGNATURE 	DATE (mm/dd/yyyy) 05/20/2010

Paperwork Reduction Act Statement

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. Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, 420A
Rockville, MD 20850

Attachment 9

Certificate of Compliance- Clinical Trials



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

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

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

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER OMNI life science	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES May 20, 2010
3. ADDRESS (Number, Street, State, and ZIP Code) 50 O'Connell Way, East Taunton, MA 02718	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 771-226-1852 (Fax) 508-822-6030

PRODUCT INFORMATION

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

APEX Modular Hip System BIOLOX® delta Femoral Head

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

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

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

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

CERTIFICATION STATEMENT / INFORMATION

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

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

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

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

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

NCT Number(s): _____

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

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Radhika Pondicherry (Title) Regulatory Affairs Specialist
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 50 O'Connell Way, E. Taunton, MA 02718	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 774-226-1852 (Fax) 508-822-6030
	15. DATE OF CERTIFICATION May 20, 2010

Instructions for Completion of Form FDA 3674

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

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

Paperwork Reduction Act Statement

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

Department of Health and Human Services
Food and Drug Administration
Office of the Chief Information Officer (HFA-250)
5600 Fishers Lane
Rockville, MD 20857

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Attachment 10

(b)(4) Trade Secret Process

Attachment 11

Test Reports

Attachment 12
Product Code List

APEX Modular Hip System BIOLOX® delta Femoral Head

Product Code	Description	Part #
H3-54099	40 mm -4 Head, Delta (12/14S)	(b)(4)Trade Secret Process
H3-54008	40 mm +8 Head, Delta (12/14XL)	
H3-54004	40 mm +4 Head, Delta (12/14L)	
H3-54000	40 mm +0 Head, Delta (12/14M)	
H3-53699	36 mm -4 Head, Delta (12/14S)	
H3-53608	36 mm +8 Head, Delta (12/14XL)	
H3-53604	36 mm +4 Head, Delta (12/14L)	
H3-53600	36 mm +0 Head, Delta (12/14M)	
H3-53299	32 mm -4 Head, Delta (12/14S)	
H3-53208	32 mm +7 Head, Delta (12/14XL)	
H3-53204	32 mm +4 Head, Delta (12/14L)	
H3-53200	32 mm +0 Head, Delta (12/14M)	
H3-52899	28 mm -3.5 Head, Delta (12/14S)	
H3-52804	28 mm +3.5 Head, Delta (12/14L)	
H3-52800	28 mm +0 Head, Delta (12/14M)	

Apex Modular Biolox detto
Femoral Head
OMNI life science Zw **N**

 TDK | CD-R

52x | 80MIN
700MB

 COMPACT
disc
Recordable



6/17/10
COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

From: Reviewer Name Dave McGurl
Subject: 510(k) Number C101451
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%20202%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	X	
510(k) Summary /510(k) Statement	Attach Summary	X	
Truthful and Accurate Statement.	Must be present for a Final Decision	X	
Is the device Class III?			X
If yes, does firm include Class III Summary?	Must be present for a Final Decision		X
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		X	
Is this a combination product? (Please specify category <u>N</u> , see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			X
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			X
Is this device intended for pediatric use only?			X
Is this a prescription device? (If both prescription & OTC, check both boxes.)		X	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		X	
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.)			X
Does this device include an Animal Tissue Source?			X
All Pediatric Patients age <=21			X
Neonate/Newborn (Birth to 28 days)			X
Infant (29 days -< 2 years old)			X
Child (2 years -< 12 years old)			X
Adolescent (12 years -< 18-years old)			X
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.)			X

Transitional Adolescent B (18 ≤ 21; No special considerations compared to adults ⇒ 21 years old)	X
Nanotechnology	X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	X

Regulation Number	Class*	Product Code
888.3353	II	L70

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

Additional Product Codes: _____

Review: *Janita* (Branch Chief) 0J03 (Branch Code) 6/21/10 (Date)

Final Review: *David Krone* (Division Director) June 22, 2010 (Date)
for

To: The Record
RE: K101451 – Apex Modular Hip System BioloX delta Femoral Head

Date: 6/17/10

From: Dave McGurl, Biomedical Engineer, Reviewer Division: DSORD/OJDB

Device Name: Apex Modular Hip System BioloX delta Femoral Head

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

Company: OMNI Life Science
50 O'Connell Way
E. Taunton MA 02718

*Dx for MRCU
6/22/2010*

Contact: Ms. Radhika Pondicherry
Tel: 774-226-1852
Fax: 508-882-6030

RECOMMENDATION: Substantially Equivalent (SE)

The 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II device. The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

- Apex Modular Alumina Femoral Head (K012918)
- ApeX-LNK Poly Acetabular Cup Liners – 36mm Alumina Femoral Heads (K073150)
- ApeX-LNK Poly Acetabular Liners and Apex Modular Head (K100555)

Reviewer Comment: The predicates are the sponsors' predicate devices. The predicates are appropriate.

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.

Indications for Use (Subject Device)

The Apex Modular Ceramic Femoral Heads are intended for use in combination with the Apex Modular Hip Stem as the femoral component in total hip replacement procedures. This ceramic head is intended to articulate with a polyethylene or metal-backed polyethylene acetabular cup or bipolar component. This prosthesis is intended for single use implantation, and may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;

- Correction of function deformity;
- Congenital dislocation;
- Revision procedures where other treatments or devices have failed
- Femoral neck and trochanteric fractures of the proximal femur.

Reviewer Comment: The indications are identical to the predicate K012918, K073150, and K100555

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including labeling, intended use, physical characteristics, etc.

Intended Use

The intended use is for total hip replacement.

Reviewer Comment: The intended use has not changed.

Labeling

Draft package labels were provided on pp. 19-33. The package label contains: the component name, component size, material, expiration date, lot number, sterile notation, "Rx Only" label, company name, company address, and company website.

(b)(4)Trade Secret Process

A draft package insert was provided on pp. 35-36. The package insert contains the identical indications statement as the Indication for Use Form. The package insert also contains a brief description of the femoral heads and the material. The package insert contains the following additional sections: contraindications, warnings and precautions, additional consideration for ceramic heads, possible adverse events, and caution.

(b)(4)Trade Secret Process

Sterilization

The sterilization method has not changed. The ceramic heads are sterilized using Ethylene oxide to a Sterility Assurance Level of 10^{-6} . The shelf life is the same as the predicate, 5 year from the date of manufacture.

(b)(4)Trade Secret Process

Physical Characteristic

The major modification to the ceramic femoral heads is the sponsor is changing the ceramic material of the femoral heads. The predicate device is manufactured from BIOLOX forte (99.7% aluminum oxide). The ceramic femoral heads will now be manufactured from BIOLOX delta (75% aluminum oxide and 25% zirconia). The supplier of the ceramic femoral heads to the sponsor is still CeramTec AG. An authorization letter for CeramTec's (b)(4)Trade Secret was provided on p. 55.

The bores on the BIOLOX forte and BIOLOX delta Apex Modular Femoral Heads are the same. The bore was designed and tested for compatibility with the neck taper on the Apex Modular Hip Stem (K000788) and the Apex ARC™ Hip Stem (K090845).

The following femoral head design modifications have been made to the Apex Modular Femoral Head from K012918, K073150, and K100555:

- K012918: The 32mm Apex BIOLOX delta femoral head is available in an additional +7 offset.
- K073150: The 36mm Apex BIOLOX delta femoral head is available in an additional +8 offset.
- The addition of the 40mm Apex BIOLOX delta femoral head is available in the following offsets: -4, +8, +4, +0.

The 40mm Apex BIOLOX delta head is identical in design to the Apex Modular 40mm CoCr Head FDA cleared in K100555 but has different offsets. The ceramic heads are intended to only be used with the Apex UHMWPE cups.

The BIOLOX delta 40mm head does not create a new worst case scenario for burst strength of the ceramic heads. (b)(4)Trade Secret

(b)(4)Trade Secret Process

5. A Design Control Activities Summary which includes:

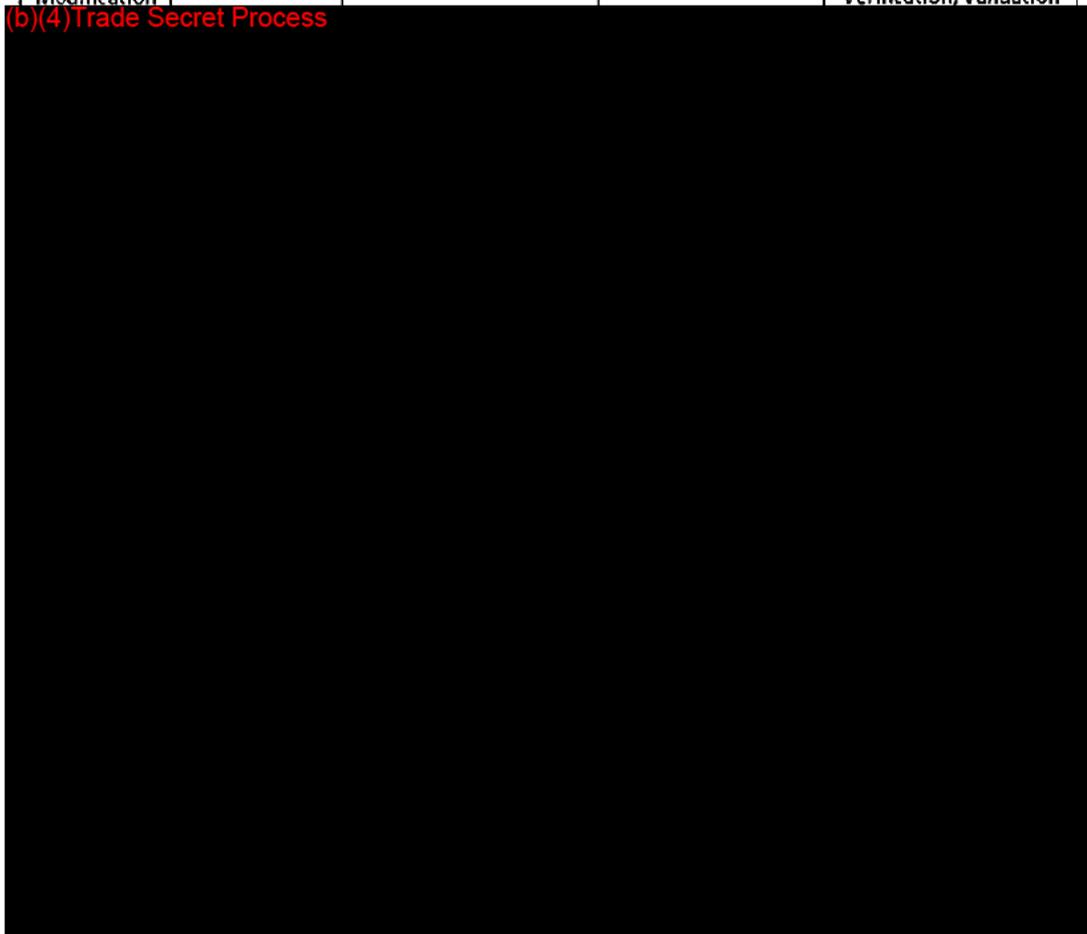
- a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

(b)(4)Trade Secret Process

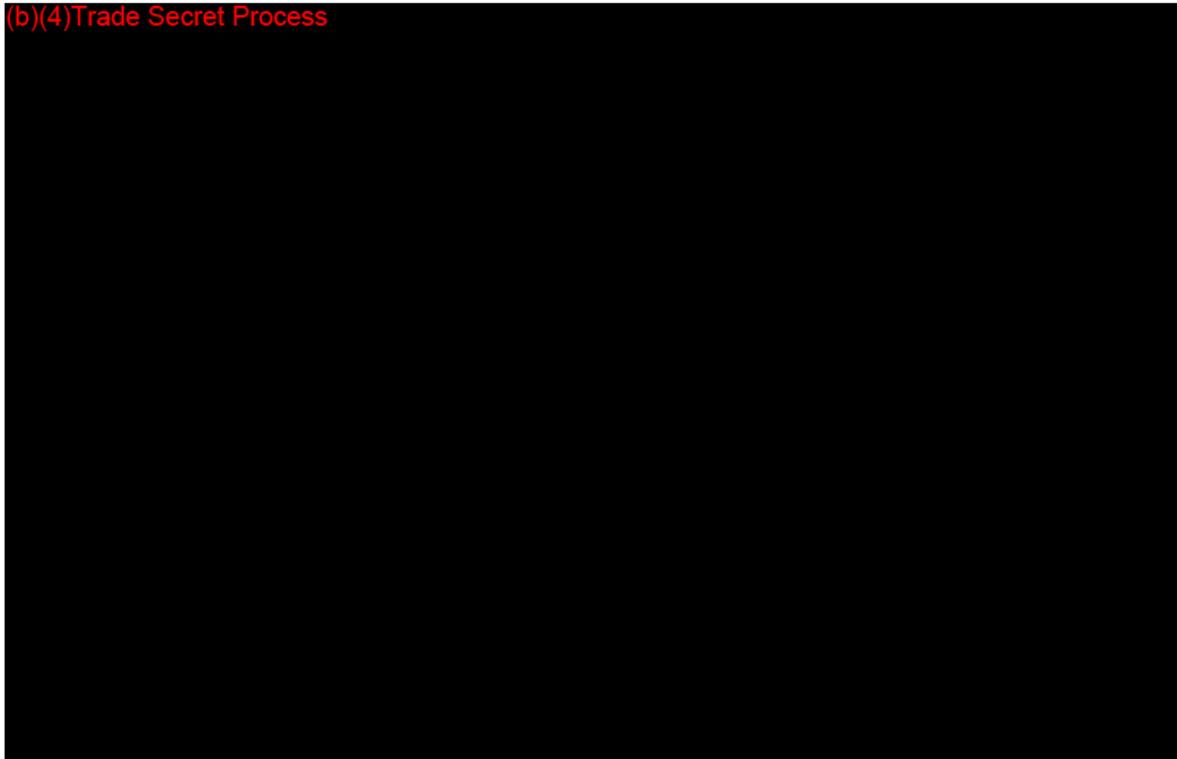
- b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

Device Modification	Hazard	Verification Activity	Acceptance Criteria	Results of Verification/Validation
---------------------	--------	-----------------------	---------------------	------------------------------------

(b)(4) Trade Secret Process



(b)(4) Trade Secret Process



6. **A Truthful and Accurate Statement, a 510(k) Summary of Safety and Effectiveness and Indications for Use are provided.**

The Indications for Use Form was provided on p. 38. The 510(k) Summary was provided on pp. 41-42. The Truthful and Accuracy Statement was provided on p. 43.

Reviewer Comment: All these forms are acceptable. The sponsor followed the regulation for the 510(k) Summary and included the necessary predicate comparison and summary of the non-clinical data. The information provided is adequate.

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

7. **Summary**

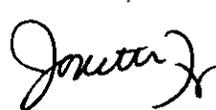
The major device modification being proposed in the subject 510(k) is a change in the ceramic material from BioloX forte to BioloX delta. The sponsor has included a letter of authorization from CeramTec AG. The BioloX delta material has been used in several other sponsors femoral head systems. The BioloX delta material has been used in several different medical devices and biocompatibility is not a concern. The sponsor has performed testing on their worst-case femoral heads. In addition, the sponsor has included a 40mm femoral head and several other offsets. None of these new offsets or femoral heads represent a new worst-case condition. The sponsor has provided adequate information to support the modifications made to their device. Based on the similarities in device design and the information provided in the design controls activities summary, I recommend the sponsors' Apex Modular Hip System BioloX delta Femoral Head be found **substantially equivalent** to the previously cleared devices.

8. **Contact History**

There has been no contact with the sponsor.


David McCurl
Biomedical Engineer, Reviewer
Orthopedic Joint Devices Branch

6/17/10
(Date)

 6/21/10

