

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

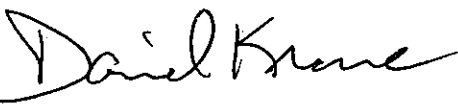
Page 2 – Ms. Radhika Pondicherry

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)

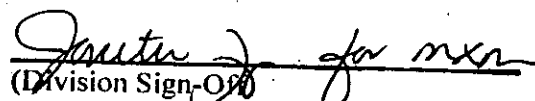
AND/OR

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)

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

510(k) Number K101451