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JUN 30 2010

Apex Modular Heads, +10.5mm offset 04June, 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)

Preparation Date	04 June 2010
Device Name	
Trade Name	APEX Modular Head, +10.5mm offset
Common/Classification Name	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class	Class II per 21 CFR §888.3358
Product Code	LPH

Legally Marketed Predicate Device(s)

- K000788 Apex Modular Hip Stem, 28 and 32 mm heads, August 02.2000
- K073150 ApeX-LNK Poly™ Acetabular Cup Liners and 36 mm Heads, February 27, 2008)
- K100555 ApeX-LNK Poly Acetabular Liners and Apex Modular Head, 40mm, March 29, 2010)

Device Description

Apex Modular Head sizes 28, 32, 36, and 40 mm with a + 10.5mm offset

Indications for Use

The Apex Hip System is intended for primary or revision total hip replacement. The femoral hip stems and acetabular cup are intended for uncemented fixation and single use implantation. These prostheses 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

	Apex Hip System, +10.5 offset (subject device)	Apex Modular femoral heads (K000788) (K073150) (K100555)
Intended Use		
Primary and revision total hip replacement	Yes	Yes
Design		
Taper Design	Size "N" bore in ASTM F1636-95	Size "N" bore in ASTM F1636-95
Head Diameters	28, 32, 36, 40 mm	28, 32, 36, 40mm
Offsets (mm)	+10.5	-3.5, +0, +3.5, +7
Materials		
Femoral Heads	Wrought cobalt chromium	Wrought cobalt chromium
Standards	ASTM F1537	ASTM F1537
PACKAGING AND STERILIZATION		
Sterilization	Ethylene oxide	Ethylene oxide
Sal	10^{-6}	10^{-6}
Packaging	Paper Board Box, Double Tyvek inner pouch	Paper Board Box, Double Tyvek inner pouch

Non-Clinical Test Summary

The following tests were conducted:

- ROM analysis per ISO-21565-2007
- Finite Element Analysis per ISO-7206-4
- Fatigue Strength Testing per ISO 7206-6,ASTM F2068-09

Clinical Test Summary

No clinical studies were performed.

Conclusions

The Apex Modular Head is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JUN 30 2010

OMNIlife science, Inc.
% Radhika Pondicherry
Regulatory Affairs Specialist
50 O'Connell Way
E.Taunton MA 02718

Re: K101575
Trade/Device Name: Apex Modular Head Size 28, 32, 36 and 40mm +10.5 offset
Regulation Number: 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: June 4, 2010
Received: June 7, 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 forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number : K101575 (pg 1/1)

Device Name: Apex Modular Head, +10.5mm offset

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K101575