Appendix C

SEP 1 4 2010

510(k) Summary

Interface Acetabular System, Acetabular Insert 17 Aug, 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	17 Aug 2010
Device Name	
Trade Name	Interface Acetabular System, Acetabular Insert
Common/Classification Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class	Class II per 21 CFR §888.3358
Product Code	LPH

Legally Marketed Predicate Device(s)

- K031110 Apex Modular Acetabular Cup, May 22, 2003
- K062489 Apex HCLA Acetabular Cup Liners August 15, 2007
- K073150 ApeX-LNK Poly™ Acetabular Cup Liners
- K100555 ApeX-LNK Poly™ Acetabular Cup Liners, March 29, 2010

Device Description

Non hooded (0 deg neutral) and Hooded (10 deg) +4mm offsets for use with 28, 32, 36, 40mm Apex Modular heads.

Indications for Use

The Apex Hip System is intended for primary or revision total hip replacement. The femoral hip stems and acetabular cups are intended for uncemented fixation and single use implantation. The Apex Acetabular Cup liners, standard and ApeX-LNK Poly, are intended for use with the Apex Modular Acetabular Cup, in combination with the Apex Modular, Apex K2, Apex K2 mid length or Apex K1 Hip in total hip replacement procedures. The acetabular cup inserts are intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. 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

	Acetabular Insert (subject device)	Apex Hip System Standard UHMWPE (K031110)	Apex Hip System Crosslinked UHMWPE (K062489, K073150, K100555)
DESIGN			
Insert engagement	19° taper and PE locking ring	19° taper and PE locking ring	19° taper and PE locking ring
Inserts- Hooded/ Neutral	Neutral	Neutral	Neutral
	10° hooded	15° hooded	10° hooded
Insert offset	+4mm	None	None
Insert Thickness (minimum)	Worst case size has a minimum thickness of 8.6mm.	Minimum thickness of 6mm at the load bearing region.	Minimum thickness of 6mm at the load bearing region.
Head Diameters	28, 32, 36 and 40mm	28 and 32, mm	28, 32, 36 and 40mm
MATERIALS			
Cross-linked UHMWPE	Yes	No	Yes
Standard UHMWP	Yes	Yes	No
Standards	ASTM F648	ASTM F648	ASTM F648

Non-Clinical Test Summary

The following tests were conducted:

- ROM analysis per ISO-21535-2007
- Extreme artificial aging per ASTM F2003-02
- Push-out & Lever-out Test

All samples tested met the acceptance criteria.

Clinical Test Summary

No clinical studies were performed.

Conclusions

The Interface Acetabular System, Acetabular Insert is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Omni Life Science, Inc.
% Radhika Pondicherry
50 O'Connell Way
East Taunton, MA 02718

SEP 14 2010

Re: K101976
Trade/Device Name: Interface Acetabular System, Acetabular Insert
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH
Dated: August 17, 2010
Received: August 19, 2010

Dear Mr. 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.

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.

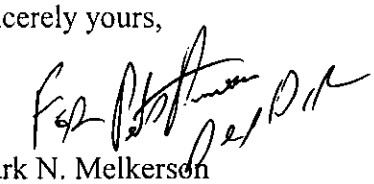
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 (240) 276-3150 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

K101976 (pg 1/1)

Indications for Use

510(k) Number:

Device Name: Interface Acetabular System, Acetabular Insert, +4 offset

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. The Apex Acetabular Cup liners, standard and ApeX-LNK Poly, are intended for use with the Apex Modular Acetabular Cup, in combination with the Apex Modular, Apex K2, Apex K2 mid length or Apex K1 Hip in total hip replacement procedures. The acetabular cup inserts are intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. 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.

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 K101976