510(K) Summary

DEC - 2 2011

Apex Interface Acetabular System, Acetabular Shell 26 October, 2011

Submitter	OMNIlife science, Inc. 50 O'Connell Way E. Taunton MA 02718	**Contact**	Christine Nassif Director, Regulatory Affairs 774-226-1871 (508) 822-6030 (fax)
Preparation Date	26 October, 2011		
Device Name	**Apex Interface Acetabular System, Acetabular Shell**		
Sizes	Standard sizes, 46-76mm and x-sizes, 48x-58x mm.		
Common name/ Classification	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		
Device Description	The Interface Acetabular System, Acetabular Shell is composed of titanium alloy (ASTM F136), coated with sintered unalloyed titanium beads. The shells are designed for cementless use. The two versions of the shells include a "no hole" and a "3 hole" version (plus an apical hole in both versions). The cup system includes titanium alloy cancellous bone screws (in separate sterile packaging) for optional supplemental fixation of the "3 hole" shell. The Shell uses plastic inserts manufactured from ultra high molecular weight polyethylene (UHMWPE, ASTM F648-00), machined from compression molded sheet, and sterilized using ethylene oxide.		

Indications for Use	The Apex Interface™ Acetabular System is intended for use in combination with the Apex Modular Hip Stem in total hip replacement procedures. This acetabular cup is intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. This prosthesis is intended for uncemented fixation and 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	The Apex Interface Acetabular System is manufactured, packaged, and sterilized using equivalent materials and processes. The subject device(s) is also substantially equivalent to its predicate(s) based on comparison of design features, intended use, and indications for use. The fundamental scientific technology of the modified device(s) has not changed relative to the predicate device(s). The safety and effectiveness of the devices has not changed relative to the predicate devices. The safety and effectiveness of the Interface Acetabular System is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.
Non-Clinical Test Summary	No additional testing required per dFMEA.
Clinical Test Summary	No clinical studies were performed.
Conclusions	In summary, the Interface Acetabular System, Acetabular Shell, in our opinion, is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Omni Life Science, Inc.
% Chrstine Nassif
50 O'Connell Way
Suite 10
East Taunton, MA 02718

DEC - 2 2011

Re: K112779
Trade/Device Name: Apex Interface Acetabular System, Acetabular Shell
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: October 26, 2011
Received: November 2, 2011

Dear Ms. Nassif:

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,

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): K112779 (pg 1/1)

Device Name: Apex Interface Acetabular System, Acetabular Shell

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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___ 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 K112779