MAR 29 2010

**ApeX-LNK Poly™ Acetabular Cup Liners** **March 09, 2010**
**Apex Modular Heads**

1. **Submitter:** OMNI life science™, Inc.
50 O'Connell Way, Suite#10
E. Taunton,MA 02718

**Contact:** Radhika Pondicherry,
Regulatory Affairs
774-226-1842
(508) 822-6030 (fax)

2. **Device Name: The device trade names and common/classification names are-**

| Device Trade Name | Common/Classification name |
|---|---|
| ApeX-LNK Poly™ Acetabular Cup Liners | Hip joint metal/ Acetabular cup Liner, uncemented<br>Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis |
| Apex Modular Head | Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis |

**Device Class**

Acetabular Liners and Femoral Heads have been classified as Class II
21 CFR §888.3353, Product Code LZO, MEH
21 CFR §888.3358, Product Code LPH
These products are reviewed by the Orthopedic Devices panel

3. **Intended use**

The Apex Hip System is intended for primary and revision total hip replacement. The femoral hip stem 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 or Apex K1 Hip in total hip replacement procedures. The acetabular cup liners are intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. These prostheses may be used for total hip arthroplasty to treat 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.

4. **Device Description**

**ApeX-LNK Poly™ Acetabular Cup Liners** are manufactured of compression molded, cross-linked and stabilized ultrahigh molecular weight polyethylene, sterilized using ethylene oxide. The articular geometry of the liners are compatible with existing Apex Modular femoral heads, manufactured from cobalt chrome or alumina ceramic, 40 mm diameter, with various offsets.

**Apex Modular Heads** have a standard tapered bore that corresponds to the mating taper on the modular neck (ASTM F1636). Various industry standard head diameters are included to allow use of a wide range of acetabular cups, at the discretion of the orthopaedic surgeon.

## 5. Predicate Device Comparison

**Predicate Device Comparison**

| Description | ApeX-LNK (subject device) | ApeX-LNK (K073150) |
|---|---|---|
| **INTENDED USE** | | |
| Modular liner in metal shell, primary and revision THA | Yes, cementless | Yes, cementless |
| **DESIGN** | | |
| Liner engagement | 19° taper and PE locking ring | 19° taper and PE locking ring |
| Liner options | Neutral and 10° hooded | Neutral and 10° hooded |
| Head diameters | 40 mm | 28, 32, and 36 mm |
| **MATERIALS** | | |
| Cross-linked UHMWPE | Yes | Yes |
| Standards | ASTM F648 | ASTM F648 |
| **PACKAGING & STERILIZATION** | | |
| Sterilization | Ethylene oxide | Ethylene oxide |
| SAL | $10^{-6}$ | $10^{-6}$ |
| Packaging | Paper board box, Foil outer pouch, Double Tyvek inner pouch | Paper board box, Foil outer pouch, Double Tyvek inner pouch |
| **Apex Modular Femoral Heads** | | |
| | **Apex Modular Femoral Heads (subject device)** | **Apex Modular Femoral Heads (K000788)** |
| **Intended Use** | | |
| Primary and revision total hip replacement | Yes | Yes |
| **Design** | | |
| Taper Design | Identical (size "N" bore in ASTM F1636-95) | Identical (size "N" bore in ASTM F1636-95) |
| Head Diameters | 40 mm | 22.225, 28, and 32 mm |
| Offsets | -3.5, +0, +3.5, +7 | -3.5, +0, +3.5, +7 |
| **Materials** | | |
| Femoral Heads | Wrought cobalt chromium (ASTM F1537) | Wrought cobalt chromium (ASTM F1537) |
| 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 |

## 6. Basis of Substantial Equivalence

The ApeX-LNK Poly Acetabular Cup Liners and Apex Modular Heads described in this submission are substantially equivalent to the predicate devices based on similarities in design, intended use, material and manufacturing methods. Performance testing, design comparisons, and functional analysis conducted on these devices demonstrate that they are equivalent to the predicate devices.

The modified ApeX-LNK Acetabular Cup Liners and Apex Modular Heads have the following similarities to their respective predicate devices:

- Same indicated use: (see indications statement)
- Same operating principle: "ball-in-socket" cobalt chromium-UHMWPE articular bearing components
- Same materials as predicates: the ApeX –LNK Acetabular Cup Liners are manufactured from ultra high molecular weight polyethylene (UHMWPE, ASTM F648) with identical specifications and processing parameters as the predicate ApeX-LNK Acetabular liners; the Apex Modular Heads are manufactured from the same material as the predicate Apex Modular Heads (wrought cobalt chromium per ASTM F1537)
- Same basic design: UHMWPE liners, cobalt chromium heads; identical modular interface dimensions and specifications as the predicates, including surface finish, taper dimensions, and locking features
- Same shelf life: 5 years from date of manufacture.
- Packaged and sterilized using the same materials and processes: ETO, SAL $10^{-6}$.

**The only modifications made are:**

1. The addition of a 40 mm size head to the Apex Modular System.
2. The addition of a 40 mm ID liner to the Apex Modular System.

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.
% Ms. Radhika Pondicherry
Regulatory Affairs Specialist
50 O'Connell Way, Suite 10
E. Taunton, Massachusetts 02718

MAR 29 2010

Re: K100555
Trade/Device Name: ApeX-LNK Poly Acetabular Cup Liners and Apex Modular Head
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, MEH
Dated: March 23, 2010
Received: March 24, 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,

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: K100555**

**Device Name: ApeX-LNK Poly™ Acetabular Cup Liners,**

**Apex Modular Head**

**Indications for Use**

The Apex Hip System is intended for primary and revision total hip replacement. The femoral hip stem 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 or Apex K1 Hip in total hip replacement procedures. The acetabular cup liners are intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. These prostheses may be used for total hip arthroplasty to treat the following conditions, as appropriate:

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- 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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for MKM

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

510(k) Number K100555