K092443

510(K) SUMMARY

OCT 2 3 2009

Interface™ Acetabular Cup Liners

August 7, 2009

1. **Submitter:** OMNI life science™, Inc.
175 Paramount Drive
Raynham, MA 02767

Contact: William McCallum
(508) 824-2444 x423 (voice)
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2. Device Name

Proprietary Name:	Interface™ Acetabular Cup Liners
Common Name:	Acetabular cup, uncemented
Classification Names:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; and Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class:	Class II per 21 CFR §888.3358

3. Intended Use

The Interface™ Acetabular Cup Liners are intended for use with the Interface™ Acetabular Cup, in combination with the Apex Modular™, Apex K2™, or Apex K1™ Hip Stem in total hip replacement procedures. The acetabular cup liners are intended to articulate with a metal (cobalt chromium) or ceramic (alumina) femoral head. 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.

4. Device Description

The Interface™ Acetabular Cup Liners are manufactured of compression molded 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, 28 mm, 32 mm or 36 mm diameter. The subject device adds an option for a 20° elevated rim that was not previously offered.

K092443

510(K) SUMMARY

5. Predicate Device Comparison

Substantial equivalence is claimed to the Interface™ (K031110), the ApeX-LNK Poly™ (K062489 and K073150), and the Zimmer Trilogy® Acetabular System (K934765, K953490, and K972774) UHMWPE cup liners. The following table summarizes the similarities and differences between the subject Apex Modular Interface™ Acetabular System cup liners and the predicate cup liners:

	Subject UHMWPE Liners	Interface™ UHMWPE Liners (K031110)	ApeX-LNK Poly™ (K062489 and K073150)	Zimmer Trilogy® Acetabular System
INTENDED USE				
Modular liner in metal shell, primary and revision THA	Yes, cementless	Yes, cementless	Yes, cementless	Yes, cementless
DESIGN				
Liner engagement	19° taper and PE locking ring	19° taper and PE locking ring	19° taper and PE locking ring	Locking ring and anti-rotation tabs
Liner options	20° elevated rim	Neutral and 15° elevated rim	Neutral and 10° elevated rim	Neutral, 10°, and 20° elevated rim; also offset, oblique, and eccentric options
Head diameters	28, 32 and 36 mm	28 and 32 mm	28, 32, and 36 mm	28, 32, and 36 mm
MATERIALS				
Cross-linked UHMWPE	No	No	Yes	No
Sterilization	Ethylene oxide	Ethylene oxide	Ethylene oxide	Gas plasma

6. Basis of Substantial Equivalence

The Interface™ Acetabular Cup Liners described in this submission are substantially equivalent to the predicate devices based on similarities in design, intended use, material and manufacturing methods. The locking mechanism is identical to the locking mechanism in the predicate Interface™ Acetabular Cup Liners (K031110) and the ApeX-LNK Poly™ Acetabular Cup Liners (K062489 and K073150). The material, manufacturing, sterilization and packaging methods are identical to those of the predicate Interface™ Acetabular Cup Liners. The 20° elevated rim liner option is equivalent to the 20° elevated rim option in the Zimmer Trilogy® Acetabular System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OMNI Life Science, Inc.
% Mr. William McCallum
175 Paramount Drive
Raynham, Massachusetts 02767

OCT 23 2009

Re: K092443
Trade/Device Name: Interface™ Acetabular Cup Liners
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH, LZO, MEH
Dated: September 15, 2009
Received: September 18, 2009

Dear Mr. McCallum:

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 (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

K092443

Indications for Use

510(k) Number (if known):

Device Name: Interface™ Acetabular Cup Liners

Indications For Use:

The Interface™ Acetabular Cup Liners are intended for use with the Interface™ Acetabular Cup, in combination with the Apex Modular™, Apex K2™, or Apex K1™ 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 single use implantation, and may be used for the following conditions, as appropriate:

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- Femoral neck and trochanteric fractures of the proximal femur.

Prescription Use X AND/OR Over-The-Counter Use

(Per 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)

for MKM

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

1

510(k) Number K092443