OMNIlife science®

FEB 1 8 2009

510(K) SUMMARY

K 082468

Apex Hip System Bipolar Head

January 14, 2009

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

Contact: William McCallum
Regulatory and Quality Systems
(508) 824-2444 x413

2. **Device Name**

Proprietary Name:	Apex Hip System Bipolar Head
Common Name:	Hemi-hip prosthesis, uncemented
Classification Name:	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class:	Class II per 21 CFR §888.3390

3. **Intended Use**

The Apex Hip System Bipolar Head is intended for use in combination with an Apex Hip System femoral stem for uncemented primary or revision hemiarthroplasty of the hip. This prosthesis may be used for the following conditions, as appropriate:

- Femoral neck and trochanteric fractures of the proximal femur;
- Osteonecrosis of the femoral head;
- Revision procedures where other devices or treatments for these indications have failed.

4. **Device Description**

The Apex Hip System Bipolar Head consists of a factory assembled UHMWPE liner in a cobalt chrome outer shell, and UHMWPE retention ring. These bipolar heads include outer diameters ranging from 38 to 60 mm, in 1 mm increments, to properly fit the patient anatomy. The smaller bipolar heads (38 to 42 mm) have an inner diameter that mates with a 22 mm diameter femoral head; the larger bipolar heads (43 mm to 60 mm) have an inner diameter that mates with a 28 mm diameter femoral head. The Apex Hip System Bipolar Head may be used for hemiarthroplasty in conjunction with the following Apex Hip System femoral stems: Apex K1™, Apex K2™, and Apex Modular™.

5. Predicate Device Comparison

Substantial equivalence is claimed to the Pivot Bipolar Femoral Head (K050986) distributed by Ortho Development, the PLUS Bipolar Prosthesis (K982447) distributed by Plus Orthopaedics (now Smith & Nephew), and the BioPro Bipolar Head (K082705). The following table summarizes the similarities and differences between the Apex Hip System Bipolar Head and these predicate devices:

	Apex Hip System Bipolar Head	Ortho Development Pivot Bipolar	Plus Orthopedics PLUS Bipolar	BioPro Bipolar Head
510(k) Number	Pending	K050986	K982447	K082705
FDA Product Code	KWY	KWY	KWY	KWY
DESIGN				
Liner-Shell	UHMWPE-CoCr	UHMWPE-CoCr	UHMWPE-CoCr	UHMWPE-CoCr
Head Outer Diameter	38 to 60 mm in 1 mm increments	38 to 60 mm in 1 mm increments	43 to 60 mm in 1 mm increments	38 to 60 mm in 1 mm increments
Self-aligning (eccentric head)	Yes	Yes	Yes	Yes
Liner Inner Diameter	22.225 or 28 mm	22.225 or 28 mm	28 mm	22.225 or 28 mm
Liner-Head Assembly	Head snap-fit into bipolar liner	Head snap-fit into bipolar liner	Head held in by retention ring	Head snap-fit into bipolar liner
UHMWPE retention ring	Yes	Yes	Yes	Yes
MATERIALS				
Femoral head	CoCr or alumina ceramic	Cobalt chromium (CoCr)	Cobalt chromium (CoCr)	CoCr or alumina ceramic
Outer shell	Cobalt chromium (ASTM F75)	Cobalt chromium (ASTM F75)	Cobalt chromium (ASTM F75)	Cobalt chromium (ASTM F75)
Liner and retention ring	UHMWPE (ASTM F648), EtO sterilized (not highly crosslinked)	UHMWPE (ASTM F648), gamma sterilized (not highly crosslinked)	UHMWPE (ASTM F648), EtO sterilized (not highly crosslinked)	UHMWPE (ASTM F648), EtO sterilized (not highly crosslinked)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2009

OMNI Life Science, Inc.
% Mr. William McCallum
Director, Regulatory and Quality Systems
175 Paramount Drive
Raynham, Massachusetts 02767

Re: K082468
Trade/Device Name: Apex Hip System Bipolar Head
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: II
Product Code: KWY
Dated: January 14, 2009
Received: January 15, 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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K082468

Device Name: Apex Hip System Bipolar Head

Indications for Use:

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- Osteonecrosis of the femoral head;
- Revision procedures where other devices or treatments for these indications have failed.

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)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082468