K100151

510(k) Summary K100151

OMNI life science Apex Hip System Bipolar Head

Submitter	OMNI life science, Inc. 50 O'Connell Way E. Taunton MA 02718	**Contact**	Robert Zoletti VP Regulatory Affairs 774-226-1845
Preparation Date	April 8, 2010		

MAY 28 2010

Device Name	
Common Name	Hemi-hip prosthesis, uncemented
Trade Name	Apex Hip System Bipolar Head
Classification Name	Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis Orthopedic (OR)
Regulatory Class	Class II per 21 CFR §888.3390
Product Code	KWY
Legally Marketed Predicate Device(s)	Apex Hip System Bipolar Head K 082468, K945793, K931655

Device Description

The Apex Hip System Bipolar Head consists of a factory assembled Ultra High Molecular Weight Polyethylene (UHMWPE) liner in a cobalt chrome outer shell and UHMWPE retention ring with a Ti-6Al-4v spring. 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 in conjunction with an Apex Hip System femoral stem (K060072) for hemiarthroplasty.

Indications for Use

The indications have not changed from the predicate. 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.

Predicate Device Comparison

The Apex Hip System Bipolar Head is identical to the Apex Hip System Bipolar Head cleared in K082468 with the following exceptions:

- The UHMWPE (ASTM F-648) retaining ring in the Acetabular component was modified to increase the amount of interference/overlap between the retaining ring and the head.
- A Retaining Spring (Ti-6Al-4V Eli) was added to the UHMWPE Retaining Ring.

Non-Clinical Test Summary

The following tests were conducted:

- Push-out and lever-out testing.
- Locking ring spring storage heat tolerance test (150°F).
- ETO sterilization validation, SAL 10^{-6}

Clinical Test Summary

No clinical studies were performed.

Conclusions

The Apex Hip System Bipolar head 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.
% Mr. Robert Zoletti
VP Regulatory Affairs
175 Paramount Drive
Raynham, MA 02767

MAY 28 2010

Re: K100151
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
Regulatory Class: Class II
Product Code: KWY
Dated: May 21, 2010
Received: May 26, 2010

Dear Mr. Robert Zoletti:

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,

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

Enclosure

K100151

Indications for Use

510(k) Number (if known): K100151

Device Name: Apex Hip System Bipolar Head

Indications For 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100151