510(K) Summary

JAN - 5 2012

Apex ARC ™ Hip Stem

7 December, 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	7 December, 2011		
Device Name	Apex Hip System		
Trade Name	Apex ARC ™ Hip Stem		
Sizes	Apex ARC Hip Stem, Size 0 Apex ARC Hip Stem, Size 0 HA Coated		
Common name/ Classification	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis		
Regulatory Class	Class II per 21 CFR § 888.3358, §888.3353, § 888.3390		
Product Code	LPH, LZO, MEH, KWY		
Legally Marketed Predicate Device(s)	Apex ARC Hip Stem (K090845), Apex ARC Hip Stem (K111193)		
Device Description	The Apex ARC Hip Stem consists of a curved, rectangular tapered stem with a distal slot, and modular necks that connect to the tapered hole in the stem. The larger size stems have a lateral feature referred to as a lateral t-flange. The T-flange is reduced in size on the smaller stem sizes (size 1 and 2), and further reduced to no t-flange on the smallest (subject) size 0 stem. The femoral stems are manufactured from titanium alloy and the modular necks are manufactured from cobalt chromium alloy. The Apex ARC Hip Stem is available with and without HA coating. The necks are compatible with the Cobalt Chromium and Ceramic modular heads, and may be used with head diameters and offsets up to a maximum offset of +7 mm. The Apex ARC Hip Stem may be used in conjunction with the Apex Interface™ Acetabular System (Shells and Inserts) for total hip arthroplasty.		

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Indications for Use	The Apex ARC™ Hip Stem is intended for use as the femoral component of a primary, or revision total hip replacement when used with the Apex Interface™ Acetabular System. The Apex Interface™ Acetabular System articulates with the Apex Modular Femoral Head (Cobalt Chromium or Ceramic). The femoral hip stem is intended for uncemented fixation and single use implantation. These prostheses may be used for 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. The Apex Hip System ARC™ Hip Stem is also intended for use in hemiarthroplasty when used with the Apex Bipolar Head. 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 treatments or devices for these indications have failed.
Predicate Device Comparison	The Apex ARC Hip Stem 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 Apex ARC Hip Stem is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.
Non-Clinical Test Summary	The following tests were conducted: • Fatigue Strength Testing per ISO 7206-6, ISO-7206-4, ISO 7206-8 and ASTM 2068-09 • ROM Evaluation per ISO 21535
Clinical Test Summary	No clinical studies were performed.
Conclusions	The addition of one new stem size for the Apex ARC Hip Stem, in our opinion, is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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

OMNIlife Science Inc.
% Ms. Christine Nassif
50 O'Connell Way
East Taunton, MA 02718 US

JAN - 5 2012

Re: K113242
Trade/Device Name: Apex ARC Hip Stem
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, LZO, MEH, KWY
Dated: December 7, 2011
Received: December 8, 2011

Dear Ms. Christine 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. 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 & Restorative Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K113242

Indications for Use

510(k) Number (if known):

Device Name: Apex ARC Hip System

The Apex ARC™ Hip Stem is intended for use as the femoral component of a primary, or revision total hip replacement when used with the Apex Interface™ Acetabular System. The Apex Interface™ Acetabular System articulates with the Apex Modular Femoral Head (Cobalt Chromium or Ceramic). The femoral hip stem is intended for uncemented fixation and single use implantation. These prostheses may be used for 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.

The Apex Hip System ARC™ Hip Stem is also intended for use in hemiarthroplasty when used with the Apex Bipolar Head.

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 treatments or devices for these indications have failed.

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)

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

510(k) Number K113242