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JUN 27 2011

510(k) Summary

Apex Hip System ARC ™ Hip Stem			01June 2011
Submitter	OMNIlife science, Inc. 50 O'Connell Way E. Taunton MA 02718	**Contact**	Radhika Pondicherry Regulatory Affairs 774-226-1852 (508) 822-6030 (fax)
Preparation Date	01 June,2011		
Device Name Trade Name	Apex Hip System Apex ARC ™ Hip Stem,		
Sizes	Apex ARC Hip Stem, Size 1 Apex ARC Hip Stem, Size 1 HA Coated Apex ARC Hip Stem, Size 2 Apex ARC Hip Stem, Size 2 HA Coated Apex ARC Hip System Modular Neck, Anteverted Apex ARC Hip System Modular Neck, Long Neutral Apex ARC Hip System Modular Neck, Long 8° Varus/Valgus		
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 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.		
Regulatory Class **Product Code**	Class II per 21 CFR § 888.3358, §888.3353, §888.3390 21 CFR Product Code- LPH, LZO, MEH, KWY		
Legally Marketed Predicate Device(s)	K090845- Apex ARC™ Hip Stem		

Device Description The Apex ARC Hip Stem consists of a curved, rectangular tapered stem, and modular necks that connect to the tapered hole in the stem. The height of the anterior and posterior lateral protrusions (Lateral T-Flange) was reduced on Size 1 and 2 ARC Hip Stems. Three new neck sizes are offered, Long Neutral, Long 8 ° Varus/Valgus and Anteverted. 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.

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

	Apex ARC Hip Stem, Additional necks and Lateral T-Flange stem design change (subject device)	**Apex ARC Hip Stem (K090845)**
Intended Use		
Primary and revision total hip replacement	Yes	Yes
Design		
T-Flange	T-Flange was reduced by half on the size 1 and size 2 ARC Hip Stem.	ARC Hip Stem T-flange size 1 and size 2
Stem Design	Curved, rectangular tapered stem.	Curved, rectangular tapered stem.
Neck Design	Long neutral, long 8 ° varus/valgus, anteverted	Neutral, 8° and 12 ° varus/valgus
Materials		
Apex ARC Hip Stem	Identical to K090845	Ti6Al4V per ASTM F136
Plasma spray Titanium coating	Identical to K090845	Unalloyed titanium plasma spray per ASTM F1580
Hydroxyapatite Coating	Identical to K090845	Hydroxyapatite plasma spray coating per ASTM F1185
Apex ARC Modular Neck	Identical to K090845	CoCr alloy

		per ASTM F1537
PACKAGING AND STERILIZATION		
Sterilization	Identical to K090845	Ethylene oxide
SAL	Identical to K090845	10^{-6}
Packaging	Identical to K090845	Paper Board Box, Double Tyvek inner pouch

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 3 new neck options; Long Neutral, Long 8 ° Varus/Valgus and Anteverted, and the reduction of height of the anterior and posterior lateral protrusions (Lateral T-Flange) for the Size 1 and 2 ARC Hip Stems described in this submission are substantially equivalent to the predicate devices.

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

OMNIlife Science, Inc.
% Ms. Radhika Pondicherry
Regulatory Affairs
50 O'Connell Way
East Taunton, Massachusetts 02718

JUN 27 2011

Re: K111193
Trade/Device Name: Apex ARC™ Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: Class II
Product Code: LZO, MEH, LPH, KWY
Dated: June 1, 2011
Received: June 2, 2011

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.

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: K111193

Device Name: Apex Hip System 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:

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- Revision procedures where other treatments or devices 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)

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for M. Melkerson

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

510(k) Number K111193