Apex ARC™ Hip Stem

1. Submitter
OMNI life science, Inc
50 O'Connell Way
E. Taunton, MA 02718

Contact:
Robert Zoletti
VP Regulatory Affairs
774-226-1845

2. Device Name
Proprietary Name: Apex ARC™ Hip Stem
Common Name: Hip prosthesis, uncemented
Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II per 21 CFR §888.3353 and §888.3358
Product Codes: LZO, MEH, and LPH

3. Legally Marketed
Predicate Device
K041950 - Apex K2,
K071946, K083495 - Aesculap Metha®

4. 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 femoral stems are manufactured from titanium alloy and the modular necks are manufactured from cobalt chromium alloy. Three neck sizes are offered, with a neutral, 8 degree, and 12 degree varus-valgus angle, respectively. The necks are compatible with the modular heads that are part of the Apex Modular and Apex K2 hip systems (K000788, K012918, and K073150) and may be used with head diameters and offsets up to a maximum offset of +7 mm. These configurations allow the user to choose a combination of stem, neck, and head components to appropriately fit the anatomy of the patient. The Apex ARC Hip Stem may be used in conjunction with the Apex Modular™ Acetabular Cup (K031110, K062489, and K073150) for total hip arthroplasty.

5. Intended Use
The Apex ARC™ Hip Stem is intended for use as the femoral component of a primary or revision total hip replacement. This femoral hip stem is intended for uncemented fixation and single use implantation. This prosthesis 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.

6. Predicate Device Comparison
Substantial equivalence is claimed to the Apex K2™ Hip System (distributed by OMNI life science, Inc.) and the Metha® Hip System (distributed by Aesculap Implant Systems, Inc.). The table below compares the features and characteristics of the Apex ARC Hip Stem to these predicate devices:
## 510(K) SUMMARY K090845

<table>
<thead>
<tr>
<th>FDA 510(k)'s</th>
<th>Apex ARC™</th>
<th>Apex K2™</th>
<th>Aesculap Metha®</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTENDED USE</td>
<td>K041950</td>
<td>K071916</td>
<td>K083495</td>
</tr>
<tr>
<td>Primary and revision hip replacement, non-cemented</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>DESIGN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Circumferential porous coating</td>
<td>Yes – plasma sprayed CP Ti</td>
<td>Yes – plasma sprayed CP Ti</td>
<td>Yes – plasma sprayed CP Ti</td>
</tr>
<tr>
<td>Proximal coating (only)</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Modular neck</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Tapered stem</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Cross-sectional shape</td>
<td>Rectangular</td>
<td>Rectangular</td>
<td>Rectangular/rounded</td>
</tr>
<tr>
<td>Distal slot(s)</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Distal flutes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>MATERIALS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Titanium alloy (Ti6Al4V) stem</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Cobalt chromium modular neck</td>
<td>Yes</td>
<td>No – titanium alloy</td>
<td>Yes</td>
</tr>
<tr>
<td>Cobalt chromium or alumina ceramic heads</td>
<td>Yes (both)</td>
<td>Yes (both)</td>
<td>Yes (both)</td>
</tr>
<tr>
<td>Titanium porous coating</td>
<td>Yes - unalloyed</td>
<td>Yes - unalloyed</td>
<td>Yes – unalloyed</td>
</tr>
<tr>
<td>Hydroxyapatite overcoat option</td>
<td>Yes</td>
<td>No</td>
<td>Yes – calcium phosphate</td>
</tr>
</tbody>
</table>

The most significant difference between these devices is that the subject Apex ARC hip stem and the predicate Aesculap Metha hip stem both employ cobalt chromium modular necks with a tapered junction between the neck and the stem, whereas the Apex K2 stem system employs titanium alloy modular necks with a cylindrical press-fit junction and alignment pin.

7. Non-Clinical Test Summary

The following tests were conducted:
- Fretting potential per ISO 17853:2003.
- Disassembly strength after fatigue testing per ASTM F2009-00.
- Proximal fatigue strength per ISO 7206-6:1992 and ASTM 2068-09.
- Torsional strength of the modular neck.
- The Hydroxyapatite coating was previously cleared in K043123

8. Clinical Test Summary

No clinical studies were performed.

9. Conclusions

The Apex ARC™ is substantially equivalent to the predicate devices.
OMNI life science, Inc.
% Mr. Robert Zoletti
Vice President Regulatory Affairs
50 O'Connell Way
E. Taunton, Massachusetts 02718

Re: K090845
Trade/Device Name: Apex ARCTM Hip Stem
Regulation Number: 21 CFR 8888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: II
Product Code: LZO, MEH, LPH
Dated: March 31, 2010
Received: April 1, 2010

Dear Mr. 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" (21 CFR 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

Sincerely yours,

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 (if known): K090845

Device Name: Apex ARC™ Hip Stem

Indications For Use:

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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 of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090845