



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

OMNIlife Science
Christina Rovaldi
Regulatory Affairs Specialist
480 Paramount Drive
Raynham, Massachusetts 02767

August 17, 2017

Re: K171156
Trade/Device Name: OMNI Anseris Hip Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip Joint Metal/Ceramic/Polymer Semi-Constrained Cemented Or
Nonporous Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LZO, LWJ
Dated: July 12, 2017
Received: July 13, 2017

Dear Christina Rovaldi:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K171156

Device Name

OMNI Anseris Hip Stem

Indications for Use (Describe)

The OMNI Anseris 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 OMNI Anseris Hip Stem is also intended for use in hemiarthroplasty when used with the Apex Bipolar Head. For further details, please refer to the Apex Bipolar Head Instructions for Use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

TABLE 1: 510(k) SUMMARY	
<i>Date Summary Prepared</i>	08/03/2017
<i>Manufacturer/Distributor/Sponsor</i>	OMNIlife Science 480 Paramount Drive Raynham, MA 02767
<i>510(k) Contact</i>	Christina Rovaldi Regulatory Affairs Specialist OMNIlife Science 480 Paramount Drive Raynham, MA 02767 Telephone: (774)-226-1857 Fax: (508)-822-6030 Email: crovaldi@omnils.com
<i>Trade Name</i>	OMNI Anseris Hip Stem
<i>Common Name</i>	prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented prosthesis, hip, semi-constrained, metal/polymer, uncemented
<i>Classification</i>	Class II per 21 CFR §888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. Product Code – LZO Class II per 21 CFR §888.3360 Hip joint femoral (hemi- hip) metallic cemented or uncemented prosthesis. Product Code – LWJ
<i>Primary Predicate Device</i>	Apex Modular HA Stem K043123
<i>Additional Predicate Devices</i>	Apex Modular Alumina Head, K012918 Apex hip System Bipolar Head, K082468 Apex Hip System Bipolar Head, K100151 Apex Modular Head, +10.5mm offset, K101575 Apex Modular Hip System Biolog delta Femoral Head,

	<p>K101451 Interface Acetabular System, Acetabular Insert +4 offset, K092443 Omni Skirted Heads, K152919 Apex Modular Hip Stem, K000788 Apex Modular Acetabular Cup, K031110 Apex Modular Acetabular Cup, K112779 Apex HCLA Acetabular Cup Liners, K062489 Apex HCLA Acetabular Liners, K073150 Biopro Bipolar Head, Models 18130-18152, K082705 OMNI Interface Acetabular System, K142201 +4 Offset Acetabular Insert, K101976 ARC Monoblock Hip Stem, K133381</p>
<i>Purpose of Submission</i>	<p>This traditional 510(k) premarket notification is being submitted to obtain clearance for the OMNI Anseris Stems to expand OMNI's product offering for total hip arthroplasty.</p>
<i>Intended Use</i>	<p>The OMNI Anseris 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:</p> <ul style="list-style-type: none"> • 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. <p>The OMNI Anseris Hip Stem is also intended for use in</p>

	<p>hemiarthroplasty when used with the Apex Bipolar Head. For further details, please refer to the Apex Bipolar Head Instructions for Use.</p>
<i>Device Description</i>	<p>The OMNI Anseris Stem is a “fit and fill” femoral stem with a tapered conical design and is intended for use as the femoral component of a primary or revision total hip replacement when</p>
<i>Sterility and Biocompatibility</i>	<p>The proposed devices undergo the same validated sterilization process, using ethylene oxide (EO), as the validated devices under the sterility assurance level (SAL) of 10^{-6}. All ethylene oxide residuals are monitored and well below standard limits. In addition, OMNI has developed a plan to test endotoxins on all OMNIlife science device groups through Limulus ameocyte lysate (LAL) testing. Products have been segregated into product families based on manufacturing process and material type and have generated 8 product groups that will be tested for endotoxins on a quarterly basis on a yearly rotation. Product will not be released if the 20 EU/device limit is exceeded.</p>
<i>Substantial Equivalence Summary: Technology Comparison</i>	<p>The proposed Anseris Stems are substantially equivalent to the predicate Apex Modular Stem (K043123) in terms of the fundamental scientific technology and intended uses and the reference predicate in terms of design and materials. Any differences between the proposed and the predicates are considered minor and do not raise any different questions of safety and effectiveness.</p> <p>The proposed devices are composed of titanium alloy, unalloyed titanium plasma spray, the identical material used in the manufacture of the predicate device. The proposed devices have an integral neck and trunnion rather than separate modular neck components that are part of the predicate Apex Modular Stem system.</p> <p>The Anseris hip stem has a “fit and fill” approach, this proposed stem will have a conical design similar to OMNI's Apex Modular Stem (K043123).</p>
<i>Substantial Equivalence Summary:</i>	<p>The results of testing of the proposed Anseris Hip Stems</p>

<i>Non-Clinical Testing</i>	<p>met the requirements for fatigue strength per ISO 7206-6 and ISO 7206-4 and the range-of-motion requirement per ISO 21535. These test methods are the same used for the predicate device (K043123).</p> <ul style="list-style-type: none"> - HTR-103 Conical Hip Fatigue Testing - HTR-062 Conical Tapered Stem Fatigue FEA - HTR-104 ROM Analysis - HTR-108 ROM Analysis with Bipolar Heads - HTR-106 Conical Stem FEA per ASTM F2996-13 - HTR-107 Solidworks Simulation Verification -HTR-109 Conical Stem Bipolar Head Impingement Risk <p>Based on the indications for use, technological characteristics, and the comparison to the predicate devices, OMNIlife Science has determined that the OMNI Anseris Hip Stem is substantially equivalent to currently marketed predicate device. Based on the similar intended use, technological characteristics, material and testing, OMNIlife science believes the proposed introduction of skirted heads to be substantially equivalent to the legally marketed predicate.</p>
<i>Conclusion Statement</i>	<p>The conclusions drawn from the nonclinical tests demonstrate that the devices are safe, as effective, and perform as well as or better than the legally marketed device</p>