December 21, 2017

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

Re: K172467
Trade/Device Name: OMNI ARC Anteverted Neck 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
Dated: October 4, 2017
Received: October 5, 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172467

Device Name
OMNI ARC Anteverted Neck Hip Stem

Indications for Use *(Describe)*

The OMNI 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 OMNI ARC™ 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

TABLE 1: 510(k) SUMMARY	
Date Summary Prepared	10/4/2017
Manufacturer/Distributor/Sponsor	OMNIlife Science, Inc. 480 Paramount Drive Raynham MA 02767
510(k) Contact	Christina Rovaldi Sr. Regulatory Affairs Specialist OMNIlife Science 480 Paramount Drive Raynham MA 02767 Telephone: 774-226-1857 Fax: 508-822-6030 Email: crovaldi@omnils.com
Trade Name	OMNI ARC Anteverted Neck Hip Stem
Common Name	Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented.
Classification	21 CFR 888.3353 prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented LZO
Predicate Device	K133381 OMNI ARC Monoblock Hip Stem
Purpose of Submission	This Traditional 510(k) premarket notification is being submitted to propose modifications to the OMNI ARC Monoblock Hip Stem (K133381) by adding additional monoblock stem types to expand the product offering.
Intended Use	The OMNI 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 OMNI ARC™ 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.
Device Description	The proposed devices are intended to be used for primary and revision total hip replacement. The OMNI ARC Anteverted Neck Hip Stem offers anteverted neck options (left and right orientations) to the monoblock stem system to meet the variety of patient anatomies expected in Total Hip Arthroplasty. This design is similar to the ARC Monoblock stem designs currently marketed. The material of the proposed OMNI ARC Anteverted Neck Hip Stems are Ti-6Al-4V E.L.I (ASTM F136)
Substantial Equivalence Summary	The proposed devices with modifications are substantially equivalent to the existing OMNI ARC Monoblock Hip Stem cleared in K133381 as the basic design, interface, fundamental technology, materials and intended use are the same. The use of the new OMNI ARC Anteverted Neck Hip Stem components with the existing ARC Monoblock Hip Stem does not introduce any new risks of safety or efficacy. Testing was not conducted but the devices were evaluated and no-testing justifications were written.

	The following justifications were written to explain the safety and effectiveness of the OMNI ARC Hip Stem with the proposed modifications. The modifications do not raise any new safety or effectiveness concerns. - HTR-082 ARC Monoblock Fatigue FEA Anteverted Neck - HTR-099 ARC Monoblock Anteverted Neck ROM The justifications are described in section 12, Device Description. Based on the design, fundamental technology, identical material, intended use and technological characteristics, OMNIlife science believes the proposed OMNI ARC Anteverted Neck Hip Stem devices to be substantially equivalent to legally marketed predicates.
Conclusion Statement	OMNIlife science has demonstrated the proposed OMNI ARC Anteverted Neck Hip Stem is substantially equivalent to the predicate device based upon indications for use, design, test results and the same fundamental scientific technology.