DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 26, 2017

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

Re: K163332
Trade/Device Name: Apex Revision Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: March 27, 2017
Received: March 28, 2017

Dear Ms. 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163332

Device Name
Apex Revision Knee System

Indications for Use *(Describe)*
The Apex Knee™ System is intended for use as a primary or revision total knee replacement. 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;
- Revision procedures where other treatments or devices have failed;

The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate component may be used uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only.
The Apex Knee™ Modular Tibia System Tibial Augments are intended to be bolted to the Tibia Baseplate and cemented to the prepared tibia. The Apex Revision Knee system augments are intended to be bolted to the femoral component and cemented to the prepared femur.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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	11/23/2016
Manufacturer/Distributor/Sponsor	OMNIlife Science, Inc. 480 Paramount Drive Raynham MA 02767
510(k) Contact	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
Trade Name	Apex Revision Knee System
Common Name	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Classification	21 CFR 888.3560 Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer JWH
Predicate Device	K153437 Apex Revision Knee System,
Purpose of Submission	This Special 510(k) premarket notification is being submitted to propose modifications to the Apex Knee Revision System (K153437) by adding additional baseplate and retaining bolt types to expand the product offering.
Intended Use	The Apex Knee™ System is intended for use as a primary or revision total knee replacement. 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; • Revision procedures where other treatments or devices have failed; The porous coated femoral component may be used cemented or uncemented (biological fixation). The porous coated tibial baseplate component may be used uncemented (biological fixation). All other femoral, tibial baseplate and patellar components are indicated for cemented use only. The Apex Knee™ Modular Tibial Augments are intended to be bolted to the Tibia Baseplate and cemented to the prepared tibia. The Apex Revision Knee system augments are intended to be bolted to the femoral component and cemented to the prepared femur.
Device Description	The proposed devices are intended to be used for primary and revision total knee replacement. The Revision Tibia Baseplates offer enhanced torsional stability by adding keels to the posterior end of the device. This design is similar to keeled stem designs currently marketed. The retaining bolt modifications offer additional bolt sizes that allow the cleared tibial inserts to lock into the proposed longer Revision tibial Baseplate. The material of the proposed Revision Tibial Baseplate is Cobalt Chrome, CoCr (ASTM F75). The material if the proposed retaining bolts is Ti-6Al-4V E.L.I (ASTM F136)
Substantial Equivalence Summary	The proposed devices with modifications are substantially equivalent to the existing Apex Revision Knee System cleared in K153437 as the basic design, interface, fundamental technology, materials and intended use are the same.

	The use of the new Revision Knee System components with the existing revision knee components do 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 revision knee with the proposed modifications. The modifications do not raise any new safety or effectiveness concerns. - KTR-116 Tray Fatigue FEA 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 Apex Revision Knee System devices to be substantially equivalent to legally marketed predicates.
Conclusion Statement	The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and performs as well as or better than the legally marketed device.