



Food and Drug Administration
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OMNIlife Science, Incorporated
Ms. Christina Rovaldi
RA/QA Associate
50 O'Connell Way, Suite 10
East Taunton, Massachusetts 02718

December 21, 2015

Re: K153437

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: November 25, 2015
Received: November 27, 2015

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 Parts 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" (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 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 yours,

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

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

Indications for Use

510(k) Number (if known)

K153437

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.

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510(k) Summary

TABLE 1: 510(k) SUMMARY	
<i>Date Summary Prepared</i>	11/25/2015
<i>Manufacturer/Distributor/Sponsor</i>	OMNIlife Science, Inc. 50 O'Connell Way Suite 10 East Taunton, MA 02718
<i>510(k) Contact</i>	Christina Rovaldi RA/QA Associate OMNIlife Science 50 O'Connell Way Suite 10 East Taunton, MA 02718 Telephone: 774-226-1857 Fax: 508-822-6030 Email: crovaldi@omnils.com
<i>Trade Name</i>	Apex Revision Knee System
<i>Common Name</i>	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
<i>Classification</i>	21 CFR 888.3560 Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer JWH
<i>Predicate Device</i>	K112891 Apex Revision Knee System, K131472 Apex Knee Modular Tibia System
<i>Purpose of Submission</i>	This Special 510(k) premarket notification is being submitted to propose modifications to the Apex Knee Revision System (K112891) and the Apex Modular Tibia System (K131472) by adding additional stem types, augments, pegs and bolts to expand the product offering.

<i>Intended Use</i>	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.
<i>Device Description</i>	The proposed devices are intended to be used for primary and revision total knee replacement. The fluted femoral stems and the keeled femoral stems are slight modifications of the existing designs. The femoral stems offer enhanced press-fit implantation and torsional stability by adding longitudinal raised ribs similar to most stems designs currently marketed. The notched 10mm posterior femoral augment has been created to increase the product offerings when using posterior augments. The new notched augment

	will allow a 10mm distal augment and 10mm posterior augment to be used together. The femoral Locking Bolt functions similarly to the tibial locking bolt. It was designed for femoral use for enhanced fixation of the stem to the femur. The current tibial peg offers additional torsional stability when added to the modular tibial baseplate. The proposed revision tibial Peg is a slight modification of that existing tibial peg and is improved in size and torque strength. The Augment Peg Bolt is similar to the tibial peg and can be used to add additional torsional stability to the modular tibia baseplate when augments are used. The material of each new component is titanium alloy Ti-6Al-4V E.L.I (ASTM F136)
<i>Substantial Equivalence Summary</i>	The proposed devices with modifications are substantially equivalent to the existing Apex Revision Knee System cleared in K112891 and Modular Tibia devices cleared under K131472 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-102 Femur Stem Bolt Testing Justification - KTR-100 Revision Knee Fluted Stem FEA Comparison - KTR-101 Notched Augment Justification - KTR-106 Keeled stem justification/FEA

	- KTR-107 Augment peg bolt justification 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.
<i>Conclusion Statement</i>	The conclusions drawn from the nonclinical and clinical tests demonstrate that the devices are as safe, as effective, and performs as well as or better than the legally marketed device.