DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 10, 2016

OMNIlife Science Incorporated
Ms. Christina Flores
Manager, Regulatory Affairs
50 O'Connell Way, Suite 10
East Taunton, Massachusetts 02718

Re: K152919
Trade/Device Name: OMNI Skirted Heads
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, MEH
Dated: December 16, 2015
Received: December 17, 2015

Dear Ms. Flores:

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

Indications for Use

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

510(k) Number *(if known)*
K152919

Device Name
OMNI Skirted Heads

Indications for Use *(Describe)*
The OMNI Skirted Heads are intended for use in combination with the NOVAE® Dual Mobility Acetabular Cup and are indicated for total hip replacement, which includes:

- Osteoarthritis
- Femoral neck fracture
- Dislocation risk
- Osteonecrosis of the femoral head
- Revision procedures where other treatments or devices have failed and if bone reconstruction so permits

SUNFIT TH, NOVAE E TH and COPTOS TH are intended for press-fit use and NOVAE STICK is indicated for cemented 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.

510(k) Summary

TABLE 1: 510(k) SUMMARY	
Date Summary Prepared	03/09/2016
Manufacturer/Distributor/Sponsor	OMNIlife Science 50 O'Connell Way Suite 10 East Taunton, MA 02718
510(k) Contact	Christina Flores Manager, Regulatory Affairs OMNIlife Science 50 O'Connell Way East Taunton, MA 02718 Telephone: (774)-226-1835 Fax: (508)-822-6030 Email: cflores@omnils.com
Trade Name	OMNI Skirted Heads
Common Name	Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.
Classification	Class II per 21 CFR §888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis. Product Code LZO, MEH
Predicate Device	K111572 NOVAE® Dual Mobility Acetabular Cup Reference Predicate: K000788 OMNI (formerly APEX) Modular Hip Stem K101575 OMNI (formerly APEX) Modular Heads
Purpose of Submission	This traditional 510(k) premarket notification is being submitted to obtain clearance for the OMNI Skirted Heads for use with the SERF Dual Mobility Acetabular Cups (K111572).

Device Description	The OMNI Skirted Heads are intended to be used in the primary/revision total hip replacement procedures in combination with the SERF Dual Mobility Acetabular Cup. These femoral heads are manufactured from cobalt chromium (CoCr) and are designed to be used with the SERF Dual Mobility Acetabular cup. These heads offer a skirted feature and when used with the Dual Mobility cups, the skirt extends over the exposed femoral taper and reduces the contact between the SERF polyethylene liner and machined surface of the K1 stem trunnion. SERF obtained clearance to use the OMNI K1 stem with its Dual Mobility NOVAE Acetabular Cup under K111572. In this submission, OMNI proposes two sizes for these skirted heads – 28mm+7 and 22mm+3.5 diameter and neck length respectively.
Intended Use/Indications for use	The OMNI Skirted Heads are intended for use in combination with the NOVAE® Dual Mobility Acetabular Cup and are indicated for total hip replacement, which includes: • Osteoarthritis • Femoral neck fracture • Dislocation risk • Osteonecrosis of the femoral head • Revision procedures where other treatments or devices have failed and if bone reconstruction so permits. SUNFIT TH, NOVAE E TH and COPTOS TH are intended for press-fit use and NOVAE STICK is indicated for cemented use.
Substantial Equivalence Summary	The proposed OMNI Skirted Heads are substantially equivalent to the predicate NOVAE Dual Mobility Acetabular Cup (K111572) in terms of the fundamental scientific technology and intended uses and the reference predicate (K101575) in terms of design and materials. Any differences between the proposed and the predicates are considered minor and do not raise any new concerns regarding safety and effectiveness.

	The proposed skirted head is similar in design to the skirted heads cleared in the reference predicate K101575 and the same size, 22mm and 28mm heads, as those cleared in K000788. The proposed skirted head is composed of cobalt chromium (CoCr), this material is identical to the OMNI skirted heads cleared in K101575. SERF obtained clearance to use OMNI heads (with diameter 22.2 and 28mm) with their Dual Mobility Cup in K111572. Range of Motion testing was conducted to demonstrate the compatibility of the SERF Dual Mobility cups and proposed OMNI skirted heads. The results of testing met the requirements for Range of Motion per ISO 21535. 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 predicates.