September 25, 2019

OMNI life science, Inc.
Ms. Christina Rovaldi
Manager, Regulatory Affairs
480 Paramount Drive
Raynham, Massachusetts 02767

Re: K191765
Trade/Device Name: OMNI TiN Coated Apex 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: June 28, 2019
Received: July 1, 2019

Dear Ms. 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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)*
K191765

Device Name
OMNI TiN Coated APEX Knee™ System

Indications for Use *(Describe)*

The OMNI TiN Coated Apex Knee™ System is intended for use as a primary or revision total knee replacement. This knee replacement system is intended for cemented single use implantation. 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 Apex Knee™ Modular Tibia System Tibial Augments with TiN coating are intended to be bolted to the TiN coated Tibia Baseplate and cemented to the prepared tibia. The Apex Knee Revision Femur System Augments are intended to be bolted to the TiN coated 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.

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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

OMNI TiN Coated APEX Knee™ System **Date: June 21, 2019**

Submitter: OMNIlife science™, Inc.
480 Paramount Dr.
Raynham, MA 02767

Contact: Christina Rovaldi
Manager, Regulatory Affairs
OMNI

Phone: (774) 226-1857
Email: crovaldi@omnils.com

1. Device Name:

Proprietary Name:	**OMNI TiN Coated APEX Knee™ System**
Common Name:	Knee prosthesis, cemented/un-cemented
Classification:	**Class II** - per 21 CFR *§888.3560 prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer*
Product Codes:	JWH

2. Indications for Use:

The **OMNI TiN Coated Apex Knee™ System** is intended for use as a primary or revision total knee replacement. This knee replacement system is intended for cemented single use implantation. 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 Apex Knee™ Modular Tibia System Tibial Augments with TiN coating are intended to be bolted to the TiN coated Tibia Baseplate and cemented to the prepared tibia. The Apex Knee Revision Femur System Augments are intended to be bolted to the TiN coated femoral component and cemented to the prepared femur.

3. Description:

The change that is the subject of this 510(k) is to add a thin coating of Titanium Nitride (TiN) to all surfaces of all CoCrMo substrate metal components (*Femoral(s), Tibial Baseplate(s), and Revision Tibia Augments*) as listed in the above Predicates. The purpose of the TiN coating is to substantially reduce release of CoCrMo metal ions into body fluids, bone or soft tissues.
There is no change to the fundamental scientific technology of the referenced OMNI Predicate Knee Systems (5) with the *modifications* in this 510(k) submission. This includes no changes to the substrate materials, design, sterilization, packaging, or method(s) of manufacture.

4. Predicate Devices:

Primary Predicate: OMNI life science™ - Apex Revision Knee System, **K163332**
Additional Predicate: Consensus Orthopedics – CKS Plus Knee System, **K163167, K110950**
Additional Predicate: DJO Surgical - Foundation Knee -Armor Coat-System, **K122239, K020114**
Additional Predicate: Aesculap Implant Systems - VEGA, Columbus,
Additional Predicate: EnduRo Knee -Advanced Surface Technology-System(s), **K143443, K143106, K120955, K101815**

5. Comparable Features to the Predicate Device(s):

Features comparable to the Predicate Devices include: indications for cemented use, dimensions, substrate materials, packaging, sterilization, surgical implantation technique, instrumentation and intended use.

6. Non-Clinical Testing:

Testing was conducted for the TiN Coating: Chemical Composition, Thickness, Hardness, Adhesion Strength to the CoCrMo substrate material, Surface Roughness and Wear Resistance Mode 1 and Mode 3.

LAL testing has been conducted, product will not be released if 20 EU/per device is exceeded.

7. Clinical Testing:

No clinical studies were performed.

8. Conclusions:

The **OMNI TiN Coated APEX Knee™ System** is substantially equivalent to the Predicate Devices.