April 2, 2021

OMNIlife science
Dipti Dharia
Chief Quality, Regulatory, & Clinical Officer
480 Paramount Drive
Raynham, Massachusetts 02767

Re: K201611/S001
Trade/Device Name: 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, MBH
Dated: February 19, 2021
Received: March 4, 2021

Dear Dipti Dharia:

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,

Ting Song, Ph.D., R.A.C.
Assistant Director
DHT6A: Division of Joint
Arthroplasty Devices
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)*

K201611

Device Name
Apex 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 is to 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.

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	06/12/2020
Manufacturer/Distributor/Sponsor	OMNIlife Science 480 Paramount Drive Raynham, MA 02767
510(k) Contact	Dipti Dharia Chief Quality, Regulatory & Clinical Officer Corin Ltd., 480 Paramount Drive Raynham, MA 02767 Telephone: +1-732-754-5466 Email: Dipti.Dharia@coringroup.com Secondary Contact: Jack Liang Senior Regulatory Affairs Specialist Corin Ltd / Corin Australia +61 2 9497 7400 Jack.Liang@coringroup.com
Trade Name	Apex Knee™ System
Common Name	prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated
Classification	21 CFR 888.3560. Class II. Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis. JWH 21 CFR 888.3565. Class II. Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. MBH
Predicate Device	OMNI TiN Coated Apex Knee™ System- K191765

Purpose of Submission	This traditional 510(k) premarket notification is being submitted to obtain clearance for the modifications to the Apex Knee™ System to expand OMNI's product offering for total knee arthroplasty.
Indications for 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 is to 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.
Device Description	The proposed devices are intended to be used for primary and revision total knee replacement. The Pegged Tibial Baseplates offer additional torsional stability by adding pegs to the posterior end of the device. The material of the proposed Pegged Tibial Baseplates are Cobalt Chrome, CoCr (ASTM F75). The ECiMa tibial inserts are machined from compression molded highly crosslinked polyethylene with Vitamin E (VE-XLPE) and attaches to the cobalt chrome tibial baseplate via dovetails and a retaining

	bolt. The insert slides onto the baseplate from the front, with the two dovetail-shaped rails on the baseplate engaging the mating slots in the insert, until the rails contact the posterior end of the slots. The retaining bolt completes the assembly.
Sterility and Biocompatibility	The proposed devices undergo the same validated sterilization process, using ethylene oxide (EO), as the predicate devices (K060192, K102578, K111184, K112891) under the sterility assurance level (SAL) of 10^{-6}. All ethylene oxide residuals are monitored and well below standard limits. In addition, OMNI has developed a plan to test endotoxins on all OMNIlife science device groups through Limulus amebocyte lysate (LAL) testing. Products have been segregated into product families based on manufacturing process and material type and have generated 8 product groups that will be tested for endotoxins on a quarterly basis on a yearly rotation, and the subject devices are included in one of the product groups. Product will not be released if the 4 EU/device limit is exceeded.
Substantial Equivalence Summary	The proposed devices with modifications are substantially equivalent to the existing Apex Knee™ System cleared in K191765 as the basic design, interface, fundamental technology and intended use are the same. The use of the new Apex Knee™ System components with the existing knee components do not introduce any new risks of safety or efficacy. <u>Tibial Baseplate:</u> In addition to the testing performed for the Apex Knee System, non-clinical testing specifically for the Pegged Porous Coated Cementless Tibial Baseplates include FEA simulation and peg location templating study. The results of the testing show that the Apex Knee Pegged Porous Coated Cementless Tibial Baseplates are

	safe and effective for the proposed indications and is substantially equivalent to the predicate devices. The justifications are described in Section 10, Device Description. <u>ECiMa Tibial Inserts & Patellae</u> In addition to the testing already performed for the Apex Knee System, non-clinical testing was conducted specifically for the ECiMa Tibial Inserts & Patellae. These tests include: ● material characterization, ● PS post strength testing, ● insert disassembly strength testing, ● wear testing. Biological testing of the ECiMa material was conducted for biocompatibility. These tests include: ● intramuscular implantation in animal models, ● implant toxicity and subcutaneous implantation in animal models. The results of the testing show that the Apex Knee ECiMa Tibial Inserts & Patellae are safe and effective for the proposed indications and is substantially equivalent to the predicate devices. Based on the design, fundamental technology, material, intended use and technological characteristics, OMNIlife science believes the proposed Apex 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 safe, as effective, and perform as well as or better than the legally marketed device