July 26, 2023

Corin USA Limited
Aaron Brunt
Senior Regulatory Affairs Specialist
12750 Citrus Park Lane
Tampa, Florida 33625

Re: K231172
Trade/Device Name: ApolloKnee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 24, 2023
Received: April 25, 2023

Dear Aaron Brunt:

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,

FDA Tejen D. Soni -S

For
Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231172

Device Name
ApolloKnee

Indications for Use *(Describe)*
ApolloKnee is indicated to aid the surgeon in locating anatomical structures and aligning endoprostheses with these anatomical structures during total knee arthroplasty.
Apollo Robot and BalanceBot are optional accessories and are specifically indicated for use in total knee arthroplasty with the ApolloKnee system.

ApolloKnee is compatible with the following implant systems:
- Apex Knee™ System.
- Unity Knee™ System.

ApolloKnee is indicated for use in surgical knee procedures in which the use of stereotactic surgery may be appropriate.

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 K231172

Applicant/Sponsor: Corin USA Limited
12750 Citrus Park Lane
Suite 120, Tampa, FL 33625
Establishment Registration No.: 1056629

Manufacturer: Corin Ltd.
The Corinium Centre
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Date: 24 April 2023

Proprietary Name: ApolloKnee
Common Name: Orthopedic Stereotaxic Instrument
Classification Name: Orthopedic Stereotaxic Instrument
Regulation Numbers: 21 CFR 882.4560
Classification Panel: Orthopedic
Product Codes: OLO – Class II

Primary Predicate Device:

- OMNIBotics Knee System (K200888)

Device Description:

ApolloKnee™ (formerly OMNIBotics) is a robotic-assisted stereotaxic surgery system that aids the surgeon in locating anatomical structures and aligning endoprostheses with these anatomical structures during total knee replacement (TKR). ApolloKnee is composed of eight sub-systems that integrate to form the ApolloKnee system. Four of these sub-components (Station, Tracking System, Communication Module and Nonsurgical Application) form the main structure of Corin's core platform for robotic or computer assisted surgeries. This core platform is referred to as "Apollo". Future Corin technologies are intended to be developed on the basis of the Apollo core platform. ApolloKnee is one such technology built upon the Apollo common platform. ApolloKnee includes four system specific sub-components (Apollo Robot, BalanceBot, TKR Instruments and ApolloKnee Software).

ApolloKnee is an evolution of the former OMNIBotics Knee System. ApolloKnee is the first launched under Corin Ltd following acquisition of the OMNIBotics' prior manufacturer OMNIlife Science. ApolloKnee differs from OMNIBotics Knee System (as previously marketed under K200888) in branding (for commercial reasons), as well as redesigns of the station and software, and introduction of additional surgical instrumentation, namely the BalanceBot Pre-Resection Paddles, Tibial Cutting Guide and V-Array.

Indications for Use: ApolloKnee is indicated to aid the surgeon in locating anatomical structures and aligning endoprostheses with these anatomical structures during total knee arthroplasty.

Apollo Robot and BalanceBot are optional accessories and are specifically indicated for use in total knee arthroplasty with the ApolloKnee system.

ApolloKnee is compatible with the following implant systems:

- Apex Knee™ System.
- Unity Knee™ System.

ApolloKnee is indicated for use in surgical knee procedures in which the use of stereotactic surgery may be appropriate.

Summary of Technologies / Substantial Equivalence:

The subject ApolloKnee is similar to the OMNIBotics Knee System (per K200888) in terms of design and performance, and the same in intended use. The ApolloKnee is an evolution of the former OMNIBotics platform, including redesigns to modernize the station and software, while maintaining similar function and performance. Furthermore, the ApolloKnee includes additional instrumentation such as the BalanceBot Pre-Resection Paddles, Tibial Cutting Guide and V-array to support new features as in pre-resection balance assessment, robotic assisted tibial resection and resection position validation, respectively.

The subject ApolloKnee has been subject to verification and validation testing as described below, with results supporting substantial equivalence with the predicate OMNIBotics Knee System (per K200888).

Non-Clinical Testing:

Non-clinical testing included:

- Software unit, integration and system testing
- Accuracy testing per custom protocols and ASTM F2554-22
- Security testing
- Electrical safety testing per IEC 60601-1:2005+A1:2012+A2:2020
- Electromagnetic compatibility testing per IEC 60601-1-2:2014+A1:2020
- Various mechanical and functional performance tests per custom protocols

Furthermore, surgeon user validation studies (cadaver evaluations) were performed in accordance with IEC 62366-1:2015+A1:2020 and IEC 60601-1-6:2010+A1:2015+A2:2020.

The results of the non-clinical testing support substantial equivalence of the subject ApolloKnee and the predicate device.

Conclusion:

The ApolloKnee was determined to be substantially equivalent to the predicate device OMNIBotics Knee System (K200888).