June 27, 2020

Corin Ltd.
℅ Robert A. Poggie
President
Bio Vera Inc.
65 Promenade Saint Louis
Notre Dame de LIle Perrot, Quebec J7v7p2
Canada

Re: K200888
Trade/Device Name: OMNIBotics Knee System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: March 31, 2020
Received: April 3, 2020

Dear Robert Poggie:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200888

Device Name

OMNIBotics Knee System

Indications for Use *(Describe)*

The OMNIBotics Knee System is indicated for stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning endoprostheses with these anatomical structures during Total Knee Arthroplasty. The BalanceBot™ is indicated as a tool for adjustment of soft tissue and the femoral implant to reduce instability from flexion gap asymmetry. The OMNIBotics Knee System supports OMNI Apex Knee™ implants and CORIN Unity Knee™ implants.

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

The OMNIBotics® Knee System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness of the OMNIBotics® Knee System.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, Quebec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796
Fax Number:	(514) 901-0796
Date of Submission:	March 31, 2020

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Corin Ltd.
Manufacturer Address:	480 Paramount Drive, Raynham, MA, 02767, USA
Registration Number:	1226188
Contact Name:	Christina Rovaldi
Title:	Regulatory Affairs Specialist
Device Trade Name:	OMNIBotics® Knee System
Device Common Name:	Stereotaxic instrument
Classification Name:	Stereotaxic instrument
Classification Code:	OLO – Class II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 882.4560

C1. PRIMARY PREDICATE DEVICE

K163338	OMNIlife Science Inc., OMNIBotics® Knee System

C2. REFERENCE DEVICE

K113060, K173884 K170808, K183533	Corin Ltd. Unity™ Total Knee System

D. DEVICE DESCRIPTION

The OMNIBotics® Knee system is a computer-assisted navigation system with a motorized bone cutting guide that is used by surgeons and operating room (OR) staff to assist in performing stereotaxic total knee arthroplasty (TKA). The OMNIBotics® Knee System consists of the OMNIBotics® Station, ART Knee Application software, the OMNIBot cutting guide for guiding femoral bone resections, the BalanceBot defined as an active (motorized) knee spacer and ligament tensioning device, and the OMNIBotics™ Tracker Kit which is comprised of single-use reflective markers that are fixed onto the associated instruments that provide a frame of reference for tracking by the 3D optical optoelectronic localizer.

The OMNIBotics® Station includes the 3D optoelectronic localizer mounted on an articulated arm, a laptop hosting the ART Knee Software and equipped with a touchscreen, an external LCD monitor and a three-button footswitch as a means for the user to interact with the system. The power supply and communication hardware required for the camera, the laptop, the OMNIBot, and BalanceBot are contained within a single enclosure, the control box, located at the base of the OMNIBotics® Station.

The OMNIBotics® Knee System was originally cleared for use with OMNI Apex Knee™ System implants in K163338. This 510(k) notification demonstrates substantial equivalence of the OMNIBotics® Knee System for use with Corin Unity™ Total Knee System implants.

E. INTENDED USE

The OMNIBotics® Knee System is indicated for stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning endoprostheses with these anatomical structures during Total Knee Arthroplasty. The BalanceBot™ is indicated as a tool for adjustment of soft tissue and the femoral implant to reduce instability from flexion gap asymmetry. The OMNIBotics® Knee System supports OMNI Apex Knee™ implants and CORIN Unity Knee™ implants.

F. TECHNOLOGICAL CHARACTERISTICS

The technology of the subject device OMNIBotics Knee System is the same as the predicate device OMNIBotics Knee System, K163338. The basis for this 510(k) notification are three-fold:

(1) New and modified instruments and software for the OMNIBotics Knee System to function with the Corin Unity Knee system,

(2) Change in manufacturer for the single-use reflective markers and associated validations of functionality and manufacturing processes, and

(3) Updated labeling, software, and hardware validations regarding the above changes.

Validation and verification testing for the subject device OMNIBotics Knee System included precision and accuracy of the single-use reflective markers (and arrays), sterility, shelf life, and biocompatibility of the reflective markers (The OMNIBotics® Tracker Kit), and surgeon-user evaluation of Corin Unity knee implants in cadaver knees. The results of these tests showed the subject OMNIBotics® Knee System to perform substantially equivalently to the predicate device.

G. PERFORMANCE DATA

The following tests and studies were performed to validate and verify the subject OMNIBotics Knee System to perform substantially equivalently to the predicate device.

- Surgeon-user verification studies of performance measures and accuracy performed by four (4) surgeons in ten (10) cadaver surgeries. The results of the cadaver evaluation demonstrated that the subject device met the established criteria for user requirements. usability, accuracy of bone resections, accuracy of implant position, magnitude of gaps, and joint stability.
- Simulated use and validation testing of precision, accuracy, and usability of the reflective markers / marker arrays.
- Sterility of the OMNIBotics® Tracker Kit was validated for a sterilization dose of 25 kGy of gamma radiation according to the VD max method NF EN ISO 11137-2: 2015.
- Endotoxin testing of the single-use reflective markers was performed according to ANSI/AAMI ST72. 5.2. The endotoxin levels for the markers were determined to be well within the minimum acceptance criteria. The single use markers were determined to be non-cytotoxic per ISO 10993-5.

The results of performance testing and process validations demonstrated substantial equivalence of the subject, predicate, and reference devices.

H. CONCLUSION

The OMNIBotics® Knee System used with Corin Unity knee implants was determined to be substantially equivalent to the predicate device OMNIBotics® Knee System (K163338).