April 12, 2021

Corin USA
% Robert Poggie
President
BioVera, Inc.
65 Promenade Saint Louis
Notre Dame de Llle Perrot, Quebec J7V 7P2
Canada

Re: K203751
Trade/Device Name: OMNIVision system
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: January 13, 2021
Received: January 19, 2021

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 -S

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)*

K203751

Device Name

OMNIVision™ system

Indications for Use *(Describe)*

The OMNIVision™ system is intended to be used as an intra-operative system to assist in the alignment of prosthetic components during Total Hip Arthroplasty, where a reference to a rigid anatomical structure can be identified.
The system achieves this by displaying intra-operative measurements of the acetabular component to the user calculated from visual information from a camera detecting fiducial markers.

The OMNIVision™ system is compatible for use with the legally marketed products
• OPSInsight™ and
• the Corin Trinity™ Acetabular System,
• Trinity-i™ Acetabular shells and
• Trinity™ non-occluded titanium plasma sprayed (TPS) acetabular shells.

The OMNIVision™ system is indicated for use with the posterior, anterolateral and direct anterior surgical approaches for primary Total Hip Arthroplasty.

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.

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510(k) SUMMARY

The OMNIVision™ 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 OMNIVision™ 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 and Fax Numbers:	(514) 901-0796
Date of Submission:	December 22, 2020

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Optimized Ortho Pty Ltd
Manufacturer Address:	17 Bridge Street, Pymble, NSW, 2073, AUSTRALIA
Registration Number:	3012916784
Contact Name:	Crissy Tomarelli
Title:	Regulatory and Quality Director
Device Trade Name:	OMNIVision™ 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

K172849	Intellijoint Surgical Inc., Intellijoint HIP® Generation 2C System

C1. PREDICATE DEVICE

K050615	Stryker Navigation System – CT Based Hip Module

D. DEVICE DESCRIPTION

The OMNIVision™ system is an image-based navigation system intended to assist the surgeon in delivering a target acetabular cup placement during Total Hip Arthroplasty (THA). The system consists of a Camera Assembly, OMNIVision™ software application installed onto the laptop, fiducial markers used to track the position of the surgical instruments, and a single use sterile drape. The fiducial markers and camera drape are supplied in packaged and EtO sterilized condition.

The OMNIVision™ system displays real-time intraoperative information, cup alignment and cup depth, with augmented and virtual reality views using a fixed reference attached to the patient's pelvis. The workflow of the OMNIVision™ system involves instrument calibration, registration of patient anatomy, and determination of cup alignment. The system uses image-based registration of the patient's anatomy and matches it to the pre-operative CT images of the patient's anatomy, thereby allowing the OMNIVision System to intra operatively calculate and display the information relative to the patient's anatomy, and independent of the patient's intra-operative pelvic position.

The OMNIVision™ System is designed for use with the Corin Trinity Acetabular System components and compatible with the Corin OPSInsight™ system for pre-operative planning.

E. INDICATIONS FOR USE

The OMNIVision™ system is intended to be used as an intra-operative system to assist in the alignment of prosthetic components during Total Hip Arthroplasty, where a reference to a rigid anatomical structure can be identified.
The system achieves this by displaying intra-operative measurements of the acetabular component to the user calculated from visual information from a camera detecting fiducial markers.

The OMNIVision™ system is compatible for use with the legally marketed products
- OPSInsight™ and
- the Corin Trinity™ Acetabular System,
- Trinity-i™ Acetabular shells and
- Trinity™ non-occluded titanium plasma sprayed (TPS) acetabular shells.

The OMNIVision™ system is indicated for use with the posterior, anterolateral and direct anterior surgical approaches for primary Total Hip Arthroplasty.

F. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject OMNIVision system uses both intra operative registration and pre-operative CT images of the patient's pelvic anatomy for the frames of reference for the purpose of guiding acetabular cup placement in THA surgery, and matches the pre-op and intra-op positions intra-operatively. The OMNIVision system determines position of the acetabular cup that is independent of the patient's intra-operative pelvic position. The predicate Stryker Navigation System CT Based Hip Module utilizes CT scans obtained pre-operatively as a frame of reference for positioning an acetabular component. The primary predicate Intellijoint system uses intra-operative registration for the frame of reference of the pelvis, but does not utilize pre-operative patient images. The table below compares technical characteristics of the subject device OMNIVision™ System and the primary predicate device, the Intellijoint HIP Generation 2C System.

Characteristic	Subject Device, OMNIVision System	Intellijoint HIP Gen 2C System, K172849
Anatomical use?	Hip	Hip
Function / Use	The system uses registration and ensures matching with pre-op patient information (CT) intra-operatively, allowing the system to calculate and display information relative to the rigid body reference (Pelvic Pin and Fiducial Marker), making it independent of the patient's intra-operative pelvic position (relative to the surgical table). The system is used as an adjunct to aid the surgeon in positioning the acetabular component in THA.	The system uses registration and aids the surgeon in performing intra-operative measurements including measurements of limb position, joint center-of-rotation, and implant component positioning. The system is used as an adjunct to aid the surgeon in positioning the acetabular component in THA.
Proprietary software?	Yes	Yes
Portable System?	Yes	Yes
Hardware	The system includes a Camera assembly, single use sterile drape for camera, fiducial markers ('or trackers') and reusable tools for tracking, laptop computer workstation, software, and bone fixation instruments/hardware.	The system includes an infrared camera, trackers for registration intra op, computer workstation, software, and bone fixation instruments / hardware.
Use of pre-op info?	Yes, CT scans of patient's pelvis	No
Intra-op registration?	Yes	Yes
Trackers sterile?	Yes	Yes

G. PERFORMANCE DATA

The following tests and studies were performed to validate and verify the subject OMNIVision™ System:

- Surgeon-user verification studies of performance measures and accuracy performed by cadaver surgeries. The results of the cadaver evaluation demonstrated that the subject device met the established criteria for user requirements. The accuracy of the OMNIVision™ System in implanting an acetabular cup was ±3° for angular position and ±3mm for linear position.
- Software bench testing with a phantom device developed with guidance from ASTM-F2554 demonstrated mean positional accuracy of ±1° for angular position and ±1mm for linear position.
- Validation testing of precision, accuracy, and usability of the fiducial markers after cleaning, packing, and sterilization and in simulated use surgeries.
- Documentation and validation of OMNIVision software were performed per the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- Electrical and emissions safety testing demonstrated compliance to EN 60601-1-2:2015, IEC 60601-1:2005 (3rd Ed.), IEC 60601-1-6:2010, EN60601-1:2006/A1:2013, ANSI/AAMI ES60601-1:2005.
- Sterility of the fiducial markers was validated per ISO 11135:2014.
- The reusable instrument kit was validated for manual and automated cleaning methods and sterilization by vacuum steam autoclave.

H. CONCLUSION

The OMNIVision™ System used with Corin Trinity acetabular cups was determined to be substantially equivalent to the Intellijoint and Stryker predicate devices.