November 2, 2023

PolarisAR Inc.
% Richelle Helman
Senior Director, Regulatory
MEDIcept, Inc.
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K232176
Trade/Device Name: STELLAR Knee
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 21, 2023
Received: October 3, 2023

Dear Richelle Helman:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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)*
K232176

Device Name
STELLAR Knee

Indications for Use *(Describe)*
STELLAR Knee is a stereotaxic system including an intraoperative software as a medical device and surgical instruments. STELLAR Knee is indicated for primary Total Knee Replacement, to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis. The STELLAR Knee is installed on a Head Mounted Device (HMD) for displaying information to the user intraoperatively. The HMD should not be relied upon solely and should always be used in conjunction with traditional methods.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

POLARIS[AR]
78 SW 7th St
Suite 500
Miami, FL 33130

510(k) SUMMARY

Date: 02-November-2023

Company:
PolarisAR Inc.
78 SW 7th Street
Suite 500
Miami, FL 33130
Phone: (617) 519-5570

Official Contact:
Richelle Helman
Senior Director, Regulatory

Proprietary or Trade Name: STELLAR Knee

Common/Usual Name: Surgical Navigation Software and Instruments

Classification Name: Orthopedic Stereotaxic Instrument

Regulation Number:
21 CFR 882.4560, Class II
Classification Product Code: OLO

Predicate Device: K220104: Pixee Medical Knee+

Device Description:
The main purpose of the STELLAR Knee is to assist the surgeon during the primary Total Knee Replacement (TKR) intervention. STELLAR Knee includes software and surgical instruments.

STELLAR Knee uses established surgical navigation techniques to provide information to help track patient bony landmarks in real time to assist the surgeon in determining resection angles and measurements as required in knee replacement surgery. STELLAR Knee allows the surgeon to adjust the cutting plane orientation and the resection level. This includes means for the surgeon to collect anatomical references during the TKR intervention using the surgical instruments. The software locates in a 3D reference frame the instruments which include marker arrays. All collected coordinates are treated by software algorithms to provide the surgeon with the relevant orientation of the tracked cutting guide. STELLAR Knee software is installed on a wearable Head Mounted Device (HMD) which includes an embedded camera and displays intraoperative information to the user. This near-eye display allows the surgeon to look at the HMD screen or the field of view when needed.

Indications for Use:

STELLAR Knee is a stereotaxic system including an intraoperative software as a medical device and surgical instruments. STELLAR Knee is indicated for primary Total Knee Replacement, to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis. The STELLAR Knee is installed on a Head Mounted Device (HMD) for displaying information to the user intraoperatively. The HMD should not be relied upon solely and should always be used in conjunction with traditional methods.

POLARIS[AR]
78 SW 7th St
Suite 500
Miami, FL 33130

Substantial Equivalence:

The PolarisAR Inc. STELLAR Knee is substantially equivalent to the predicate device, the Pixee Medical Knee+ (510(k) K220104). The table below presents the similarities and differences between the products for substantial equivalence purposes. The differences between the subject device and the predicate device do not raise any new issues of safety and effectiveness. Performance data are available to support substantial equivalence.

Characteristic	**Subject Device:** STELLAR Knee	**Predicate Device:** Pixee Medical Knee+ [510(k) K220104]	**Substantial Equivalence**
Indications for Use	Stellar Knee is a stereotaxic system including an intraoperative software as a medical device and surgical instruments. Stellar Knee is indicated for primary Total Knee Replacement, to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis. The Stellar Knee is installed on a Head Mounted Device (HMD) for displaying information to the user intraoperatively. The HMD should not be relied upon solely and should always be used in conjunction with traditional methods.	Knee+ is a stereotaxic system including an intraoperative software as a medical device and surgical instruments. Knee+ is intended for primary Total Knee Replacement, to assist the surgeon in determining reference alignment axes in relation to anatomical landmarks, in order to position the cutting guide regarding computed mechanical axis. The Knee+ includes smart glasses as a Head Mounted Device (HMD) for displaying information to the user intraoperatively. The smart glasses should not be relied upon solely and should always be used in conjunction with traditional methods.	**SIMILAR**
Principle of Operation	Assists the surgeon in determining reference alignment axes in relation to anatomical landmarks in order to position alignment instruments regarding computed mechanical axis.	Assists the surgeon in determining reference alignment axes in relation to anatomical landmarks in order to position alignment instruments regarding computed mechanical axis.	**SIMILAR**

POLARIS[AR]
78 SW 7th St
Suite 500
Miami, FL 33130

Characteristic	Subject Device: STELLAR Knee	Predicate Device: Pixee Medical Knee+ [510(k) K220104]	Substantial Equivalence
Surgical Workflow	No change to surgical workflow currently used for Total Knee Replacement	No change to surgical workflow currently used for Total Knee Replacement	**SIMILAR**
Environment of use	Surgical Suite	Surgical Suite	**SIMILAR**
Main system components	Intraoperative software, surgical instruments, Head Mounted Device	Intraoperative software, surgical instruments, Head Mounted Device	**SIMILAR**
Means of navigation	Use of surgical instruments for navigation with markers	Use of surgical instruments for navigation with markers	**SIMILAR** The subject device uses fiducials as markers while the predicate device uses QR codes.
Use Type	Intraoperative	Intraoperative	**SIMILAR**
Information provided to user	Orientation and positioning of bone resections	Orientation and positioning of bone resections	**SIMILAR**
Tracking system technology	Visible imaging	Visible imaging	**SIMILAR**
Means of providing information to the surgeon	Head Mounted Device	Head Mounted Device	**SIMILAR** The subject device uses a headset while the predicate device uses glasses.

From the comparison form above, the subject device and predicate device have the same indications for use and the same operating principle for assisting the surgeon primary Total Knee Replacement. The minor differences in the devices do not raise different questions of safety or effectiveness.

Non-clinical performance testing:

Bench / Performance Testing –

- Bench testing was conducted in order to demonstrate that STELLAR Knee performs according to its requirements and specifications when installed on the Head Mounted Device. In particular, overall system repeatability and accuracy were tested.
- Software verification and validation testing were conducted as required by IEC 62304 and documentation was provided as recommended by FDA Guidance “Content of Premarket Submissions for Software Contained in Medical Devices”.
- Functional and performance testing were conducted on the instruments to provide confirmation that mechanical instrumentation satisfies the functional and performance requirements.
- Cleaning and sterilization processing of the reusable instruments was validated to SAL 10^{-6}.

POLARIS[AR]
78 SW 7th St
Suite 500
Miami, FL 33130

Validation was performed in accordance with AAMI TIR12 guidance, and for steam sterilization, in compliance with the half-cycle validation approach outlined in ISO 17665-1, in accordance with the requirements of ISO 17664 and FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling”.

- Biocompatibility testing of the instruments was conducted. Testing was done according to the ISO 10993 series. All tests indicated the patient contact materials were biocompatible.
- Human factors testing was conducted in compliance with the requirements of IEC 62366-1 and FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices”. Test participants representing the intended users of the device were included in the human factors validation testing. Observational data as well as interview data were recorded. The observation of participant performance and the assessment of their understanding of essential information through the interview confirmed that the design of the device is safe and effective for the intended users, uses and use environments.

The results demonstrated that the STELLAR Knee performs according to its specifications and functions as intended.

Substantial Equivalence Conclusion

The STELLAR Knee has the same indications for use and the same operating principle as the predicate device. The performance testing demonstrated that the subject device can perform the same intended use as safely and effectively as the predicate device. Therefore, the subject device is substantially equivalent to the predicate device.