December 23, 2022

Polarean, Inc.
℅ Rita King
CEO
Methodsense, Inc.
1 Copley Pkwy, Ste. 410
Morrisville, North Carolina 27560

Re: K223071
Trade/Device Name: Xenoview VDP
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 29, 2022
Received: September 30, 2022

Dear Rita King:

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,

Daniel M. Krainak, Ph.D.
Assistant Director
Magnetic Resonance and Nuclear Medicine Team
DHT8C: Division of Radiological Imaging
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OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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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)*
K223071

Device Name
XENOVIEW VDP

Indications for Use *(Describe)*
XENOVIEW VDP is image processing software that analyzes a pulmonary hyperpolarized 129-Xe MR image and a proton chest MR image to provide visualization and evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

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.

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Summary of 510(k)

Polarean, Inc K223071

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: Polarean, Inc.
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Date Prepared: September 30, 2022

Device Name and Classification

Trade Name: XENOVIEW VDP
Common Name: Medical Imaging Software
Classification: Class II
Regulation Number: 21 CFR 892.2050
Classification Panel: Radiology

Product Code: LLZ

Predicate Device:

Trade Name	THORACIC VCAR
Common Name	THORACIC VCAR
510(k) Submitter / Holder	GE Healthcare, (GE Medical Systems LLC)
510(k) Number	K103480
Regulation Number	21 CFR 892.2050
Classification Panel	Picture Archiving and Communications System
Product Code	LLZ

The predicate device has not been subject to a design-related recall.

Device Description

XENOVIEW VDP is an image analysis platform that quantifies normalized xenon intensity of a ventilated space using a pulmonary hyperpolarized 129-Xe ventilation MR image and accompanying proton chest MR image.

The XENOVIEW VDP image analysis process includes loading and viewing images, image registration and segmentation, normalization and statistical analysis of ^{129}Xe signal intensity distribution within the ventilation scan, and ultimately reporting the fraction of ventilated lung volume as a percentage of thoracic cavity volume.

This software will be used by clinicians to assist in the interpretation and numerical classification of hyperpolarized 129-Xe ventilation MR images.

The HP ^{129}Xe ventilation MR images are generated using an MRI scanner and appropriate RF chest coil with a patient that has inhaled XENOVIEW (xenon Xe 129 hyperpolarized).

The software provides a user-friendly interface and simple workflow that helps guide the user through the image analysis process, including the loading of images, registration of the anatomical image sets to the HP ^{129}Xe image sets, segmentation of the lung, and automated classification of normalized ventilation distribution into multiple intensity levels via analysis of hyperpolarized ^{129}Xe signal intensity within the segmented lung volume. The results of the image analysis are output as medical images of the classified ventilation, a summary report, and data files containing quantitative statistical analysis results.

Indications for Use

XENOVIEW VDP is image processing software that analyzes a pulmonary hyperpolarized 129-Xe MR image and a proton chest MR image to provide visualization and evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

Substantial Equivalence

The Polarean XENOVIEW VDP is substantially equivalent to predicate device, the GE Medical Systems Thoracic VCAR (K103480) currently on the market.

The table below provides a detailed comparison of the Polarean XENOVIEW VDP software to the predicate device.

Detailed Comparison of the Subject and Predicate Devices

Characteristic	Subject Device XENOVIEW VDP	Predicate Device Thoracic VCAR (K103480)	Comparison
Intended Use / Indications for Use	XENOVIEW VDP is an image processing software technology that analyzes a pulmonary hyperpolarized ^{129}Xe MR image and a proton chest MR image to provide visualization and evaluation of lung ventilation in adults and pediatric patients aged 12 years and older	Thoracic VCAR is a CT, non-invasive image analysis software package, which may be used in conjunction with CT lung images to aid in the assessment of thoracic disease diagnosis and management. The software will provide automatic segmentation of the lungs and automatic segmentation and tracking of the airway tree. The software will provide quantification of Hounsfield units and display by color the thresholds within a segmented region.	Identical intended use as both subject and predicate device are non-invasive image processing technologies of the lung. Equivalent indications for use as both predicate and subject device provide visualization and evaluation of the lungs. XENOVIEW VDP uses hyperpolarized ^{129}Xe MR images and proton MR images, while Thoracic VCAR (K103480) uses CT lung images. This difference does not impact the intended use of the device, and the safety and effectiveness are confirmed with testing.
Modality Supported (MRI / CT)	MRI	CT	Different modality. The difference does not impact the intended use of the device, and the safety and effectiveness are confirmed with testing.

Characteristic	Subject Device XENOVIEW VDP	Predicate Device Thoracic VCAR (K103480)	Comparison
Lung Analysis Performed	Yes – Entirety of lung is analyzed by the software	Yes – Entirety of lung is analyzed by the software; also, analysis of Lobes, Airway, or user-defined "zone", may be individually analyzed by the software	Equivalent, with the difference being that Thoracic VCAR (K103480) performs additional analysis of the individual lung lobes and the airway.
Input Radiological Images of the Lungs	Yes – Anatomical and xenon images are registered	Yes – Anatomical image	Equivalent, with the difference being the number of images by each. This difference does not impact the intended use of the device, and the safety and effectiveness are confirmed with testing.
User Interface:			
Screen Save	Yes	Yes	Identical
Window Level	Yes	Yes	Identical
Magnification	Yes	Yes	Identical
Dynamic rotation	Yes	Yes	Identical
User annotation	Yes	Yes	Identical
Simultaneous loading of two studies	No – only one study may be opened at once within the XENOVIEW VDP program.	Yes – Two standard CT images may be viewed at once within the Thoracic VCAR program.	Different; XENOVIEW VDP does not contain a feature to open multiple studies within the same instance of the program.
Image Functionality			
Image Registration	Yes – Anatomical MR and Xenon MR Images	No – CT Image Only	Different; additional registration functionality is needed due to difference in modalities. This difference does not impact the intended use of the device, and the safety and effectiveness are confirmed with testing.

Characteristic	Subject Device XENOVIEW VDP	Predicate Device Thoracic VCAR (K103480)	Comparison
Automatic Segmentation	Yes – Lung segmentation	Yes – Lung segmentation, lobe segmentation, airway segmentation, and airway tracking	Equivalent, with the difference being that Thoracic VCAR (K103480) performs segmentation of additional anatomical structures.
Manual Segmentation Adjustment	Yes – Lung segmentation	Yes – Lung segmentation, lobe segmentation, airway segmentation, and airway tracking	Equivalent, with the difference being that Thoracic VCAR (K103480) performs segmentation of additional anatomical structures.
Volume Measurement	Yes – Thoracic Cavity Volume	Yes – Thoracic Cavity Volume and User-Defined Zone Volumes	Equivalent, with the difference being that Thoracic VCAR (K103480) additionally performs user-defined zone volumes measurements.
Lung Volume Rendering	Yes	Yes	Identical
Color Mapping	Yes – Color mapping of the MR images from diagnostic imaging agent ^{129}Xe.	Yes – Color mapping of the tissue density from CT images.	Equivalent, with the difference being that XENOVIEW VDP color mapping is based on contrast of imaging from ^{129}Xe, while the Thoracic VCAR (K103480) color mapping is based on the tissue density obtained from of the quantification of Hounsfield units unique to CT scans. This difference does not impact the intended use of the device, and the safety and effectiveness are confirmed with testing.

Characteristic	Subject Device XENOVIEW VDP	Predicate Device Thoracic VCAR (K103480)	Comparison
Density Mapping by User-Defined Threshold	Yes – Lung Volume Fraction	Yes – Hounsfield Units	Equivalent, with the difference being that the XENOVIEW VDP value for threshold is defined by Xenon, while the Thoracic VCAR (K103480) value for threshold is defined by Hounsfield Units. This difference does not impact the intended use of the device, and the safety and effectiveness are confirmed with testing.
Statistics displayed by lung	Yes – Bins calculated based on Lung Volume Percentage	Yes – "Bins" or ranges of data calculated by Hounsfield Units	Equivalent, with the difference being that the XENOVIEW VDP value for threshold is defined by Lung Volume Fraction, while the Thoracic VCAR (K103480) value for threshold is defined by Hounsfield Units. This difference does not impact the intended use of the device, and the safety and effectiveness are confirmed with testing.
Image Measurement Tool	Yes – Ruler tool available	Yes – Ruler / measurement tool available, explicit labeling of various anatomical features	Equivalent, with the difference being that the Thoracic VCAR (K103480) user interface provides additional functionality for measurements.
Simultaneous loading of exams	No – Only one exam can be opened at once for analysis	Yes – Multiple exams can be open simultaneously for comparison	Different; XENOVIEW VDP does not contain a feature to load multiple exams within the same instance of the program.

Characteristic	Subject Device XENOVIEW VDP	Predicate Device Thoracic VCAR (K103480)	Comparison
Save State	No – Save to files without ability to restore sessions	Yes - Ability to save and restore at any time the current work for staged analysis	Different; XENOVIEW VDP does not contain a feature to re-open a previous work session.
Reporting capabilities	Yes – Medical report available for clinical analysis	Yes – Medical report available for clinical analysis	Identical

Summary of Non-Clinical Testing
The safety and performance of the XENOVIEW VDP software has been evaluated and verified in accordance with software specifications through software verification and validation testing per FDA's guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005).

Summary of Clinical Testing
XENOVIEW VDP did not require clinical studies to support substantial equivalence.

Conclusion
Based on the information submitted in this premarket notification, and based on the indications for use, technological characteristics, and performance testing, the XENOVIEW VDP software raises no new questions of safety and effectiveness and is substantially equivalent to the predicate device in terms of safety and effectiveness.