December 23, 2022

Polarean, Inc.
% Rita King
CEO
MethodSense, Inc.
1 Copley Parkway, Suite 410
Morrisville, North Carolina 27560

Re: K212239
Trade/Device Name: XENOVIEW 3.0T Chest Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic Resonance Diagnostic Device
Regulatory Class: Class II
Product Code: MOS
Dated: December 16, 2022
Received: December 19, 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
and Radiation Therapy Devices
OHT8: Office of Radiological Health
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)*
K212239

Device Name
XENOVIEW 3.0T Chest Coil

Indications for Use *(Describe)*
The Polarean XENOVIEW 3.0T Chest Coil is to be used in conjunction with compatible 3.0T Magnetic Resonance Imaging (MRI) scanners and approved xenon Xe 129 hyperpolarized for oral inhalation for 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.

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."

510(k) Summary

Polarean, Inc. K212239

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

Submitter: Polarean, Inc.
PO Box 14805
Research Triangle Park, NC 27709-4805

Primary Contact: Rita King, CEO
MethodSense, Inc.
Email: ritaking@methodsense.com
Phone: (919) 313-3961
Fax: (919) 313-3979

Company Contact: Neil Wadehra
Title: VP of Operations
Email: nwadehra@polarean.com
Phone: (919) 206-7900

Date Prepared: December 22, 2022

Trade Name: XENOVIEW 3.0T Chest Coil

Common Name: Coil, Magnetic Resonance

Classification: Class II

Regulation Number: 21 CFR 892.1000

Classification Panel: Radiology

Product Code: MOS

Prior Submissions: No prior submissions.

Predicate Device:

Trade Name	Cardiovascular Array Coils, Models CAC-63-16, CAC-63-32, CAC-123-32, and CAC-127-16
510(k) Submitter / Holder	INVIVO
510(k) Number	K061952
Regulation Number	21 CFR 892.1000 Magnetic resonance diagnostic device
Classification	Class II
Classification Panel	Radiology
Product Code	MOS

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

Device Description

The Polarean XENOVIEW 3.0T Chest Coil (hereafter Chest Coil) is a flexible, single channel, transmit-receive (T/R) RF coil tuned to ^{129}Xe frequency on a 3.0T MRI magnetic field in order to image ^{129}Xe nuclei while the patient is positioned inside a compatible multi-nuclear-capable MRI scanner. The Chest Coil is intended to be worn by a patient who inhales hyperpolarized ^{129}Xe gas (XENOVIEW) to obtain an MR image of the regional distribution of hyperpolarized ^{129}Xe in the lungs.

The coil is constructed of a durable, flexible circuit board material within which the antenna elements and all electronic components are contained. These components are electrically isolated from the rest of the coil packaging by being enclosed within suitable non-conductive, water-rated, and flame-rated materials. A layer of padding is located on either side of the coil circuitry to provide patient comfort and protection against potential heating generated by circuitry components. The RF coil is a “fixed matching and tuning device” (i.e. not tunable by the operator), thereby eliminating the need to tune and match it for every patient.

Indications for Use

The Polarean XENOVIEW 3.0T Chest Coil is to be used in conjunction with compatible 3.0T Magnetic Resonance Imaging (MRI) scanners and approved xenon Xe 129 hyperpolarized for oral inhalation for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

Substantial Equivalence

The Polarean XENOVIEW 3.0T Chest Coil is substantially equivalent to its predicate device, Cardiovascular Array Coils, Models CAC-63-16, CAC-63-32, CAC-123-32, and CAC-127-16 (K061952).

The table below provides a detailed comparison of Polarean XENOVIEW 3.0T Chest Coil to the predicate device.

Detailed Comparison of the Subject and Predicate Devices

Characteristic	Subject Device Polarean XENOVIEW 3.0T Chest Coil	Predicate Device Cardiovascular Array Coils (K061952)	Comparison
Intended Use/Indications for Use	The Polarean XENOVIEW 3.0T Chest Coil is to be used in conjunction with compatible 3.0T Magnetic Resonance Imaging (MRI) scanners and approved xenon Xe 129 hyperpolarized for oral inhalation for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.	To be used in conjunction with a Magnetic Resonance Scanner to produce diagnostic images of the cardiovascular, pulmonary, renal, and abdominal systems that can be interpreted by a trained physician.	The intended use of the Polarean XENOVIEW 3.0T Chest Coil is identical to the predicate device (K061952). Both devices are being used to help produce diagnostic images in MRI scanners interpreted by a trained physician.
Anatomical Area	Chest	Chest	The anatomical area imaged by the Polarean XENOVIEW 3.0T Chest Coil is identical to the anatomical area imaged by the predicate device (K061952).
Compatible MRI Systems	Siemens 3T	Siemens 3T and 1.5T and GE 3T and 1.5T	The Polarean XENOVIEW 3.0T Chest Coil is equivalent to the predicate device (K061952), in that both devices support 3T MRI Systems. The difference between the Polarean XENOVIEW 3.0T Chest Coil and the predicate device (K061952) is that the predicate device (K061952) is additionally compatible with Siemens 1.5T and GE 3T and 1.5T MRI scanners. This difference does not affect the intended use or the safety and effectiveness of the device.

Characteristic	Subject Device Polarean XENOVIEW 3.0T Chest Coil	Predicate Device Cardiovascular Array Coils (K061952)	Comparison
Mode of Operation	Transmit / Receive	Receive Only	The mode of operation of the Polarean XENOVIEW 3.0T Chest Coil is equivalent to that of the predicate device (K061952) as the both have a receive mode of operation. The Polarean XENOVIEW 3.0T Chest Coil additionally has a transmit mode of operation which the predicate device (K061952) does not. This difference does not affect the intended use of the device and safety and effectiveness of the device has been confirmed with testing.
Flexible / Rigid	Flexible	Flexible with rigid sections	The flexibility of the Polarean XENOVIEW 3.0T Chest Coil compared to the predicate device (K061952) is equivalent.
Nucleus	^{129}Xe (Multinuclear Channel)	^{1}H (Proton Channel)	The Polarean XENOVIEW 3.0T Chest Coil is different to the predicate device (K061952) as the Polarean XENOVIEW 3.0T Chest Coil uses the MRI multinuclear channel to image ^{129}Xe and the predicate device (K061952) uses the MRI proton channel to image ^{1}H. This difference does not affect the intended use of the device and safety and effectiveness of the device has been confirmed with testing.
Frequency of Operation	34.07 MHz	63.6, 63.86, 123.2, 127.72 MHz	The frequency of operation of the Polarean XENOVIEW 3.0T Chest Coil is different than the frequencies of operation of the predicate device (K061952) as the subject device is intended to image ^{129}Xe. This difference does not affect the intended use of the device and safety and effectiveness of the device has been confirmed with testing.

Characteristic	Subject Device Polarean XENOVIEW 3.0T Chest Coil	Predicate Device Cardiovascular Array Coils (K061952)	Comparison
Antenna Configuration	Quadrature (co-rotating saddle coil pairs)	Flat array of loops	The antenna configuration of the Polarean XENOVIEW 3.0T Chest Coil is different from the predicate device (K061952) as the Polarean XENOVIEW 3.0T Chest Coil uses a quadrature configuration while the predicate device (K061952) uses a flat array of loops. This difference does not affect the intended use of the device and safety and effectiveness of the device has been confirmed with testing.
Tuning / Impedance Matching	Fixed tuning and matching. Factory set.	Fixed tuning and matching. Factory set.	The tuning / impedance matching mode of the Polarean XENOVIEW 3.0T Chest Coil is identical to the predicate device (K061952).
Method of Decoupling	Passive decoupling for ^{1}H.	Active and passive decoupling.	The method of decoupling of the Polarean XENOVIEW 3.0T Chest Coil is equivalent to the method of predicate device (K061952). Both devices use passive decoupling. The predicate device (K061952) also uses active decoupling. This difference does not affect the intended use of the device and safety and effectiveness of the device has been confirmed with testing.
Materials	Foam and fabric.	Foam and fabric.	The materials of the Polarean XENOVIEW 3.0T Chest Coil are equivalent to the material of the predicate device (K061952).

Characteristic	Subject Device Polarean XENOVIEW 3.0T Chest Coil	Predicate Device Cardiovascular Array Coils (K061952)	Comparison
# of receive channels	1	16 or 32	The number of receive channels of the Polarean XENOVIEW 3.0T Chest Coil is different than the predicate device (K061952) as the Polarean XENOVIEW 3.0T Chest Coil has one receive channel while the predicate device (K061952) has 16 or 32 receive channels. This difference does not affect the intended use of the device or the safety and effectiveness of the device.

Non-Clinical Testing

The XENOVIEW 3.0T Chest Coil was verified and validated in accordance with documented Verification & Validation plans and protocols to ensure conformance with established performance criteria. See below for the type of tests performed. Polarean has completed the following testing:

Performance – Bench

Bench testing was performed by Polarean to confirm the safety and performance of various components of the Chest Coil in accordance with the following standards:

- NEMA MS 6-2008 (R2014), Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging
- NEMA MS 8-2016, Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems
- NEMA MS 14-2019, Characterization of Radiofrequency (RF) Coil Heating in Magnetic Resonance Imaging Systems

Electrical Safety and Electromagnetic Compatibility

Electrical Safety and Electromagnetic Compatibility testing was performed to confirm the safety and performance of various components of the Chest Coil in accordance with the following standards:

- Basic Safety and Essential Performance (IEC 60601-1)
- Basic Safety and Essential Performance of MR Equipment (IEC 60601-2-33:2015)
- Electromagnetic Compatibility (IEC 60601-1-2:2014)

Biocompatibility

Biocompatibility testing was performed per ISO 10993-1:2018 to confirm the safety and performance of various components of the Chest Coil in accordance with the following standards:

- Cytotoxicity (ISO 10993-5:2009)
- Sensitization (ISO 10993-10:2010)
- Irritation (ISO 10993-10:2010)

Substantial Equivalence Conclusions

In conclusion, the intended use/indications for use of the Polarean XENOVIEW 3.0T Chest Coil is identical to the intended use/indications for use of the predicate device (K061952) as both devices are used to help produce diagnostic images in MRI scanners and are being interpreted by a trained physician. The technological characteristics demonstrate that the Polarean XENOVIEW 3.0T Chest Coil is substantially equivalent to the predicate device (K061952). The testing demonstrates that the Polarean XENOVIEW 3.0T Chest Coil is substantially equivalent to the predicate device (K061952) and assures that the Polarean XENOVIEW 3.0T Chest Coil is as safe and effective as the predicate device.

Conclusion

The 510(k) Premarket Notification for the XENOVIEW 3.0T Chest Coil contains adequate information and data to determine that XENOVIEW 3.0T Chest Coil is as safe and effective as the legally marketed predicate device.