November 19, 2024

Polarean, Inc.
% Rita King
CEO
MethodSense, Inc.
1 Copley Pkwy, Ste. 130
Morrisville, NC 27560

Re: K243316
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: October 18, 2024
Received: October 22, 2024

Dear Neil Wadehra:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Daniel M. Krainak, Ph.D.
Assistant Director
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K243316

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.***

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# 510(k) Summary

## Polarean, Inc.

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

**Submitter:** Polarean, Inc.
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**Primary Contact:** Rita King, CEO
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**Company Contact:** Neil Wadehra
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**Date Prepared:** October 17, 2024

**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:** K231647

**Predicate Device:**

| | |
|---|---|
| **Trade Name** | Polarean XENOVIEW 3.0T Chest Coil |
| **510(k) Submitter / Holder** | Polarean |
| **510(k) Number** | K231647 |
| **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, Polarean XENOVIEW 3.0T Chest Coil (K231647). This submission adds compatibility of the Chest Coil with General Electric Healthcare (GEHC) 3T MR750 and Premier MRI scanners. The safety and performance testing that was performed in the previous submission (K231647) was repeated to demonstrate that the Chest Coil is as safe and effective when used with GEHC 3T MR750 and Premier MRI scanners as when used with Philips 3T MRI scanners.

The table below provides a detailed comparison of Polarean XENOVIEW 3.0T Chest Coil to the predicate device (K231647).

**Detailed Comparison of the Subject and Predicate Devices**

| Characteristic | Subject Device<br>Polarean XENOVIEW 3.0T Chest Coil *(Models 44315-02 and 44315-04)* | Primary Predicate Device<br>Polarean XENOVIEW 3.0T Chest Coil *(Model 44315-03)* (K231647) | 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. | 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. | Identical |
| **Anatomical Area** | Chest | Chest | Identical |

| Characteristic | Subject Device<br>Polarean XENOVIEW 3.0T Chest Coil *(Models 44315-02 and 44315-04)* | Primary Predicate Device<br>Polarean XENOVIEW 3.0T Chest Coil *(Model 44315-03)* (K231647) | Comparison |
|---|---|---|---|
| **Compatible MRI Systems** | GEHC MR750 (44315-02) and Premier (44315-04) 3T | Philips 3T | Equivalent. Subject devices are compatible with GEHC MR750 and Premier 3T MRI scanners and the predicate device is compatible with Philips 3T MRI scanners. Both the subject devices and predicate device are compatible with 3T MRI scanners. Both devices use a connector that is compatible with the respective MRI scanner. The addition of the new configurations with compatibility with GEHC MR750 and Premier 3T MRI scanners does not affect the intended use of the device and safety and effectiveness of the device has been confirmed with testing. |
| **Mode of Operation** | Transmit / Receive | Transmit / Receive | Identical |
| **Flexible / Rigid** | Flexible | Flexible | Identical |
| **Nucleus** | $^{129}$Xe (Multinuclear Channel) | $^{129}$Xe (Multinuclear Channel) | Identical |
| **Frequency of Operation** | 35.33 MHz | 35.33 MHz | Identical |

| Characteristic | **Subject Device**<br>**Polarean XENOVIEW 3.0T Chest Coil *(Models 44315-02 and 44315-04)*** | **Primary Predicate Device**<br>**Polarean XENOVIEW 3.0T Chest Coil *(Model 44315-03)* (K231647)** | **Comparison** |
|---|---|---|---|
| **Antenna Configuration** | Quadrature (co-rotating saddle coil pairs) | Quadrature (co-rotating saddle coil pairs) | Identical |
| **Tuning / Impedance Matching** | Fixed tuning and matching. Factory set. | Fixed tuning and matching. Factory set. | Identical |
| **Method of Decoupling** | Passive decoupling for $^{1}H$. | Passive decoupling for $^{1}H$. | Identical |
| **Materials** | Foam and fabric. | Foam and fabric. | Identical |
| **# of receive channels** | 1 | 1 | Identical |

## 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 repeated by Polarean for the new model of the Chest Coil with compatible MRI scanners 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 repeated for the new model of the Chest Coil 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 60601-1:2005/(R)2012 and A1:2012)
- Basic Safety and Essential Performance of MR Equipment (IEC 60601-2-33:2015)
- Electromagnetic Compatibility (IEC 60601-1-2:2020)

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)

## Summary Clinical Testing

No clinical tests were required to demonstrate substantial equivalence.

## Conclusion

The conclusions drawn from the nonclinical testing demonstrate that the subject device, XENOVIEW 3.0T Chest Coil is as safe, as effective, and performs as well as or better than the legally marketed predicate, XENOVIEW 3.0T Chest Coil (K231647).