

K212239 XENOVIEW 3.0T Chest CoilDec 23, 2022
522 days to decisionK212239 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k212239/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Coil, Magnetic Resonance, Specialty (MOS) |
| Date received | Jul 19, 2021 |
| Decision date | Dec 23, 2022 |
| Days to decision | 522 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Polarean, Inc. |
| Location | Research Triangle Park, NC, US |
| Contact | Neil Wadehra |
| 510(k) history | 4 submissions · 4 cleared · 2022-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|--------------------------|
| Consulting firm | MethodSense, Inc. |
| Contact | Rita King |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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