

K231647 XENOVIEW 3.0T Chest CoilJun 29, 2023
24 days to decisionK231647 · Product code: **MOS** · Radiology
Source: <https://www.510kdatabase.net/k231647/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Jun 5, 2023
Decision date	Jun 29, 2023
Days to decision	24 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231647/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026