

**K243316 XENOVIEW 3.0T Chest Coil**Nov 19, 2024  
28 days to decisionK243316 · Product code: **MOS** · Radiology  
Source: <https://www.510kdatabase.net/k243316/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coil, Magnetic Resonance, Specialty (MOS)
Date received	Oct 22, 2024
Decision date	Nov 19, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243316/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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