

**K223071 Xenoview VDP**Dec 23, 2022  
84 days to decisionK223071 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k223071/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 30, 2022
Decision date	Dec 23, 2022
Days to decision	84 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

**REGULATORY CONSULTANT**

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Consulting firm	<b>MethodSense, Inc.</b>
Contact	Rita King

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223071/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026