

**K252235 PVAD IQ Software**Dec 18, 2025  
154 days to decisionK252235 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k252235/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 17, 2025
Decision date	Dec 18, 2025
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ultrasight , Ltd.</b>
Location	Ness Ziona, IL
Contact	Noa Avisar
510(k) history	2 submissions · 2 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252235/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026