

**K251416 UltraSight Guidance**Dec 17, 2025  
224 days to decisionK251416 · Product code: **QJU** · Radiology  
Source: <https://www.510kdatabase.net/k251416/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Image Acquisition And/or Optimization Guided By Artificial Intelligence (QJU)
Date received	May 7, 2025
Decision date	Dec 17, 2025
Days to decision	224 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/k251416/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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