FDA 510(k) Premarket Notification

K251416 UltraSight Guidance

CLEARED

Dec 17, 2025
224 days to decision

K251416 · Product code: **QJU** · Radiology
Source: https://www.510kdatabase.net/k251416/

SUBMISSION DETAILS

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

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