

K243235 LVivo Software ApplicationMar 3, 2025
144 days to decisionK243235 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k243235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 10, 2024
Decision date	Mar 3, 2025
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dia Imaging Analysis, Ltd.
Location	Beer-Sheva, IL
Contact	Michal Yaacobi
510(k) history	10 submissions · 10 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Medicsense USA, LLC
Contact	George Hattub

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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