

K240769 LVivo IQS

May 24, 2024
64 days to decision

K240769 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k240769/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 21, 2024
Decision date	May 24, 2024
Days to decision	64 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)
