

K210053 LVivo Software ApplicationFeb 5, 2021
28 days to decisionK210053 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k210053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jan 8, 2021
Decision date	Feb 5, 2021
Days to decision	28 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
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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