FDA 510(k) Premarket Notification

K243235 LVivo Software Application

CLEARED

Mar 3, 2025
144 days to decision

K243235 · 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