FDA 510(k) Premarket Notification

CLEARED

K240553 LVivo Software Application

Oct 4, 2024
219 days to decision

K240553 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k240553/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Feb 28, 2024
Decision date	Oct 4, 2024
Days to decision	219 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