FDA 510(k) Premarket Notification

K222970 LVivo IQS

CLEARED

Feb 1, 2023
127 days to decision

K222970 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k222970/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Sep 27, 2022
Decision date	Feb 1, 2023
Days to decision	127 days
Third-party review	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