

K242244 Viewer+Mar 14, 2025
226 days to decisionK242244 · Product code: **QKQ** · Pathology
Source: <https://www.510kdatabase.net/k242244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Digital Pathology Image Viewing And Management Software (QKQ)
Date received	Jul 31, 2024
Decision date	Mar 14, 2025
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lumea, Inc.
Location	Lehi, UT, US
Contact	Emre Gulturk
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242244/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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