FDA 510(k) Premarket Notification

K251730 LIA Console (542-7)

CLEARED

Dec 19, 2025
196 days to decision

K251730 · Product code: **NQQ** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k251730/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Jun 6, 2025
Decision date	Dec 19, 2025
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Leadoptik, Inc.**
Location	San Jose, CA, US
Contact	Mohammadreza Khorasaninejad
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Qserve Group US**
Contact	Lorry Weaver

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov