FDA 510(k) Premarket Notification

K251402 LIA-1 Catheter (542-1)

CLEARED

Dec 19, 2025
227 days to decision

K251402 · Product code: **KTI** · Anesthesiology
Source: https://www.510kdatabase.net/k251402/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bronchoscope Accessory (KTI)
Date received	May 6, 2025
Decision date	Dec 19, 2025
Days to decision	227 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**
Contact	Lorry Weaver

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