

K150237 ILUMIEN, Dragonfly OPTIS Imaging CatheterMay 5, 2015
92 days to decisionK150237 · Product code: **NQQ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k150237/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Optical Coherence Tomography (oct) (NQQ)
Date received	Feb 2, 2015
Decision date	May 5, 2015
Days to decision	92 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lightlab Imaging, Inc.
Location	Rockville, MD, US
Contact	ERDIE DE PERALTA
510(k) history	10 submissions · 10 cleared · 2010-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150237/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 2, 2026