

**K141769 OPTIS INTEGRATED SYSTEM, DRAGONFLY OPTIS
IMAGING CATHETER**Aug 18, 2014
48 days to decisionK141769 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k141769/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jul 1, 2014
Decision date	Aug 18, 2014
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141769/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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