

**K141453 ILUMIEN OPTIS, DRAGONFLY OPTIS IMAGING  
CATHETER**Sep 19, 2014  
109 days to decisionK141453 · Product code: **DQO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k141453/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jun 2, 2014
Decision date	Sep 19, 2014
Days to decision	109 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k141453/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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