

**K153426 Ox-Imager CS**Dec 21, 2016  
392 days to decisionK153426 · Product code: **MUD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k153426/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter, Tissue Saturation (MUD)
Date received	Nov 25, 2015
Decision date	Dec 21, 2016
Days to decision	392 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Modulated Imaging, Inc.</b>
Location	Irvine, CA, US
Contact	DAVID CUCCIA
510(k) history	2 submissions · 2 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k153426/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026