

**K123462 OCELOT CATHETER**Dec 7, 2012  
28 days to decisionK123462 · Product code: **PDU** · Cardiovascular  
Source: <https://www.510kdatabase.net/k123462/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Nov 9, 2012
Decision date	Dec 7, 2012
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avinger, Inc.</b>
Location	Redwood City, CA, US
Contact	Albert Boniske
510(k) history	25 submissions · 25 cleared · 2009-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123462/> 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 June 9, 2026