

**K122380 OCELOT SYSTEM**Nov 7, 2012  
93 days to decisionK122380 · Product code: **PDU** · Cardiovascular  
Source: <https://www.510kdatabase.net/k122380/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Aug 6, 2012
Decision date	Nov 7, 2012
Days to decision	93 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/k122380/> 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 15, 2026