

**K152275 Pantheris System**Oct 14, 2015  
63 days to decisionK152275 · Product code: **MCW** · Cardiovascular  
Source: <https://www.510kdatabase.net/k152275/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Aug 12, 2015
Decision date	Oct 14, 2015
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avinger, Inc.</b>
Location	Redwood City, CA, US
Contact	Patty Hevey
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/k152275/> 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 3, 2026