

**K212468 Tigereye CTO-Crossing Catheter**Jan 6, 2022  
153 days to decisionK212468 · Product code: **PDU** · Cardiovascular  
Source: <https://www.510kdatabase.net/k212468/>**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, 2021
Decision date	Jan 6, 2022
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avinger, Inc.</b>
Location	Redwood City, CA, US
Contact	Thomas Lawson
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/k212468/> 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 14, 2026