

K230594 Tigereye ST CTO-Crossing CatheterApr 25, 2023
53 days to decisionK230594 · Product code: **PDU** · CardiovascularSource: <https://www.510kdatabase.net/k230594/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Mar 3, 2023
Decision date	Apr 25, 2023
Days to decision	53 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avinger, Inc.
Location	Redwood City, CA, US
Contact	Thomas Lawson
510(k) history	25 submissions · 25 cleared · 2009-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230594/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026