

K230005 Pantheris LV Atherectomy CatheterJun 6, 2023
154 days to decisionK230005 · Product code: **MCW** · CardiovascularSource: <https://www.510kdatabase.net/k230005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jan 3, 2023
Decision date	Jun 6, 2023
Days to decision	154 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

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