

K212047 Pantheris SystemNov 16, 2021
139 days to decisionK212047 · Product code: **MCW** · Cardiovascular
Source: <https://www.510kdatabase.net/k212047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Peripheral, Atherectomy (MCW)
Date received	Jun 30, 2021
Decision date	Nov 16, 2021
Days to decision	139 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

CLINICAL EVIDENCE - NCT03192696**Pantheris Atherectomy Treatment of In-Stent Restenosis In Lower Extremity Arteries**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	127 patients (actual)
Study sites	12 sites
Condition studied	Peripheral Arterial Disease
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 1, 2021
Sponsor	Avinger, Inc. (Industry)

Primary outcome

Freedom from a composite of major adverse events (MAEs) through 30-day follow-up (safety)

Secondary outcome

Stent structure freedom from new or worsening stent fracture post Pantheris treatment (safety)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03192696