

K251189 Aventus Thrombectomy SystemJun 13, 2025
57 days to decisionK251189 · Product code: **QEW** · Cardiovascular
Source: <https://www.510kdatabase.net/k251189/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Apr 17, 2025
Decision date	Jun 13, 2025
Days to decision	57 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inquis Medical
Location	Redwood City, CA, US
Contact	Zachary Woodson
510(k) history	8 submissions · 8 cleared · 2023-2026

CLINICAL EVIDENCE - NCT05907564**Aventus Thrombectomy System Pulmonary Embolism Clinical Study**

Status	Active not recruiting - <i>No results published to ClinicalTrials.gov</i>
Enrollment	130 patients (actual)
Study sites	26 sites
Condition studied	Pulmonary Embolism; Embolism; Embolism and Thrombosis; Vascular Diseases; Cardiovascular Diseases; Lung Diseases; Respiratory Tract Diseases
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Oct 1, 2026
Sponsor	Inquis Medical, Inc. (Industry)

Primary outcome**Change in RV/LV Ratio**Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05907564510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k251189/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026