FDA 510(k) Premarket Notification

CLEARED

K252956 Helo Thrombectomy System

Dec 18, 2025
93 days to decision

K252956 · Product code: **QEW** · Cardiovascular
Source: https://www.510kdatabase.net/k252956/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Peripheral Mechanical Thrombectomy With Aspiration (QEW)
Date received	Sep 16, 2025
Decision date	Dec 18, 2025
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Endovascular Engineering, Inc.**
Location	Menlo Park, CA, US
Contact	Debra Cogan
510(k) history	1 submissions · 1 cleared · 2025-2025

CLINICAL EVIDENCE - NCT05597891

Endovascular Engineering ENGULF Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	177 patients (actual)
Study sites	21 sites
Condition studied	Pulmonary Embolism
Primary purpose	Treatment
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Mar 30, 2026
Sponsor	Endovascular Engineering (Industry)

Primary outcome

Primary Safety Objective

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05597891

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k252956/ Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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