FDA 510(k) Premarket Notification

K252527 Surfacer Inside-Out Access Catheter System

CLEARED

Sep 10, 2025
30 days to decision

K252527 · Product code: **QJH** · Cardiovascular
Source: https://www.510kdatabase.net/k252527/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Reverse Central Venous Recanalization System (QJH)
Date received	Aug 11, 2025
Decision date	Sep 10, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Merit Medical System, Inc.**
Location	Galway, IE
Contact	Desiree Bond
510(k) history	5 submissions · 4 cleared · 2020-2025

CLINICAL EVIDENCE - NCT05050799

US Post-Market Surveillance Study of the Surfacer System

Status	Recruiting - *No results published to ClinicalTrials.gov*
Enrollment	30 patients (estimated)
Study sites	6 sites
Condition studied	Venous Disease
Study type	Observational
Completion date	Dec 15, 2026
Sponsor	Merit Medical Systems, Inc. (Industry)

Primary outcome

Central Venous Access operational

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05050799

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k252527/ Data sourced from FDA 510(k) public records (accessdata.fda.gov), ClinicalTrials.gov (U.S. National Library of Medicine).
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