FDA 510(k) Premarket Notification

CLEARED

K251877 JMS CAVEO A.V. Fistula Needle Set

Aug 15, 2025
58 days to decision

K251877 · Product code: **FIE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k251877/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Fistula (FIE)
Date received	Jun 18, 2025
Decision date	Aug 15, 2025
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**JMS North America Corporation**
Location	Crofton, MD, US
Contact	Sho Hososki
510(k) history	9 submissions · 9 cleared · 2011-2025

CLINICAL EVIDENCE - NCT05493423

Confirmatory Study to Assess the V Needle in End-Stage Renal Disease Patients During In-Clinic Hemodialysis

Status	Completed
Enrollment	15 patients (actual)
Study sites	1 site
Condition studied	End Stage Renal Disease
Primary purpose	Prevention
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jul 17, 2023
Sponsor	Hemotek Medical Inc (Industry)

Primary outcome

Percentage of Successful Hemodialysis Sessions

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05493423