

K251275 VitalStream ART Connect

Sep 26, 2025
155 days to decision

K251275 · Product code: **DXG** · Cardiovascular
Source: <https://www.510kdatabase.net/k251275/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Pre-programmed, Single-function (DXG)
Date received	Apr 24, 2025
Decision date	Sep 26, 2025
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	VitalStream-Hemo

APPLICANT

Company	Caretaker Medical
Location	Charlottesville, VA, US
Contact	Jeff Pompeo
510(k) history	2 submissions · 2 cleared · 2021-2025

CLINICAL EVIDENCE - NCT05035719

Comparison Studies Comparing Hemodynamic Parameters Provided by the Caretaker Against Respective Gold Standard References

Status	Unknown - <i>No results published to ClinicalTrials.gov</i>
Enrollment	60 patients (estimated)
Study sites	1 site
Condition studied	Cardiac Output, Low
Study type	Observational
Completion date	Mar 31, 2022
Sponsor	CareTaker Medical LLC (Industry)

Primary outcome

Cardiac output performance comparison

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05035719