

K250283 RAP Femoral Venous CannulaeJul 10, 2025
160 days to decisionK250283 · Product code: **DWF** · CardiovascularSource: <https://www.510kdatabase.net/k250283/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jan 31, 2025
Decision date	Jul 10, 2025
Days to decision	160 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	LivaNova USA, Inc.
Location	Arvada, CO, US
Contact	Luigi Vecchi
510(k) history	3 submissions · 3 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	Sorin Group Italia S.R.L.
Contact	Martina Carlini

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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