

**K250937 Venous Return Cannulae**Mar 11, 2026  
348 days to decisionK250937 · Product code: **DWF** · CardiovascularSource: <https://www.510kdatabase.net/k250937/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Mar 28, 2025
Decision date	Mar 11, 2026
Days to decision	348 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sorin Group Italia S.R.L.</b>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k250937/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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