FDA 510(k) Premarket Notification

K250610 Easyflow (103-200

CLEARED

Jun 27, 2025
119 days to decision

K250610 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k250610/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Feb 28, 2025
Decision date	Jun 27, 2025
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	103-300); Easyflow Duo (103-210; 103-310)

APPLICANT

Company	**Sorin Group Italia S.R.L.**
Location	Mirandola, IT
Contact	Luigi Vecchi
510(k) history	61 submissions · 61 cleared · 1995-2026

REGULATORY CONSULTANT

Consulting firm	**LivaNova USA, Inc.**
Contact	Jennifer Houck

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