

K233702 SMARxT Tubing and ConnectorsAug 8, 2024
265 days to decisionK233702 · Product code: **DWE** · CardiovascularSource: <https://www.510kdatabase.net/k233702/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Pump, Cardiopulmonary Bypass (DWE)
Date received	Nov 17, 2023
Decision date	Aug 8, 2024
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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