

K242503 Trilly Pediatric Oxygenator with Integrated Arterial Filter (US5232)Nov 24, 2025
459 days to decisionK242503 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k242503/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Aug 22, 2024
Decision date	Nov 24, 2025
Days to decision	459 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eurosets S.R.L
Location	Medolla, Modena, IT
Contact	Katia Vescovini
510(k) history	6 submissions · 6 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	Accurate Consultants, Inc.
Contact	Sebastian Feye

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

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