

K231652 D100 KIDSNov 16, 2023
163 days to decisionK231652 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k231652/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jun 6, 2023
Decision date	Nov 16, 2023
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	D101 KIDS

APPLICANT

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

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