

**K072091 D101 KIDS INFANT HOLLOW FIBER MEMBRANE
OXYGENATOR WITH INTEGRATED HARDSHELL
CARDIOTOMY/VENOUS RESERVOIR**Oct 29, 2007
91 days to decisionK072091 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k072091/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 30, 2007
Decision date	Oct 29, 2007
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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