

**K061031 D 100 L001 PH.I.S.I.O.: NEWBORN HOLLOW FIBER
MEMBRANE OXYGENATOR WITH INTEGRATED HARDSHELL
CARDIOTOMY/VENOUS RESERVOIR W**

Jun 2, 2006
49 days to decision

K061031 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k061031/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Apr 14, 2006
Decision date	Jun 2, 2006
Days to decision	49 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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k061031/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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