

**K122254 INSPIRE 8 HOLLOW FIBER OXYGENATOR WITH
INTEGRATED HARDSHELL VENOUS/CARDIOTOMY
RESERVOIR**Aug 24, 2012
28 days to decisionK122254 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k122254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 27, 2012
Decision date	Aug 24, 2012
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122254/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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