

**K120185 INSPIRE 6F HOLLOW FIBER OXYGENATOR WITH
INTEGRATED ARTERIAL FILTER AND HARDSHELL
VENOUS/CARDIOTOMY RESERVIOR**May 11, 2012
109 days to decisionK120185 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k120185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jan 23, 2012
Decision date	May 11, 2012
Days to decision	109 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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