

K130433 INSPIRE 8 HOLLOW FIBER OXYGENATOR WITH INTEGRATED HARDSHELL RESERVOIR, INSPIRE 8F HOLLOW FIBER OXYGENATOR WITH INTEGRATEMar 20, 2013
27 days to decisionK130433 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k130433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 21, 2013
Decision date	Mar 20, 2013
Days to decision	27 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

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