

**K121536 INSPIRE 8F OXYGENATOR WITH INTEGRATED  
ARTERIAL FILTER & HARDSHELL RESERVOIR**Aug 22, 2012  
90 days to decisionK121536 · Product code: DTZ · Cardiovascular  
Source: <https://www.510kdatabase.net/k121536/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	May 24, 2012
Decision date	Aug 22, 2012
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121536/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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