

**K180448 INSPIRE 6M Hollow Fiber Oxygenator**Mar 15, 2018  
30 days to decisionK180448 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180448/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 13, 2018
Decision date	Mar 15, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary
Other names	INSPIRE 6F M Hollow Fiber Oxygenator with Integrated Arterial Filter; INSPIRE 8M Hollow Fiber Oxygenator; INSPIRE 8F M Hollow Fiber Oxygenator with Integrated Arterial Filter

**APPLICANT**

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Company	<b>Sorin Group Italia S.R.L.</b>
Location	Mirandola, IT
Contact	Luigi Vecchi
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/k180448/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 30, 2026