

**K931444 PLEXUS 2 & 3.5 HOLLOW FIBER OXYGENATORS**May 27, 1994  
431 days to decisionK931444 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k931444/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 22, 1993
Decision date	May 27, 1994
Days to decision	431 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sorin Biomedica, Fiat, USA, Inc.</b>
Location	Mchenry, IL, US
Contact	DAVID TAYLOR
510(k) history	20 submissions · 20 cleared · 1980-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k931444/> 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 26, 2026