

**K043323 D 905 EOS HOLLOW FIBER OXYGENATOR WITH  
INTEGRATED HARDSHELL VENOUS/CARDIOTOMY  
RESERVOIR**Feb 1, 2005  
61 days to decisionK043323 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k043323/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 2, 2004
Decision date	Feb 1, 2005
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dideco S.R.L.</b>
Location	Waltham, MA, US
Contact	BARRY SALL
510(k) history	6 submissions · 6 cleared · 1996-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k043323/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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