

**K020997 APEX PH.I.S.I.O. ADULT HOLLOW FIBER MEMBRANE  
OXYGENATOR**Apr 4, 2002  
7 days to decisionK020997 · Product code: **DTZ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k020997/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 28, 2002
Decision date	Apr 4, 2002
Days to decision	7 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dideco S.P.A.</b>
Location	Waltham, MA, US
Contact	BARRY SALL
510(k) history	22 submissions · 22 cleared · 1997-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k020997/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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