

K022450 INTEGRATED UNIT: SYNTHESIS: ADULT MEMBRANE OXYGENATOR WITH INTEGRATED ARTERIAL FILTER AND HARDSHELL VENOUS/CARDIOTOMY

Oct 22, 2002
88 days to decision

K022450 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k022450/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jul 26, 2002
Decision date	Oct 22, 2002
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k022450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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