

K014080 APEX ADULT HOLLOWE FIBER OXYGENATORJan 8, 2002
28 days to decisionK014080 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k014080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 11, 2001
Decision date	Jan 8, 2002
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k014080/> Data sourced from FDA 510(k) public records (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. - Generated May 25, 2026