

K004001 MONOLYTH MIMESYS HOLLOW FIBER OXYGENATOROct 4, 2001
282 days to decisionK004001 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k004001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 26, 2000
Decision date	Oct 4, 2001
Days to decision	282 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dideco
Location	Mirandola (Modena), IT
Contact	BARBARA WATSON
510(k) history	5 submissions · 5 cleared · 1995-2001

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