

**K990103 MONOLYTH C 600 AND 1200 HOLLOW FIBER
MEMBRANE LUNG WITH INTEGRATED SOFTSHELL VENOUS
RESERVOIR , CVR 600 AND 1200 SOFTSHE**Nov 5, 1999
297 days to decisionK990103 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k990103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Jan 12, 1999
Decision date	Nov 5, 1999
Days to decision	297 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sorin Biomedical, Inc.
Location	Irvine, CA, US
Contact	LYNNE LEONARD
510(k) history	15 submissions · 15 cleared · 1993-1999

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