

**K964908 VRF40 VENOUS RESERVOIR WITH INTEGRAL
CARDIOTOMY FILTER**Sep 3, 1997
268 days to decisionK964908 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k964908/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Dec 9, 1996
Decision date	Sep 3, 1997
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964908/> 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