

**K092315 SORIN VVR 4000I AND 4000I SMARXT FILTERED
HARDSHELL VENOUS RESERVOIR**Aug 12, 2009
13 days to decisionK092315 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k092315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Jul 30, 2009
Decision date	Aug 12, 2009
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sorin Group Italia S.R.L.
Location	Mirandola, IT
Contact	BARRY SAIL
510(k) history	61 submissions · 61 cleared · 1995-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092315/> 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 June 22, 2026