

K002019 RETROGRADE CARDIOPLEGIA CANNULA, SELF-INFLATING, WITH MALLEABLE OR GUIDEWIRE STYLETMar 30, 2001
270 days to decisionK002019 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k002019/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jul 3, 2000
Decision date	Mar 30, 2001
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002019/> 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 28, 2026