

K093986 AF 620 PH.I.S.I.O., AF 640 PH.I.S.I.O. ARTERIAL FILTERSJan 22, 2010
29 days to decisionK093986 · Product code: **DTM** · Cardiovascular
Source: <https://www.510kdatabase.net/k093986/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Dec 24, 2009
Decision date	Jan 22, 2010
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093986/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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