FDA 510(k) Premarket Notification

K113626 INSPIRE 6 HOLLOW FIBER OXYGENATOR WITH INTEGRATED HARDSHELL VENOUS/CARDIOTOMY RESERVOIR

CLEARED

Apr 5, 2012
119 days to decision

K113626 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k113626/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 8, 2011
Decision date	Apr 5, 2012
Days to decision	119 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.net
Device record: https://www.510kdatabase.net/k113626/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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