

**K063255 D130 PH.I.S.I.O DIDECO KIDS NEONATAL ARTERIAL
FILTER WITH 40 MICRON SCREEN PHOSPHORYLCHOLINE
COATED**Jan 11, 2007
76 days to decisionK063255 · Product code: **DTM** · Cardiovascular
Source: <https://www.510kdatabase.net/k063255/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Oct 27, 2006
Decision date	Jan 11, 2007
Days to decision	76 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/k063255/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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