

K945198 DIDECO PEDIATRIC ARTERIAL FILTERSJun 27, 1995
246 days to decisionK945198 · Product code: **DTM** · Cardiovascular
Source: <https://www.510kdatabase.net/k945198/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM)
Date received	Oct 24, 1994
Decision date	Jun 27, 1995
Days to decision	246 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sorin Biomedical, Inc.
Location	Irvine, CA, US
Contact	RONALD S WARREN
510(k) history	15 submissions · 15 cleared · 1993-1999

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