

**K964907 VENOMIDICARD PEDIATRIC VENOUS RESERVOIR
WITH INTEGRALCARDIOTOMY FILTER/MIDICARD PEDIATRIC
CARDIOTOMY RESERVOIR WITH FILT**Aug 21, 1997
255 days to decisionK964907 · Product code: **DTN** · Cardiovascular
Source: <https://www.510kdatabase.net/k964907/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reservoir, Blood, Cardiopulmonary Bypass (DTN)
Date received	Dec 9, 1996
Decision date	Aug 21, 1997
Days to decision	255 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sorin Biomedical, Inc.
Location	Irvine, CA, US
Contact	RICHARD J DERISIO
510(k) history	15 submissions · 15 cleared · 1993-1999

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