

**K981601 CALIFORNIA MEDICAL LABORATORIES INC.
MALLEABLE VENT CATHETER**Jul 28, 1998
85 days to decisionK981601 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k981601/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	May 4, 1998
Decision date	Jul 28, 1998
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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