

K981009 HEARTPORT ENDOPULMONARY VENT CATHETERSep 4, 1998
170 days to decisionK981009 · Product code: **DWF** · Cardiovascular
Source: <https://www.510kdatabase.net/k981009/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Mar 18, 1998
Decision date	Sep 4, 1998
Days to decision	170 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Heartport, Inc.
Location	Redwood City, CA, US
Contact	MARIANNE D DRENNAN
510(k) history	24 submissions · 24 cleared · 1996-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k981009/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated July 4, 2026