FDA 510(k) Premarket Notification

K981009 HEARTPORT ENDOPULMONARY VENT CATHETER

CLEARED

Sep 4, 1998
170 days to decision

K981009 · 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