CLEARED

K994243 DIRECTFLOW KIT, 24 FR, SOFTCLAMP KIT, 24FR, STRAIGHTSHOT KIT, 23 FR, STRAIGHT TIP, STRAIGHTSHOT KIT, 23 FR, ANGLED TIP

May 5, 2000
141 days to decision

K994243 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k994243/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Dec 16, 1999
Decision date	May 5, 2000
Days to decision	141 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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