FDA 510(k) Premarket Notification

K974736 HEARTPORT DIRECT AORTIC RETURN CANNULA WITH INTRODUCER

CLEARED

Jul 15, 1998
208 days to decision

K974736 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k974736/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Dec 19, 1997
Decision date	Jul 15, 1998
Days to decision	208 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k974736/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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