FDA 510(k) Premarket Notification

K955121 HEARTPORT ENDOARTERIAL RETURN CANNUAL

CLEARED

May 10, 1996
183 days to decision

K955121 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k955121/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 9, 1995
Decision date	May 10, 1996
Days to decision	183 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k955121/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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