FDA 510(k) Premarket Notification

K971291 HEARTPORT ENDOARTERIAL RETURN CANNULA

CLEARED

Jun 17, 1997
71 days to decision

K971291 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k971291/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Apr 7, 1997
Decision date	Jun 17, 1997
Days to decision	71 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