FDA 510(k) Premarket Notification

K052081 REMOTE ACCESS PERFUSION (RAP) FEMORAL VENOUS CANNULA

CLEARED

Dec 16, 2005
136 days to decision

K052081 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k052081/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Aug 2, 2005
Decision date	Dec 16, 2005
Days to decision	136 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Estech, Inc.**
Location	Danville, CA, US
Contact	CRAIG COOMBS
510(k) history	7 submissions · 7 cleared · 1999-2013