FDA 510(k) Premarket Notification

CLEARED

K081933 AVALON ELITE MULTI-PORT VENOUS FEMORAL CATHETER, 20FR, 22FR, 24FR, 26FR, 28FR

Oct 3, 2008
88 days to decision

K081933 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k081933/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jul 7, 2008
Decision date	Oct 3, 2008
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Avalon Laboratories, LLC**
Location	Austin, TX, US
Contact	LEE WIRTH
510(k) history	3 submissions · 3 cleared · 2008-2008