FDA 510(k) Premarket Notification

K000830 CANNULATION TOURNIQUET SET, 2 TUBE OR 5 TUBE

CLEARED

Sep 7, 2000
177 days to decision

K000830 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k000830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Mar 14, 2000
Decision date	Sep 7, 2000
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**California Medical Laboratories, Inc.**
Location	Irvine, CA, US
Contact	MEHMET BICAKCI
510(k) history	3 submissions · 3 cleared · 1998-2000