FDA 510(k) Premarket Notification

K993818 ANTEGRADE/RETROGRADE PERFUSION ADAPTER WITH OR WITHOUT PRESSURE LINE

CLEARED

Feb 8, 2000
90 days to decision

K993818 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k993818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Nov 10, 1999
Decision date	Feb 8, 2000
Days to decision	90 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