FDA 510(k) Premarket Notification

K023251 PEDIATRIC ARTERIAL CANNULA

CLEARED

Dec 4, 2002
65 days to decision

K023251 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k023251/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Sep 30, 2002
Decision date	Dec 4, 2002
Days to decision	65 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Polystan A/S**
Location	Denmark, DK
Contact	DANA OLSEN
510(k) history	6 submissions · 6 cleared · 1991-2002