FDA 510(k) Premarket Notification

K002019 RETROGRADE CARDIOPLEGIA CANNULA, SELF-INFLATING, WITH MALLEABLE OR GUIDEWIRE STYLET

CLEARED

Mar 30, 2001
270 days to decision

K002019 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k002019/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jul 3, 2000
Decision date	Mar 30, 2001
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sorin Group Italia S.R.L.**
Location	Mirandola, IT
Contact	Luigi Vecchi
510(k) history	61 submissions · 61 cleared · 1995-2026