FDA 510(k) Premarket Notification

K180979 PureFlex Arterial Cannulae

CLEARED

Nov 16, 2018
217 days to decision

K180979 · Product code: **DWF** · Cardiovascular
Source: https://www.510kdatabase.net/k180979/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Apr 13, 2018
Decision date	Nov 16, 2018
Days to decision	217 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	**LivaNova USA, Inc.**
Contact	Scott Light

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov