FDA 510(k) Premarket Notification

CLEARED

K190650 Revolution Centrifugal Blood Pump

Aug 7, 2019
147 days to decision

K190650 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k190650/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Mar 13, 2019
Decision date	Aug 7, 2019
Days to decision	147 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