

**K190650 Revolution Centrifugal Blood Pump**Aug 7, 2019  
147 days to decisionK190650 · Product code: **KFM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k190650/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>LivaNova USA, Inc.</b>
Contact	Scott Light

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190650/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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