

K232132 LifeSPARC System

Aug 3, 2023
16 days to decision

K232132 · Product code: **KFM** · Cardiovascular
Source: <https://www.510kdatabase.net/k232132/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Jul 18, 2023
Decision date	Aug 3, 2023
Days to decision	16 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cardiacassist, Inc.
Location	Pittsburgh, PA, US
Contact	Arielle Drummond
510(k) history	21 submissions · 21 cleared · 2000-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k232132/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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