FDA 510(k) Premarket Notification

K232132 LifeSPARC System

CLEARED

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