FDA 510(k) Premarket Notification

K211830 LifeSPARC System

CLEARED

Nov 15, 2022
519 days to decision

K211830 · Product code: **QNR** · Cardiovascular
Source: https://www.510kdatabase.net/k211830/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pump For Ecmo, Long-term (> 6 Hours) Use (QNR)
Date received	Jun 14, 2021
Decision date	Nov 15, 2022
Days to decision	519 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k211830/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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