

**K233736 LifeSPARC System**Jan 19, 2024  
58 days to decisionK233736 · Product code: **QNR** · CardiovascularSource: <https://www.510kdatabase.net/k233736/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pump For Ecmo, Long-term (> 6 Hours) Use (QNR)
Date received	Nov 22, 2023
Decision date	Jan 19, 2024
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233736/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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