

K223898 VitalFlow™ Centrifugal PumpAug 25, 2023
240 days to decisionK223898 · Product code: **QNR** · CardiovascularSource: <https://www.510kdatabase.net/k223898/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pump For Ecmo, Long-term (> 6 Hours) Use (QNR)
Date received	Dec 28, 2022
Decision date	Aug 25, 2023
Days to decision	240 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Michigan Critical Care Consultants, Inc. (D.B.A Mc3 Inc.)
Location	Dexter, MI, US
Contact	Martha Rumford
510(k) history	2 submissions · 2 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223898/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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