

**K230364 VitalFlow™ Console**Aug 25, 2023  
196 days to decisionK230364 · Product code: **QNR** · CardiovascularSource: <https://www.510kdatabase.net/k230364/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pump For Ecmo, Long-term (> 6 Hours) Use (QNR)
Date received	Feb 10, 2023
Decision date	Aug 25, 2023
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230364/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026