FDA 510(k) Premarket Notification

K230364 VitalFlow™ Console

CLEARED

Aug 25, 2023
196 days to decision

K230364 · Product code: **QNR** · Cardiovascular
Source: 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	**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