FDA 510(k) Premarket Notification

K232767 Nautilus VF ECMO Oxygenator

CLEARED

Oct 4, 2023
23 days to decision

K232767 · Product code: **BYS** · Cardiovascular
Source: https://www.510kdatabase.net/k232767/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Long Term Support Greater Than 6 Hours (BYS)
Date received	Sep 11, 2023
Decision date	Oct 4, 2023
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mc3, Inc.**
Location	Dexter, MI, US
Contact	Martha Rumford
510(k) history	2 submissions · 2 cleared · 2021-2023