

**K232767 Nautilus VF ECMO Oxygenator**Oct 4, 2023  
23 days to decisionK232767 · Product code: **BYS** · CardiovascularSource: <https://www.510kdatabase.net/k232767/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232767/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026