

K191935 Nautilus Smart ECMO ModuleApr 9, 2020
265 days to decisionK191935 · Product code: **BYS** · Cardiovascular
Source: <https://www.510kdatabase.net/k191935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Long Term Support Greater Than 6 Hours (BYS)
Date received	Jul 19, 2019
Decision date	Apr 9, 2020
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mc3 Incorporated
Location	Dexter, MI, US
Contact	Adam Viitala
510(k) history	4 submissions · 4 cleared · 2017-2020

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