October 4, 2023

Michigan Critical Care Consultants, Inc. (d.b.a MC3 Inc.)
Martha Rumford
VP Regulatory
2555 Bishop Circle West
Dexter, Michigan 48130

Re: K232767
Trade/Device Name: Nautilus VF ECMO Oxygenator
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term Respiratory/Cardiopulmonary Failure
Regulatory Class: Class II
Product Code: BYS
Dated: September 7, 2023
Received: September 11, 2023

Dear Martha Rumford:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Nicole M. Gillette -S

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232767

Device Name

Nautilus VF ECMO Oxygenator

Indications for Use *(Describe)*

The Nautilus VF ECMO Oxygenator with integrated heat exchanger is intended to provide assisted long-term extracorporeal circulation and physiologic gas exchange (oxygenation and carbon dioxide removal) of the patient's blood for up to 48 hours in adult and pediatric adolescent patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The integrated heat exchanger is intended to heat or cool the blood as needed during use. Integrated fluid path pressure, temperature, and oxygen saturation monitoring is achieved by built-in sensor modules.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

Sponsor Information:

Owner/Applicant/Submitter:	Michigan Critical Care Consultants, Inc. (d.b.a. MC3 Inc.) 2555 Bishop Circle West Dexter, MI 48130 1-734-995-9089 Registration number: 3011468686
Contact Person:	Martha Rumford
Date Prepared:	Sept 5, 2023

Device Names/Classification:

Device Trade Name:	Nautilus™ VF ECMO Oxygenator
Device Common Name:	Oxygenator, Long Term Support Greater Than 6 hours
Regulation Name:	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulation Number:	21 CFR 870.4100
Product Code:	BYS
Predicate:	Nautilus™ Smart ECMO Module (K191935) Nautilus™ ECMO Oxygenator (K191935)

Indications for Use:

The Nautilus™ VF ECMO Oxygenator with integrated heat exchanger is intended to provide assisted extracorporeal circulation and physiologic gas exchange of the patient's blood for up to 48 hours in adult and pediatric adolescent patients with acute respiratory failure or acute cardiopulmonary failure, where other available treatment options have failed, and continued clinical deterioration is expected or the risk of death is imminent. The integrated heat exchanger is intended to heat or cool the blood as needed during use. Integrated fluid path pressure, temperature, and oxygen saturation monitoring achieved by built-in sensors.

Device Description:

The Nautilus™ ECMO oxygenators are diffusion membrane oxygenators used in extracorporeal life support procedures to oxygenate blood, remove carbon dioxide and regulate blood temperature. Blood enters the device and passes through both the heat exchange membrane, where temperature is adjusted, and the gas transfer membrane, where oxygen is added and carbon dioxide is removed.

The Nautilus™ VF ECMO Oxygenator device contains integrated sensors that connects to the VitalFlow Console (K230364) for the display of measured parameters. The following measured parameters are

measured: inlet pressure, inlet oxygen saturation, outlet pressure, outlet oxygen saturation, and outlet blood temperature. The difference between the inlet and outlet pressure, delta pressure, is calculated. The device is intended to be interconnected with a VitalFlow Console device that receives digital data from the oxygenator.

The oxygenator devices are single-use, nontoxic, non-pyrogenic, and not made from natural latex rubber materials.

Performance Evaluations:

Evaluation and testing were executed to demonstrate the substantial equivalence of the subject devices. Performance assessments for substantial equivalence were accomplished through bench studies that included the following evaluations:

- Electrical Safety/EMC
- Software Validation
- Cyber security analysis

Substantial Equivalence:

Substantial equivalence analysis includes comparison to the Nautilus™ Smart ECMO Module (Predicate).

Special Controls met for the Nautilus™ oxygenators are:

- ***Technological Characteristics:*** Geometry and design parameters are consistent with the device's intended use in extracorporeal life support procedures. The subject device is designed to be compatible with other extracorporeal circuit devices and accessories. Geometry and design parameters of the oxygenator are the same for the Nautilus, Nautilus Smart and Nautilus VF oxygenators. The electronic module of the Nautilus Smart (hardware and software) included for monitoring the circuit parameters have been modified for the Nautilus VF Oxygenator and demonstrated to perform equivalently.

- ***Biocompatibility:*** The subject device is demonstrated to be biocompatible for prolonged use in circulating blood in accordance with ISO 10993-1:2009 and in accordance with GLP (21 CFR 58). There were no modifications to the blood contact surfaces or design.

- ***Sterility and Shelf-life:*** Testing demonstrates the sterility of the subject device as provided and that it maintains its sterility, integrity, durability, and reliability over the stated shelf-life of the device.

- ***Non-clinical Performance:*** Substantial equivalence is demonstrated by performance characteristics on the bench, mechanical integrity, electromagnetic compatibility, software, durability, reliability, and accuracy. Substantial equivalence is demonstrated by performance characteristics of electromagnetic compatibility and software validation, as well as an additional analysis for cybersecuity.

- ***In vivo Evaluation:*** In vivo evaluation demonstrates the subject device's performance over a long-term duration of use in a biologic test system. In addition to in-vivo study, a summary was prepared that described the initial real-world clinical experience of the device with the first records of clinical ECMO cases entered sequentially into the ELSO registry. This in vivo

evaluation of the original design remains applicable to the Nautilus VF Oxygenator because the oxygenator design is unchanged while the non-patient contacting components were modified.

- ***Labeling:*** The Instructions for Use includes a detailed summary of the non-clinical evaluations pertinent to the device's use in an extracorporeal circuit. Adequate instructions are included with respect to installation, circuit setup, maintenance during a procedure, changeout, adverse effects, and performance characteristics relevant to compatibility among different devices and accessories in the circuit.

Conclusion:

The Nautilus™ VF ECMO Oxygenators are substantially equivalent to the Predicate device with respect to intended use, design, materials of construction, principles of operation, performance and specifications. The risks of this device are mitigated by meeting the Special Controls required by the regulation, 21 CFR 870.4100.