August 25, 2023

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

Re: K230364
Trade/Device Name: VitalFlow™ Console
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term Respiratory/Cardiopulmonary Failure
Regulatory Class: Class II
Product Code: QNR
Dated: July 13, 2023
Received: July 14, 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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.

510(k) Number *(if known)*
K230364

Device Name
VitalFlow™ Console

Indications for Use *(Describe)*
The VitalFlow™ Console controls the speed of the VitalFlow™ Centrifugal blood pump during extracorporeal cardiopulmonary life support for adult 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 VitalFlow Centrifugal pump is driven by the VitalFlow Motor Drive or the VitalFlow Emergency Handcrank.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
VitalFlow™ Console

Date Prepared:	June 22, 2023
Sponsor Information:	
Owner/Applicant/Submitter:	Michigan Critical Care Consultants, Inc (dba MC3, Inc.) 2555 Bishop Circle West Dexter, MI 48130 1-734-995-9089 Registration number: 3011468686
Contact Person:	Martha Rumford Vice President of Regulatory Affairs 2555 Bishop Circle West Dexter, MI 48130 734.995.9089
Device Names/Classification:	
Device Trade Name:	VitalFlow™ Console
Device Common Name:	Blood Pump For ECMO, Long-Term (> 6 Hours) Use
Regulation Name:	Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure
Regulation Number:	21 CFR 870.4100
Product Code:	QNR
Predicate:	TandemHeart Escort Controller (K202751)
Reference Devices:	Medtronic Bio-Console 560 (K131964) and Medtronic External Drive Motor 560A (K191077)

Indications for Use:

The VitalFlow™ Console controls the speed of the VitalFlow™ Centrifugal blood pump during extracorporeal cardiopulmonary life support for adult 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 VitalFlow Centrifugal pump is driven by the VitalFlow™ Motor Drive or the VitalFlow™ Emergency Hand Crank.

Device Description:

The VitalFlow Console provides control of blood pumping through an extracorporeal circuit during extracorporeal life support (ECLS) procedures. The console powers the VitalFlow motor drive unit

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which provides rotation of the VitalFlow Centrifugal pump. Pump motor speed (RPM) can be adjusted by the user and flow and bubble detection is provided by an ultrasonic flow probe and displayed on the touchscreen. The touchscreen display allows users to set alarm limits for all measured parameters. The device will alarm visually and audibly when limits are exceeded. Status indicators, power / battery life and secondary RPM indicator is provided. Data download and data streaming from the console is available for ECLS circuit data only; no patient data are stored or exported.

The VitalFlow Emergency Handcrank (drive unit) can be used in emergency situations to manually drive the centrifugal pump in the case of console and or motor drive failure.

Bench Performance Evaluations:

Design verification studies of the VitalFlow Console and components were performed including long-term characterization. This data supports a finding of substantial equivalence to the Predicate with respect to the Special Controls described by 21CFR 870.4100.

- Hydraulic performance
- Reliability
- Motor Bearing wear
- Magnetic coupling
- EMC
- Electrical Safety
- Software Validation
- Usability Studies

Substantial Equivalence:

Substantial equivalence analysis includes a comparison to the predicate device. The VitalFlow Console was also compared to the Reference devices. The VitalFlow Console controls the pump speed of the VitalFlow centrifugal pump, using the identical drive motor as the Reference device. The design, principles of operation, materials of construction, performance, and fundamental scientific technology are substantially equivalent to the TandemHeart Escort Controller.

Comparison of Technological Characteristics with the Predicate Device

The subject and predicate devices control the speed of the blood pump during extracorporeal cardiopulmonary life support for adult patients. At a high level, the subject and predicate devices are based on the following same technological elements:

- Both use a DC motor drive driven by a microprocessor-based motor controller to control the blood pump speed.
- Display pump RPM and flow rate.
- Use a flow sensor based on ultrasonic transit-time technology (clamps outside of tubing).

The following technological differences exist between the subject and predicate devices:

- The TandemHeart pump head is smaller in diameter and volume than the Subject Device. As a result, the predicate pump requires a higher RPM to achieve similar flows and has a maximum output pressure of 450 mmHg at pump speed of 7500 RPM. The Subject Device has a maximum output pressure of 680 mmHg at pump speed of 3800 RPM.
- The Predicate device does not offer the optional bubble detection feature.

- The Subject device has the capability to receive and display device information from a compatible VitalFlow oxygenator.
- The maximum flow rate of the Subject device is 7 L/min, the maximum flow rate of the Predicate device is 5 L/min (percutaneous connection) or 8 L/min (surgical connection).

The VitalFlow Centrifugal Pump meets all special controls required by 21 CFR 870.4100. Special Controls met are:

- ***Technological Characteristics:*** Design parameters are consistent with the devices intended use in extracorporeal life support procedures. The subject device is designed to be compatible with other extracorporeal circuit devices and accessories.
- ***Biocompatibility:*** NA This device is not patient contacting
- ***Sterility and Shelf-life:*** NA This device is not a sterile or disposable product.
- ***Non-clinical Performance:*** Substantial equivalence is demonstrated by performance characteristics on the bench, including reliability. The Console meets international standards for safety and has demonstrated effectiveness at maintaining the device performance.
- ***In vivo Evaluation:*** The device does not directly contact the test system. Reference the VitalFlow Centrifugal Pump 510(k) for in vivo evaluation.
- ***Clinical Evidence of Performance:*** A summary of real-world evidence of the clinical experience of the VitalFlow Centrifugal Pump is included with the VitalFlow Centrifugal Pump 510(k).
- ***Labeling:*** Adequate instructions for the VitalFlow Console and components are included with respect to installation, circuit setup, maintenance during a procedure, adverse effects, and performance characteristics relevant to compatibility among different devices and accessories in the circuit.

Conclusion:

The VitalFlow Console device is substantially equivalent to the predicate device. The risks of this device are mitigated by meeting the Special Controls required by the regulation, 21 CFR 870.4100.