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: K223898
Trade/Device Name: VitalFlow™ Centrifugal Pump
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: August 11, 2023
Received: August 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 (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)*

Device Name
VitalFlow™ Centrifugal Pump

Indications for Use *(Describe)*
The VitalFlow™ Centrifugal Pump is intended to pump blood through the extracorporeal circuit for circulatory support up to 48 hours, in 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™ Console and Drive Motor, or the 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™ Centrifugal Pump

Date Prepared:	August 11, 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™ Centrifugal Pump
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 Pump (K202751)
Reference Device 1:	Affinity CP Centrifugal Blood Pump BBAP40 (K111657)
Reference Device 2:	Maquet Rotaflow Centrifugal Pump (K991864)

Indications for Use:

The VitalFlow™ Centrifugal Pump is intended to pump blood through the extracorporeal circuit for circulatory support up to 48 hours, in 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™ Console and Drive Motor, or the Emergency Handcrank.

Device Description:

The VitalFlow Centrifugal Pump is a sterile, single-use centrifugal blood pump. It is a non-invasive, non-pyrogenic device designed to move blood through the extracorporeal circuit by centrifugal force. The pump is the disposable portion of the pumping system and it is electromagnetically coupled to an instrument that monitors and displays the flow and pressure of the blood. Blood enters the inlet port of the pump, where a cone with impeller blades within the pump housing rotates and the blood is gently accelerated toward the outlet of the pump.

The VitalFlow Centrifugal Pump can be driven through magnetic coupling by an External Drive Motor or the Emergency Handcrank.

Bench and Animal Performance Evaluations:

Design verification studies were performed by the original manufacturer of the subject device and supplemented by MC3 bench performance testing, including long-term characterization. This data is coupled with animal studies to support a finding of substantial equivalence to the Predicate with respect to the Special Controls described by 21CFR 870.4100. The following testing demonstrated the pump's duration of use:

- Bearing wear
- Coating coverage
- Mechanical integrity
- Pressure integrity
- Hydraulic performance
- High flow blood trauma testing
- In-vivo performance testing
- Magnetic coupling
- Port and Pull strength
- Prime volume

Substantial Equivalence:

Substantial equivalence analysis includes both comparison to the predicate device and clinically relevant Reference Devices. The VitalFlow Centrifugal Pump is the same as the Affinity™ CP Centrifugal Blood Pump with Balance™ Biosurface in design, principles of operation, materials of construction, performance, and fundamental scientific technology. The design, principles of operation, materials of construction, performance, and fundamental scientific technology are substantially equivalent to the TandemHeart Pump.

Comparison of Technological Characteristics with the Predicate Device

The subject and predicate devices are centrifugal pumps that are designed to move blood through the extracorporeal circuit. Blood enters the inlet port of the pump, where a cone with impeller blades within the pump housing rotates and the blood is gently accelerated toward the outlet of the pump. The pump is the disposable portion of the pumping system that is electromagnetically coupled to an instrument that monitors and displays the blood flow.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Principle of operation

- Design characteristics
- Coupled to a motor for control via a pump console
- Connection to extracorporeal circuit via 3/8" inlet and outlet connectors
- Sterilization method

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

- The subject device has a shaft seal around the bearing, whereas the predicate device has a hydrodynamic bearing with an infusate line included in the device.
- The capacity of the pump of the Predicate (prime volume 10 ml) is lower compared to the Subject pumping system (prime volume 40 ml) because TandemHeart pump head is smaller in diameter and volume. As a result, the predicate pump requires a higher RPM to achieve similar flows with output pressure of 450 mmHg at pump speed of 7500 RPM. The maximum RPM for Subject device is 3800 RPM with an output pressure of 680 mmHg.
- Maximum flow rate of Subject device is 7 L/min, maximum flow rate of 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:*** Geometry and 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:*** The subject device is demonstrated to be biocompatible in accordance with ISO 10993-1:2018 and in accordance with GLP (21 CFR 58).

- ***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, durability, and reliability.

- ***In vivo Evaluation:*** Animal testing demonstrates the subject device's performance over a long-term duration of use in a biologic test system.

- ***Clinical Evidence of Performance:*** A summary of real-world evidence of the clinical experience with this pump was prepared by ELSO.org and presented which demonstrated acceptable longterm performance of the device in ECMO patients.

- ***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 also 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.

ECMO Performance Evidence

- Bench studies demonstrating a blood pump use duration of 14 days were performed, including a bench durability study at 37° C in blood analog to assure mechanical stability with a substantial

margin of safety. The device was mounted in the orientation as described by these instructions and met all critical flow performance attributes after this study, including pressure-flow performance and product integrity.

- A 96-hour animal study was conducted to evaluate the safety and performance of the VitalFlow Centrifugal Pump used for extracorporeal membrane oxygenation (ECMO) when used for long term use with a target ACT of 180-220 sec. The study was conducted on a total of 13 sheep. High (5 L/min) and low (2 L/min) blood flow rates were sustained for 96 hours and there were no clots in any location in the device and blood pump functionality was confirmed.

- Clinical Performance
  A summary of real-world evidence (1048 reports) of the clinical experience with this pump was presented which demonstrated acceptable long-term performance of the device in ECMO patients. The performance of the pump was shown to be excellent with the data representing over 200,000 hours of ECMO time with this device, with the ECMO duration averaging 225.6 hours in the adult group.

  Complications on ECMO (adult): For the complications that were specified to be of interest to pump performance, the overall complication rate in the adult ECMO population was 34.7% [364/1048] in the AP40 group versus 35.0% [17852/51032] in the non-AP40 group. For specific mechanical complications, the proportion of runs with a pump complication was 1.2% [13/1048] in the AP40 group versus 0.7 [355/51032] in the non-AP40 group, and the proportion of runs with at least one hemolysis complication was 1.1% [12/1048] in the AP40 group, lower than the corresponding percentage of 4.6% [2322/51032] in the non-AP40 group. The proportion of runs with the neurologic complication CNS infarction by US/ CT/MRI was 2.8% [29/1048] in the AP40 group versus 2.3% [1199/51032] in the non-AP40 group.

Complication	**VitalFlow Pump (AP40) (n=1048)**	**All Other Pumps (Non-AP40) (n=51032)**
≥ 1 of any	**34.7% (364)**	**35.0% (17852)**
Mechanical		
Oxygenator Failure	5.1%(53)	7.1%(3632)
Pump failure (Prevalence)[a]	1.2% (13)	0.7% (355)
Pump failure (Rate per 1000 hrs)[b]	0.06	0.03
Heat Exchanger Malfunction	0.1%(1)	0.0%(22)
Air in circuit	1.3% (14)	0.9% (444)
Circuit change	7.8% (82)	5.6% (2851)
Emboli (clots or air)	0.2% (2)	0.2% (94)
Thrombosis/Clots in circuit	2.9% (30)	2.8% (1429)
Hemorrhagic		
Cannulation site bleeding	9.4%(98)	8.1%(4157)
Surgical site bleeding	10.8%(113)	7.9%(4019)
Neurologic		
CNS infarction (US/CT/MRI)	2.8% (29)	2.3% (1199)
CNS Hemorrhage (US/CT/MRI)	3.6%(38)	3.7%(1875)
CNS Diffuse Ischemia (CT/MRI)	1.5%(16)	1.6%(801)
Hemolysis		
Moderate Hemolysis	0.7%(7)	2.4%(1242)
Severe Hemolysis	0.4%(4)	1.8%(925)
Moderate or Severe Hemolysis	1.1% (12)	4.6% (2322)

a: Prevalence of failures corresponding to the initial pump
b: Rate of failures per 1000 hours corresponding to the initial pump

Conclusion:

The VitalFlow Centrifugal Pump device is substantially equivalent to the predicate device and the clinically used reference extracorporeal blood pump devices. The risks of this device are mitigated by meeting the Special Controls required by the regulation, 21 CFR 870.4100.