September 12, 2024

Medtronic Inc.
Anna Wetherille
Senior Regulatory Affairs Specialist
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K240880
Trade/Device Name: VitalFlow™ Set with Balance™ Biosurface
Regulation Number: 21 CFR 870.4100
Regulation Name: Extracorporeal Circuit And Accessories For Long-Term Respiratory/Cardiopulmonary Failure
Regulatory Class: Class II
Product Code: QJZ, QNR, BYS, QWF
Dated: July 30, 2024
Received: July 30, 2024

Dear Anna Wetherille:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240880

Device Name
VitalFlow™ Set with Balance™ Biosurface

Indications for Use *(Describe)*
The VitalFlow Set with Balance Biosurface is indicated for respiratory/cardiopulmonary support up to 48 hours that provides assisted extracorporeal circulation and physiologic gas exchange (oxygenation) of the patient's blood in adults 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of Safety and Effectiveness

Date Prepared: **March 29, 2024**

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
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Establish Registration Number: 2184009

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Trade Name: VitalFlow™ Set with Balance™ Biosurface

Common Name: Extracorporeal Life Support Circuit and Accessories

Classification Name: Extracorporeal circuit and accessories for long-term respiratory/cardiopulmonary failure

Classification: Class II (with special controls)

Regulation Number: 21 CFR 870.4100

Product Codes: QJZ, QNR, BYS, QWF

Name of Predicate Device: Novalung System (K191407)

Name of Reference Devices: Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance™ Biosurface (K223168)
Nautilus VF ECMO Oxygenator (K232767)
VitalFlow Centrifugal Pump (K223898)
Tubing Pack (K171979)

Device Description:

VitalFlow Sets with Balance™ Biosurface contain components used to prepare an extracorporeal circuit for ECMO procedures. The components include the VitalFlow Tubing Sets packaged together with the legally marketed Nautilus VF Oxygenator and VitalFlow Centrifugal Pump as a standard kit. The components are connected together to prepare an extracorporeal circuit for ECMO procedures.

The VitalFlow Tubing Set contains a preassembled drainage and return loop "ECMO Circuit," tubing assemblies, and other components used to prepare a basic extracorporeal circuit. The tubing assembly is provided pre-connected to the inlet of the VitalFlow Centrifugal Pump. The "Priming Circuit" contains components to supplement the basic extracorporeal circuit, as needed per hospital protocols for setting up the ECMO circuit. A venous reservoir and one-way valve are included in the priming circuit to facilitate ease of priming the ECMO circuit.

This product is nonpyrogenic, is intended for single use, and has been sterilized using ethylene oxide.

Indications for Use:

The VitalFlow Set with Balance Biosurface is indicated for respiratory/cardiopulmonary support up to 48 hours that provides assisted extracorporeal circulation and physiologic gas exchange of the patient's blood in adults 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.

Substantial Equivalence:

Substantial equivalence analysis includes both comparison to the predicate device and clinically relevant reference devices. The VitalFlow Sets design, principles of operation, and fundamental scientific technology are substantially equivalent to the primary predicate device, Novalung System.

Comparison to Predicate:

A comparison of the VitalFlow™ Set with Balance™ Biosurface to the predicate device indicates the following similarities:

- Same intended use
- Similar technological characteristics
- Same operating principle
- Similar design features
- Similar materials

Comparison to Reference Devices:

The components of the VitalFlow™ Set with Balance™ Biosurface are substantially equivalent with respect to the following technological characteristics of the reference devices:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same materials
- Same shelf-life, the subject device has a 2-year shelf life

The VitalFlow™ Set with Balance™ Biosurface device meets all special controls identified in 21 CFR 870.4100, as follows:

- Technological Characteristics: The geometry and design parameters of the subject device are consistent with the device's intended use in extracorporeal support procedures, and the device is compatible with the other devices and accessories in the extracorporeal circuit.
- Biocompatibility: The subject device is demonstrated to be biocompatible in accordance with ISO 10993-1.
- Sterility and Shelf-life: Sterilization adoption evaluation and shelf-life assessment demonstrate that the subject device maintains its sterility, integrity, durability, and reliability over the stated shelf life of the device.
- Non-clinical Performance: Substantial equivalence of the performance characteristics is demonstrated on bench, mechanical integrity, durability, and reliability testing.
- Clinical Evidence of Performance: A summary of real-world evidence of the clinical experience with this device was prepared by ELSO and presented which demonstrates acceptable performance of the device in ECMO patients.
- Labeling: The Instructions for Use include a detailed summary of the non-clinical evaluations pertinent to use of the device in an extracorporeal circuit and adequate instructions with respect to anticoagulation, circuit setup, performance characteristics with respect to compatibility among different devices and accessories in the circuit, and maintenance during a procedure.

Summary of Performance Data

Pre-clinical bench testing was used to verify the performance characteristics of this device.

The following preclinical bench studies were conducted:

- Simulated use durability testing
- Tensile strength after life conditioning (long term use)
- Pressure test after life conditioning (long term use)
- Functional testing

- Kink testing
- Blood trauma testing
- Coating coverage

Clinical Summary:
A summary of real-world evidence (195 reports) of the clinical experience with the VitalFlow Set from the ELSO Registry was presented which demonstrated acceptable long-term performance of the subject device in ECMO patients. The performance of the device was shown to be excellent with the data representing over 39,000 hours of ECMO time with this device, with the ECMO duration averaging 201.8 hours in the adult group.

Complications on ECMO (adult): The overall complication rate in the adult ECMO population was 38.5% (75/195) for the VitalFlow Set group versus 35.1% (21501/61176) in the non-subject device group. For specific mechanical complications, the proportion of runs with an oxygenator failure was 4.6% [9/195] in the VitalFlow Set group versus 8.0% [4878/61176] in the non-subject device group, and the pump failure was 2.6% [5/195] in the VitalFlow Set group versus 0.6 [368/61176] in the non-subject device group. The proportion of runs with hemolysis was 2.1% [4/195] in the VitalFlow Set group, lower than the corresponding percentage of 5.2% [3197/611762] in the non-subject device group. The proportion of runs with thrombosis or clots in the circuit was 1.0% [2/195] in the VitalFlow Set group, lower than the corresponding percentage of 2.1% [3197/611762] in the non-subject device group.

Complication	**VitalFlow Sets (n=195 patients)**	**All other ECMO Systems (n=61176)**
≥ 1 of any	**38.5% (75)**	**35.1% (21501)**
Mechanical		
Oxygenator Failure (Prevalence)[a]	4.6% (9)[a]	8.0% (4878)[a]
Oxygenator Failure (Rate per 1000 Hrs)	0.30	0.35
Pump Failure (Prevalence)[b]	2.6% (5)[b]	0.6% (368)[b]
Pump Failure (Rate per 1000 Hrs)	0.16	0.02
Heat Exchanger Malfunction	0.0% (0)	0.0% (27)
Air in Circuit	1.0% (2)	0.8% (507)
Cannula Problems	2.6% (5)	4.6% (2825)
Circuit Change	6.2% (12)	4.6% (2896)
Emboli (Clots or Air)	0.5% (1)	0.2% (150)
Thrombosis/Clots in Circuit Component	1.0% (2)	2.1% (1272)
Neurologic		
CNS Infarction (US/CT/MRI)	2.6% (5)	2.8% (1688)
CNS Hemorrhage (US/CT/MRI)	3.6% (7)	3.8% (2296)
CNS Diffuse Ischemia (CT/MRI)	2.1% (4)	1.9% (1145)
Hemolysis		
Moderate Hemolysis	1.0% (2)	3.4% (2052)
Severe Hemolysis	1.5% (3)	2.6% (1605)
Moderate or Severe Hemolysis	2.1% (4)	5.2% (3197)

Row Notes:
a) Prevalence of failures corresponding to the initial equipment
b) Rate of failures per 1000 hours corresponding to the initial equipment

Conclusion:

The data included in this submission are sufficient to demonstrate that the VitalFlow™ Set with Balance™ Biosurface is substantially equivalent to the predicate device, Novalung System, and the legally marketed reference devices, Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance™ Biosurface, Nautilus VF ECMO Oxygenator, and VitalFlow Centrifugal Pump, and does not raise different questions of safety or effectiveness.