July 31, 2026

Medtronic, Inc.
Vinoda Palanisamy
Senior Regulatory Affairs Specialist
7611 Northland Dr.
Minneapolis, Minnesota 55428

Re: K261335
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: June 2, 2026
Received: June 3, 2026

Dear Vinoda Palanisamy:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Meaghan Erlewein -S

For 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261335

Please provide the device trade name(s).

VitalFlow Set with Balance™ Biosurface

Please provide your Indications for Use below.

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 when continued clinical deterioration is expected or the risk of death is imminent.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary of Safety and Effectiveness

June 2, 2026

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
Establishment Registration Number: 2184009

Contact Person: Vinoda Palanisamy
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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 Code: QJZ, QNR, BYS, QWF

Name of Predicate Device: VitalFlow Set with Balance™ Biosurface (K240880)

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.

Description of Change:

This Traditional 510(k) submission is limited to a filter membrane material change to the bidirectional oxygen filter included in the VitalFlow Sets with Balance™ Biosurface. The bidirectional oxygen filter is located in the gas pathway supplying the Nautilus VF Oxygenator and has indirect blood contact via the gas pathway, with no direct blood contact.

The change consists of replacing the existing filter membrane material containing perfluoroalkyl substances (PFAS) with a PFAS-free alternative. The filter housing, dimensions, design, placement within the gas pathway, filtration function, and operating principle remain unchanged.

Substantial Equivalence:

Substantial equivalence analysis includes comparison to the previously cleared VitalFlow Sets with Balance™ Biosurface (K240880). The VitalFlow Sets design, principles of operation, and fundamental scientific technology are substantially equivalent to the predicate device.

Comparison to Predicate:

A comparison of the VitalFlow Sets with Balance™ Biosurface incorporating the modified bidirectional oxygen filter to the predicate device (K240880) indicates the following similarities:

- Same intended use
- Same technological characteristics
- Same operating principle
- Same design features
- Same Shelf life
- Same materials for all components except for the filter membrane material of the bidirectional oxygen filter used in the gas pathway

When compared to the predicate device (K240880), the modified VitalFlow Sets presented in this submission have the following difference:

- Filter membrane material formulation (PFAS-free alternative)

Special Controls

The VitalFlow Sets with Balance™ Biosurface incorporating the modified bidirectional oxygen filter continue to meet all applicable special controls identified in 21 CFR 870.4100, consistent with the previously cleared configuration under K240880, as follows

- Technological Characteristics: No change. The geometry and configuration of the device remain consistent with the device's intended use in extracorporeal support procedures and 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: No change. 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 remains demonstrated on bench, mechanical integrity, durability, and reliability testing.
- Clinical Evidence of Performance: No change to clinical performance. The existing clinical evidence demonstrates acceptable performance of the device in ECMO patients.
- Labeling: No change. 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 Testing:

Biocompatibility:

According to ISO 10993-1:2018, The following component level biocompatibility testing was performed per ISO 18562 and demonstrated no new or increased biocompatibility risks.

- Particulate Matter (PM) Emissions
- Volatile Organic Compounds and Aldehydes Testing

Summary of Performance Data

Design verification activities were conducted to evaluate the bidirectional oxygen filter membrane material change. Component-level non-clinical testing, such as Gas Flow, Pressure Drop, and Filtration Performance was performed in accordance with ISO 29463 and IEST RP-CC007.4 (2023) to assess the impact of the material change on gas-path performance. The results demonstrate that the filter membrane material change does not adversely affect device performance.

Table 1 – Summary of Testing

Component	Material Change	Design Verification and Validation	Results
Bidirectional Oxygen filter	Filter membrane material of the bidirectional oxygen filter included in the VitalFlow Sets with Balance™ Biosurface has undergone a material change	Risk-based testing and evaluations to qualify this change included product functional testing and biocompatibility testing.	Pass

Conclusion:

The data included in this submission are sufficient to demonstrate that the VitalFlow Sets with Balance™ Biosurface incorporating the modified bidirectional oxygen filter are substantially equivalent to the predicate device, VitalFlow Sets with Balance™ Biosurface (K240880), and do not raise new questions of safety or effectiveness.