May 20, 2025

Medtronic Inc
Elizabeth Rose
Regulatory Affairs Contingent
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K250199
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: January 23, 2025
Received: April 25, 2025

Dear Elizabeth Rose:

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

Submission Number *(if known)*

K250199

Device Name

VitalFlow Console (58100)

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 of Safety and Effectiveness

Date Prepared: **May 20, 2025**

Applicant: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428

Establish Registration Number: 2184009

Contact Person: Elizabeth Rose
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Trade Name: VitalFlow Console

Common Name: Blood Pump for ECMO, Long-term (> 6 Hours) Use

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: **QNR**

Name of Predicate Device: VitalFlow Console (K230364, cleared August 25, 2023)

Device Description

The VitalFlow Console provides control of blood pumping through an extracorporeal circuit during extracorporeal membrane oxygenation (ECMO) procedures. The console powers the VitalFlow motor drive unit 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 are provided. Data download and data streaming from the console is available for ECMO circuit data only; no patient data is stored for output.

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 Handcrank.

Substantial Equivalence

Substantial equivalence analysis includes both comparison to the predicate device and clinically relevant reference devices. The VitalFlow Console (Upgrade Over USB) design, principles of operation, and fundamental scientific technology are substantially equivalent to the primary predicate device, VitalFlow Console (K230364).

Comparison to Predicate

A comparison of the VitalFlow Console (Upgrade Over USB) to the predicate device indicates the following similarities:

- Same intended use
- Similar technological characteristics
- Same operating principle
- Same performance characteristics
- Same design features
- Same materials
- Same packaging
- Same sterilization (non-sterile)

The predicate VitalFlow Console (K230364) uses the USB port to update the GUI software and export data logs only; no patient data is stored in the console. To update the MC, SC and FPGA on the predicate console it requires Medtronic service personnel to open the console, connect a laptop to each board, and updating the software for each as necessary.

The proposed change that is being implemented, VitalFlow Console (Upgrade Over USB), is a new feature for the VitalFlow Console that will enable software upgrades to be uploaded through the USB port. This enhancement will include updated software requirements along with necessary mitigation strategies related to the upgrade process and cybersecurity measures. The software can only be upgraded in the field by Medtronic service personnel using the USB port.

The VitalFlow Console (Upgrade Over USB) device meets all special controls identified in 21 CFR 870.4100, as follows:

- Technological Characteristics: The 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: N/A – the subject device is not patient contacting.
- Sterility and Shelf-life: N/A – the subject device is not a sterile or disposable device.
- Non-clinical Performance: Substantial equivalence of the performance characteristics is demonstrated through regression testing. The VitalFlow Console (Upgrade Over USB) continues to meet international standards for safety and has demonstrated effectiveness at maintaining the device performance.
- Labeling: Adequate instructions for the VitalFlow Console (Upgrade Over USB) are included with respect to installation, circuit setup, maintenance during a procedure, adverse effects, and performance characteristics relevant to compatibility among different device and accessories in the circuit. The Instructions for Use remain unchanged from the predicate submission K230364.

Summary of Performance Data

Software verification (which included Cybersecurity) was used to verify the performance characteristics of the subject device with the upgrade over USB change.

Conclusion

The data included in this submission are sufficient to demonstrate that the modified VitalFlow Console (Upgrade Over USB) is substantially equivalent to the predicate device, VitalFlow Console (K230364) and does not raise new or different questions of safety or effectiveness.