July 10, 2024

Medtronic Perfusion Systems
Megan Schlichting
Regulatory Affairs Manager
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K240666
Trade/Device Name: Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface (BB811); Affinity Fusion Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance Biosurface (BB841); Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface NON STERILE (BB811-NS)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: June 7, 2024
Received: June 7, 2024

Dear Megan Schlichting:

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Affinity FusionTM Oxygenator with Integrated Arterial Filter and BalanceTM Biosurface (BB811);
Affinity FusionTM Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with BalanceTM Biosurface (BB841);
Affinity FusionTM Oxygenator with Integrated Arterial Filter and BalanceTM Biosurface NON STERILE (BB811-NS)

Indications for Use *(Describe)*

Model BB811 and Model BB811-NS
The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.
The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Model BB841
Oxygenator with Integrated Arterial Filter
The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.
The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Cardiotomy/Venous Reservoir
The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.
The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement

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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12.0 510(k) Summary

Date Prepared: June 3, 2024

Submitter: Medtronic, Inc.

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

Contact Person: Megan Schlichting

Regulatory Affairs Manager
Medtronic Perfusion Systems
Phone: (763) 526-3087
Fax: (763) 514-9521
Email: megan.schlichting@medtronic.com

Alternate Contact: Kimberly Peterson

Regulatory Affairs Director
Medtronic Perfusion Systems
Phone: (763) 526-6751
Email: kimberly.m.peterson@medtronic.com

12.1 Device Name and Class

Model	Trade name	Common Name	Classification Name	Class	Class Classification Panel	Regulation (21 CFR)	Product Code
BB811	Affinity™ Fusion Oxygenator with Integrated Arterial Filter and Balance™ Biosurface	Oxygenator	Cardiopulmonary bypass oxygenator	Class II	Cardiovascular	870.4350	DTZ
BB841	Affinity™ Fusion Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface	Oxygenator	Cardiopulmonary bypass oxygenator and Cardiopulmonary bypass blood reservoir	Class II	Cardiovascular	870.4350 870.4260 870.4400	DTZ DTM DTN
BB811-NS	Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Balance™ Biosurface (Non-Sterile)	Oxygenator	Cardiopulmonary bypass oxygenator	Class II	Cardiovascular	870.4350	DTZ

12.2 Predicate Device Information

Trade Name	Affinity Fusion™ Oxygenator with Integrated Arterial Filter and Balance™ Biosurface (BB811) Affinity Fusion ™ Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance ™ Biosurface (BB841) Affinity Fusion ™ Oxygenator with Integrated Arterial Filter and Balance ™ Biosurface (Non-Sterile) (B811-NS)
510(k)	K230640
Concurrence Date	**April 6, 2023**

12.3 Device Description

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface (BB811), Affinity Fusion Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance Biosurface (BB841), and Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface (Non-Sterile) (B811-NS) are collectively referred to as the Affinity Fusion Oxygenator in the summary. The Affinity Fusion Oxygenator is intended to be used in an extracorporeal perfusion blood circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration. The Affinity Fusion Oxygenator contains both an integrated arterial filter and integrated heat exchanger. The Affinity Fusion Oxygenator is a microporous, hollow-fiber, gas-exchange devices available with Balance Biosurface bonded to the blood contacting surface of the device. The integrated arterial filter is designed to filter from the circuit microemboli larger than the specified micron size from the circuit for periods up to six hours during cardiopulmonary bypass surgery. Some models of the Affinity Fusion Oxygenator are packaged with an Affinity Fusion Cardiotomy/Venous Reservoir (CVR) with Balance Biosurface which is designed to be an integral part of a cardiopulmonary bypass circuit for use during cardiac surgery. The Affinity Fusion CVR is designed to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to six (6) hours in duration. Additionally, the Affinity Fusion CVR may be used during vacuum assisted venous drainage (VAVD) procedures and collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement during open heart surgery.

12.4 Principles of Operation

Affinity Oxygenators are designed to be an integral part of the cardiopulmonary heart bypass circuit for use during cardiac surgery. The Affinity Oxygenators are intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

The oxygenator is composed of the “fiber bundle” which is the gas exchange portion of an oxygenator. The “fiber bundle” is comprised of tiny hollow tubes, or “hollow fibers” that consist of a microporous membrane that allows for gas exchange. Blood flows over the outside surfaces of the hollow fibers while fresh gas is delivered to the inside of the fibers allowing for gas exchange.

Blood that comes from the patient is delivered through a pump to the oxygenator and other auxiliary devices, and back to the patient. The oxygenator can be connected to a heater/cooler device, recirculation circuit, cardioplegia circuit, and the main blood path. The oxygenator is under constant fluid pressure.

There is pressure exerted on the blood-side of the device from the blood pump and patient, the water side of the device due to the flow of the heater-cooler for water, and the gas-side of the device due to the flow of gases through the device. The water-side of the oxygenator is connected to a heater/cooler device to enable temperature control of the blood.

12.5 Indications for Use

Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance™ Biosurface (Model BB811 and BB811-NS)

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Affinity Fusion Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model BB841)

Oxygenator with Integrated Arterial Filter

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

The Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to six hours during cardiopulmonary bypass surgery.

Cardiotomy/Venous Reservoir

The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement.

12.6 Comparison to Predicate Device

A comparison of the modified product to the currently marketed predicate product Affinity Fusion Oxygenator (K230640) indicates the following similarities:

- Intended Use / Indications for use
- Contraindications
- Operating Principle
- Mechanism of action
- Performance
- Shelf Life
- Packaging configuration and materials
- Sterilization process and requirements

When compared to the predicate device, the Affinity Fusion Oxygenator devices presented in this submission have the following differences:

- addition of an alternate supplier of the hollow fiber for use in the oxygenator fiber bundle

The alternate hollow fiber was previously cleared for use in Medtronic Affinity NT Oxygenator (K191077).

Design verification and biocompatibility testing were completed, and they have led to the conclusion that no newly emerging hazards or risks were identified.

12.6.1 Design Verification testing

The proposed Affinity Fusion Oxygenator has been evaluated through testing to demonstrate that it meets the pressure integrity, burst, and other Special Controls requirements. Test results are presented in Table 12-1. Testing demonstrated results within specification, and therefore the Affinity Fusion Oxygenator manufactured with the hollow fiber supplied by the new supplier is deemed to be substantially equivalent to the predicate Affinity Fusion Oxygenator manufactured with the current hollow fiber supplier. Testing results demonstrate that the performance is comparable to the predicate Affinity Fusion Oxygenator devices (BB811, BB841, and BB811-NS) currently in market.

Table 12-1: Summary of Device Testing

Test Item	T=0	T=2yrAA	T=20 months RTA
O2 Transfer	**PASS**	**PASS**	**NA**
CO2 Transfer	**PASS**	**PASS**	**NA**
Blood Side Pressure Drop	**PASS**	**PASS**	**NA**
6 Hour O2 Transfer	**PASS**	**PASS**	**NA**

6 Hour CO2 Transfer	**PASS**	**PASS**	**NA**
Pressure Integrity	**PASS***	**PASS***	**NA**
Burst	**PASS**	**PASS**	**NA**
Gas Pathway Integrity	**NA**	**NA**	**PASS**
Plasma Breakthrough	**PASS**	**PASS**	**NA**
Filtration Efficiency	**PASS**	**PASS**	**NA**
Hemolysis (Max Flow)	**PASS**	**PASS**	**NA**
White Blood Cell Retention	**PASS**	**PASS**	**NA**
Platelet (PLT) retention	**PASS**	**PASS**	**NA**
Functional platelet retention	**PASS**	**PASS**	**NA**
Platelet PLT Function (min flow)	**PASS**	**PASS**	**NA**
Prime Volume	**PASS**	**PASS**	**NA**
Coverage	**PASS**	**PASS**	**NA**
Leaching	**PASS**	**PASS**	**NA**

*Devices conditioned only to factors significant for leaks (per Two Proportion statistical test)

12.6.2 Biocompatibility

Biocompatibility testing was performed in accordance with ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process. The Affinity Fusion Oxygenator is categorized as an external communicating device in contact with circulating blood for less than twenty-four (24) hours per ISO 10993-1:2018 and appropriate tests were selected. Test results are presented in Table 12-2. The results of the biological endpoint testing concluded that the Affinity Fusion Oxygenator with the alternate hollow fiber is non-cytotoxic, a non-sensitizer, a non-irritant, non-pyrogenic, non-hemolytic, non-genotoxic, and hemocompatible in regard to complement activation, partial thromboplastin time and platelet & leukocyte count.

Table 12-2: Summary of Biocompatibility Testing

Biocompatibility Test Method	Testing Category	Results
ISO MEM Elution Cytotoxicity, L929 Mouse Fibroblast Cells	Cytotoxicity	**PASS**
ISO Maximization Sensitization Study, 0.9%Sodium Chloride & Sesame Oil, NF extract	Sensitization	**PASS**
ISO Intracutaneous Study – 0.9%Sodium Chloride & Sesame Oil, NF extract	Intracutaneous Reactivity	**PASS**
ISO Systemic Toxicity Study - 0.9%Sodium Chloride & Sesame Oil, NF extract	Acute Systemic Toxicity	**PASS**
Pyrogen Study – Material Mediated -0.9%Sodium Chloride	Material Mediated Pyrogen Study – 0.9% Sodium Chloride	**PASS**
ASTM *In-vitro* Hemolysis, Rabbit Blood	Hemocompatibility	**PASS**
Complement Activation, SC5b-9, Human Serum	Hemocompatibility	**PASS**
ASTM Partial Thromboplastin Time, Direct Contact, Human Plasma	Hemocompatibility	**PASS**
Genotoxicity, Bacterial Reverse Mutation Study	Genotoxicity	**PASS**
Genotoxicity: Mouse Lymphoma Assay	Genotoxicity	**PASS**
Platelet and Leukocyte Count- with comparison article	Hemocompatibility	**PASS**

12.7 Conclusion

Medtronic has demonstrated through testing completed that the addition of a second hollow fiber supplier for the Affinity Fusion Oxygenator described in this summary results in a substantially equivalent device because fundamental scientific principle, operating principle, design features and intended use are unchanged.