Medtronic Inc.
Aj Thakkar
Sr. Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428
04/06/2023

Re: K230640
Trade/Device Name: Affinity Fusion™ Oxygenator System
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: March 7, 2023
Received: March 8, 2023

Dear Aj Thakkar:

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,

Kathleen M. Grunder -S

Digitally signed by Kathleen M. Grunder -S
Date: 2023.04.06 19:15:50 -04'00'

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

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

Indications for Use *(Describe)*
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.

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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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

Indications for Use *(Describe)*
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)

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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
Affinity Fusion Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface (Model CB811)

Indications for Use *(Describe)*
The Affinity Fusion oxygenator with integrated arterial filter and Cortiva bioactive surface 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 (CPB) procedures up to 6 hours in duration.

The Affinity Fusion oxygenator with integrated arterial filter and Cortiva bioactive surface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB surgery.

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)

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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
Affinity Fusion Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model CB841)

Indications for Use *(Describe)*
Oxygenator with Integrated Arterial Filter

The Affinity Fusion oxygenator with integrated arterial filter and Cortiva bioactive surface 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 (CPB) procedures up to 6 hours in duration.

The Affinity Fusion oxygenator with integrated arterial filter and Cortiva bioactive surface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB 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)

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K230640
510(k) Summary Complying with 21 CFR 807.92

510(k) Summary

Submitter

Date Prepared: March 7, 2023

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

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Device

Model Nos.	Trade Name	Common Name	Classification Name	Class	Classification Panel	Regulation (21 CFR)	Product Code
CB811	Affinity Fusion Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface	Oxygenator	Cardiopulmonary bypass oxygenator	Class II	Cardiovascular	870.4350 870.4260	DTZ DTM
CB841	Affinity Fusion Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface 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	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

Predicate Device

Trade Name	510(k)	Clearance Date
Affinity Fusion Oxygenator	K203111	September 16, 2021

No reference devices were used in this submission.

Device Description

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 Cortiva BioActive Surface or 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.

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.

Indications for Use

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

Affinity Fusion Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface (Model CB811)
The Affinity Fusion oxygenator with integrated arterial filter and Cortiva bioactive surface 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 (CPB) procedures up to 6 hours in duration.
The Affinity Fusion oxygenator with integrated arterial filter and Cortiva bioactive surface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB surgery.

K230640
510(k) Summary Complying with 21 CFR 807.92

Affinity Fusion Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model CB841)

Oxygenator with Integrated Arterial Filter
The Affinity Fusion oxygenator with integrated arterial filter and Cortiva bioactive surface 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 (CPB) procedures up to 6 hours in duration.
The Affinity Fusion oxygenator with integrated arterial filter and Cortiva bioactive surface is designed to filter from the circuit microemboli larger than the specified micron size for periods up to 6 hours during CPB 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.

Comparison of Technological Characteristics with the Predicate Device
A comparison of the modified product to the currently marketed predicate products (K203111) 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
- Did not require clinical data to verify safety and efficacy

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

- Temperature Monitoring Adapter (TMA) insert component material and insertion depth

Performance Data
Operation and performance qualification, biocompatibility rationale and the design characterization activities were completed, and they have led to the conclusion that no newly emerging hazards or risks were identified.

Operation Qualification and Performance Qualification (OQ/PQ)
Operation qualification and performance qualification was carried out to provide objective evidence that the manufacturing process consistently produces product that meets predetermined requirements under challenge and normal operating conditions respectively, including pressure integrity, burst, torque and insertion depth testing.

Design Characterization
The bond between the new material and adhesive was evaluated utilizing the interfacial surface, geometry, material and adhesive compatibility. This evaluation indicated improved bond performance relative to the current material. The PQ torque data for the new TMA serves as an approximation of the long-term shelf-life performance of the TMA bond.

Biocompatibility Assessment
A biocompatibility assessment was carried out to demonstrate that new material, which is currently used in the Affinity Pixie CVR Oxygenator, is biocompatible per the ISO 10993 standard and does not require new biocompatibility testing. The unique interaction of the new material with the adhesive is non-patient contacting. The new TMA creates a seal preventing contact with the circulating blood volume, and this interference fit has been verified through the part specifications, along with random sampling and statistical modeling.

Conclusion
Medtronic has demonstrated through testing completed that the modifications made to the Affinity Fusion Oxygenator System described in this submission result in a substantially equivalent device because the fundamental scientific principle, operating principle, design features and intended use are unchanged from the predicate device.