September 16, 2021

Medtronic, Inc.
Kaitlin Cady
Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K203111

Trade/Device Name: Affinity Fusion Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface (Model CB811), Affinity Fusion Oxygenator with Integrated Arterial Filter and Cortiva™ BioActive Surface and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model CB841), Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface (Model BB811), Affinity Fusion Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance Biosurface (Model BB841), Affinity Pixie Oxygenator with Cortiva BioActive Surface (Model CBP211), Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Cortiva BioActive Surface (Model CBP241), Affinity Pixie Oxygenator with Balance Biosurface (Model BBP211), Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface (Model BBP241)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: August 9, 2021
Received: August 10, 2021

Dear Kaitlin Cady:

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,

for Nicole Gillette
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known):*
K203111

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known):*
K203111

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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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known):*
K203111

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)

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510(k) Number *(if known):*
K203111

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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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known):*
K203111

Device Name
Affinity Pixie Oxygenator with Cortiva BioActive Surface (Model CBP211)

Indications for Use *(Describe)*
The Affinity Pixie hollow fiber oxygenator with Cortiva bioactive surface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass (CPB) procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie hollow fiber oxygenator 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 CPB procedures up to 6 hours in duration.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known):*
K203111

Device Name
Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Cortiva BioActive Surface (Model CBP241)

Indications for Use *(Describe)*
The Affinity Pixie hollow fiber oxygenator and cardiotomy/venous reservoir with Cortiva bioactive surface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass (CPB) procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie hollow fiber oxygenator 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 CPB procedures up to 6 hours in duration.

The Affinity Pixie cardiotomy/venous reservoir 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.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known):*
K203111

Device Name
Affinity Pixie Oxygenator with Balance Biosurface (Model BBP211)

Indications for Use *(Describe)*
The Affinity Pixie Hollow Fiber Oxygenator with Balance Biosurface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie Hollow Fiber Oxygenator 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.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known):*
K203111

Device Name
Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface (Model BBP241)

Indications for Use *(Describe)*
The Affinity Pixie Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie Hollow Fiber Oxygenator 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 Pixie Cardiotomy/Venous Reservoir 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.

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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510(k) Summary

Date Prepared: September 16, 2021

Submitter: Medtronic, Inc.
Medtronic Perfusion Systems
7611 Northland Dr North
Brooklyn Park, MN 55428
Establishment Registration Number: 2184009

Contact Person: Kaitlin Cady
Regulatory Affairs Specialist
Medtronic Cardiac Surgery
Phone : 763.526.0278
Email : kaitlin.cady@medtronic.com

Alternate Contact : Wendy Pinor
Principal Regulatory Affairs Specialist
Medtronic Cardiac Surgery
Phone : 763.526.3309
Email : wendy.pinor@medtronic.com

Device Name and Classification

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

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

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

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

Affinity Pixie Oxygenator with Cortiva BioActive Surface (Model CBP211)

Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Cortiva BioActive Surface (Model CBP241)

Affinity Pixie Oxygenator with Balance Biosurface (Model BBP211)

Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface (Model BBP241)

Common Name: Oxygenator

Regulation Number: 21 CFR 870.4350

Product Code: DTZ

Product Classification: II

Name of Predicate Device
K183490 Affinity Fusion Oxygenator
K183511 Affinity Pixie Oxygenation System

Device Description

Affinity Fusion Oxygenator
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.

Affinity Pixie Oxygenator

The Affinity Pixie 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 (CPB) procedures up to 6 hours in duration.

The Affinity Pixie hollow fiber oxygenator is a single-use, microporous, hollow-fiber, gas exchange device with plasma-resistant fiber and integrated heat exchanger. The primary blood-contacting surfaces of the oxygenator are coated with either Balance Biosurface or Cortiva BioActive Surface.

Some models are packaged with an Affinity Pixie Cardiotomy/Venous Reservoir (CVR) which are designed to be an integral part of a cardiopulmonary bypass circuit for use during cardiac surgery. The Pixie CVR associated with the Balance or Cortiva coated Oxygenators are also Balance or Cortiva coated respectively. The Affinity Pixie CVR is designed to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to six (6) hours in duration. Additionally, the Affinity Pixie CVR may be used during vacuum assisted venous drainage (VAVD) procedures.

All are provided sterile, nonpyrogenic, and for single use.

Indications for Use

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.

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.

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 Pixie Oxygenator with Cortiva BioActive Surface (Model CBP211)

The Affinity Pixie hollow fiber oxygenator and cardiotomy/venous reservoir with Cortiva bioactive surface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass (CPB) procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie hollow fiber oxygenator 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 CPB procedures up to 6 hours in duration.

Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Cortiva BioActive Surface (Model CBP241)

The Affinity Pixie hollow fiber oxygenator and cardiotomy/venous reservoir with Cortiva bioactive surface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass (CPB) procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie hollow fiber oxygenator 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 CPB procedures up to 6 hours in duration.

The Affinity Pixie cardiotomy/venous reservoir 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.

Affinity Pixie Oxygenator with Balance Biosurface (Model BBP211)

The Affinity Pixie Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie Hollow Fiber Oxygenator 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.

Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface (Model BBP241)

The Affinity Pixie Hollow Fiber Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface are indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass procedures requiring a blood flow rate up to 2.0 L/min.

The Affinity Pixie Hollow Fiber Oxygenator 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 Pixie Cardiotomy/Venous Reservoir 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.

Comparison to Predicate Devices

A comparison of the modified product to the currently marketed predicate products (K183490, K183511) indicates the following similarities:

- Intended Use
- Technological Characteristics
- Operating Principle
- Design Features
- Base Materials
- Shelf Life

The purpose of this submission is a modification to use an alternative resin used to mold the temperature monitor adapter component of the oxygenator used on both the Medtronic Affinity Fusion and Pixie Oxygenator product lines. Biocompatibility and design verification testing were submitted to demonstrate that the proposed modifications are similar to the predicate device.

Conclusion

Medtronic has demonstrated that the modifications made to the Affinity Fusion Oxygenator System and the Affinity Pixie Oxygenation System product family 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 devices.