November 20, 2017

Medtronic, Inc.
Lisa Stone
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K172984
Trade/Device Name: Affinity Pixie Oxygenator with Balance Biosurface (Model BBP211), Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface (Model BBP241), Affinity Pixie Oxygenator with Cortiva BioActive Surface (Model CBP211), Affinity Pixie Oxygenator and Cardiotomy/Venous Reservoir with Cortiva BioActive Surface (Model CBP241)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass (CPB) Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DTN, JOD
Dated: September 25, 2017
Received: September 27, 2017

Dear Lisa Stone:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 G. Ibrahim -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172984

Device Name

Affinity Pixie Oxygenator with Balance Biosurface (Model BBP211)

Indications for Use *(Describe)*

The Affinity Pixie hollow fiber oxygenator with Balance biosurface is indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass (CPB) procedures requiring a blood flow rate up to 2.0 Lmin.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172984

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 (CPB) procedures requiring a blood flow rate up to 2.0 Lmin.

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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Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172984

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 is indicated for use for neonate, infant, and small pediatric patients undergoing cardiopulmonary bypass (CPB) procedures requiring a blood flow rate up to 2.0 Lmin.

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172984

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 Lmin.

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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5 510(K) SUMMARY

Date Prepared:	September 25, 2017
Submitter's Name and Address:	Medtronic, Inc. Medtronic Perfusion Systems 8200 Coral Sea Street NE Mounds View, MN 55112 Establishment Registration Number: 2184009
Contact Person:	Lisa J. Stone, RAC Principal Regulatory Affairs Specialist Medtronic Perfusion Systems Phone: (763) 514-9866 Email: lisa.j.stone@medtronic.com
Alternate Contact:	Jake Roeller Senior Regulatory Affairs Manager Medtronic Perfusion Systems Phone: (763) 526-0404 Email: jake.w.roeller@medtronic.com
Proprietary Name:	Affinity Pixie™ Oxygenator with Balance™ Biosurface (Model BBP211) Affinity Pixie™ Oxygenator and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model BBP241) Affinity Pixie™ Oxygenator with Cortiva™ BioActive Surface (Model CBP211) Affinity Pixie™ Oxygenator and Cardiotomy/Venous Reservoir with Cortiva™ BioActive Surface (Model CBP241)
Common Name:	Oxygenator
Classification Name:	Cardiopulmonary Bypass Oxygenator

Classification:	Classification: Class II Panel: Cardiovascular Regulation: 21 CFR 870.4350 Product Code: DTZ
Predicate Device:	Affinity Pixie™ Oxygenator with Balance™ Biosurface (Model BBP211) – K100645 Affinity Pixie™ Oxygenator and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model BBP241) – K100645 and K141233 Affinity Pixie™ Oxygenator with Cortiva™ BioActive Surface (Model CBP211) – K100645 Affinity Pixie™ Oxygenator and Cardiotomy/Venous Reservoir with Cortiva™ BioActive Surface (Model CBP241) – K100645 and K141233

Device Description

The Affinity Pixie Oxygenators are microporous, hollow-fiber, gas-exchange devices available with Cortiva BioActive Surface or Balance Biosurface bonded blood contacting surface. The oxygenator is used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool and warm the blood during routine cardiopulmonary bypass procedures up to six (6) hours in duration. The oxygenator has a low prime volume which is appropriate for use in neonate, infant and small pediatric patients.

The Affinity Pixie Cardiotomy/Venous Reservoir (CVR) with Cortiva BioActive Surface or Balance Biosurface is a single use device 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 and collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement during open heart surgery. The CVR allows a lower operating volume which is appropriate for use in neonate, infant and small pediatric patients.

The oxygenator can be connected to a heater/cooler device, recirculation circuit, cardioplegia circuit, and the main blood path. These connections are made with tubing connected to barbed or

luer ports. 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 three compartments (blood-side, water-side and gas-side) must not leak into one another for the oxygenator to function properly.

The water-side of the oxygenator is connected to a heater/cooler device to enable temperature control of the blood. To prevent microbial growth within the heater/cooler, some manufacturers specify the addition of disinfectants to the heater/cooler water. During operation, the water path of the polyethylene terephthalate (PET) heat exchanger is exposed to these disinfectants.

The purpose of this 510(k) Notification is to notify the FDA of a change to allow for the use of hydrogen peroxide (330 ppm) in the water path of the oxygenator. There are no actual changes to the oxygenators.

Indications for Use

There is no change to the intended use of the devices within the scope of the proposed change in this 510(k) Notification. The current Indications for Use statement for each device model are noted below:

Affinity Pixie Oxygenator with Balance Biosurface (Model BBP211)

The Affinity Pixie hollow fiber oxygenator with Balance biosurface is 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 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 (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 Cortiva BioActive Surface (Model CBP211)

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.

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.

Comparison to Predicate Devices

When compared to the predicate devices, the Affinity Pixie Oxygenators are substantially equivalent. The oxygenators within scope of this 510(k) Notification have the following similarities:

- Same intended use
- Same operating principle
- Same fundamental technological characteristics

- Same design, dimensions and performance
- Same device materials
- Same packaging materials and design
- Same sterilization requirements

Summary of Performance Data

While these devices are subject to special controls, most of the special control requirements are not applicable for this proposed change. During use, the water path of the heat exchanger is the only part of the oxygenator that is exposed to a disinfectant. Because of this, it is not necessary to repeat all recommended testing by the specified special control guidance documents. It is however necessary to conduct testing to verify the chemical disinfectant has no adverse effects on the oxygenator water path. The following testing and analysis was performed:

- Heat Exchanger Product Material Compatibility with Hydrogen Peroxide
- Structural Integrity Testing (pressure integrity, burst and port break tests)
- Toxicological Risk Assessment for Hydrogen Peroxide
- Heat Exchanger Permeability Testing

Conclusion

In conclusion, the information provided within this submission demonstrates the Affinity Pixie Oxygenators with/without Cardiotomy/Venous Reservoir and Balance Biosurface or Cortiva BioActive Surface are substantially equivalent to the marketed predicate devices.