DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 21, 2016

Medtronic – Cardiac and Vascular Group
Renee Cveykus
Principal Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K162016
Trade/Device Name: Affinity NT Oxygenator with Cortiva™ Bioactive Surface
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR
Dated: July 20, 2016
Received: July 21, 2016

Dear Ms. Cveykus:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

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)*

K162016

Device Name

Affinity NT Oxygenator with Cortiva™ BioActive Surface

Indications for Use *(Describe)*

Model CB511:
The Affinity NT Oxygenator with 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 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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5.1 510(k) Summary

Date Prepared: July 19, 2016

Submitter:
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Proprietary Name:

Models	Description
CB511	Affinity NT Oxygenator with Cortiva™ BioActive Surface

Device Name and Classification:

Trade Name:	Affinity NT Oxygenator with Cortiva™ BioActive Surface
Common Name:	Oxygenator
Classification Name:	Cardiopulmonary bypass Oxygenator
Classification Panel:	Cardiovascular
Regulation Number:	21 CFR 870.4350
Product Code:	DTZ
Classification:	Class II

Predicate Device:

Medtronic Affinity NT Oxygenators (K143073)

Device Description

The device listed in this 510(k) Notification is a single use, non-toxic, non-pyrogenic, and is supplied sterile in packaging.

The Medtronic Affinity NT Oxygenator is a single use device designed to oxygenate and remove carbon dioxide from the blood and with the heat exchanger and arterial filter cools or warms the blood during extracorporeal circulation. The oxygenator has a blood contacting Cortiva™ [1] BioActive Surface.

The Affinity NT Hollow Fiber Oxygenator (Affinity NT 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 NT Oxygenator is designed to be an integral part of the cardiopulmonary heart lung bypass circuit for use during cardiac surgery. Blood that comes from the patient is delivered through a blood pump to the oxygenator and other auxiliary devices, and back to the patient.

The purpose of this 510(k) Notification is to notify the FDA of a labeling change to the disinfectant warning on the Instructions for Use to allow for disinfectant use in the water path of the oxygenator as well as report previous changes for the Affinity NT Oxygenator model included in this submission.

Indications for Use

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

The Affinity NT Oxygenator with Cortiva™ BioActive Surface is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to

[1] Note: Product Name changed from Affinity NT Oxygenator with Carmeda® BioActive Surface to Affinity NT Oxygenator with Cortiva™ BioActive Surface (Submitted to FDA in Add to File K143073/A002 dated June 15, 2016).

cool or warm the blood during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration.

Comparison to Predicate Devices

The Affinity NT Oxygenator has the same intended use, design and materials, and principles of operation and technology when compared to the predicate Affinity NT Oxygenator.

- Intended Use: The intended use is the same as the predicate device.
- Design: The design is the same as the predicate device.
- Materials: The materials of the Affinity NT Oxygenator are the same as the predicate device.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Performance: The performance of the device is the same as the predicate device.

Summary of Performance Data

Testing was used to verify the performance characteristics of this device. Clinical testing was not required to establish substantial equivalence. The following performance tests were conducted:

Testing	Description	Result
Pressure Integrity	Water path must withstand 45 PSI pressure for 6 hours without leaking	Pass
Burst	Water path burst testing should be comparable to that of the control devices	Pass
Port Break	Water path break force shall be comparable to that of the control device	Pass

An analysis was also completed to characterize the physical properties of the materials used to construct the water side of the heat exchanger.

Conclusion

Medtronic has demonstrated that the modification made to the Affinity NT Oxygenator with Cortiva™ BioActive Surface is substantially equivalent to the predicate devices based upon design, test results, and indications for use.