June 12, 2024

Medtronic Inc.
Kaitlin Cady
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K241352
Trade/Device Name: Affinity NT Oxygenator and Uncoated Cardiotomy/ Venous Reservoir (541); Affinity NT Oxygenator with Balance Biosurface and Uncoated Cardiotomy/Venous Reservoir (541B)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: May 13, 2024
Received: May 13, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 NT Oxygenator and Uncoated Cardiotomy/ Venous Reservoir (541);
Affinity NT Oxygenator with Balance Biosurface and Uncoated Cardiotomy/Venous Reservoir (541B)

Indications for Use *(Describe)*

Affinity NT Oxygenator and Uncoated Cardiotomy/ Venous Reservoir (541);
The AFFINITY NT Integrated CVR Membrane Oxygenator with Plasma Resistant Fiber is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

Indications for Use(541B)
The Affinity NT oxygenator with 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 (CPB) procedures up to 6 hours in duration.
The Affinity NT cardiotomy/venous reservoir (CVR) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned 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.**

# 510(k) Summary

**Date Prepared:** June 12, 2024

**Submitter:** Medtronic, Inc.

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

**Contact Person:** Kaitlin Cady

Sr. Regulatory Affairs Specialist
Medtronic Perfusion Systems
Phone: +1-763-291-8500
Email: kaitlin.cady@medtronic.com

**Alternate Contact:** Megan Schlichting

Regulatory Affairs Manager
Medtronic Perfusion Systems
Phone: +1-651-955-4743
Email: megan.schlichting@medtronic.com

## Device Name

| | |
|---|---|
| **Trade Name** | Affinity NT Oxygenator and Uncoated Cardiotomy/ Venous Reservoir (541)<br><br>Affinity NT Oxygenator with Balance Biosurface and Uncoated Cardiotomy/Venous Reservoir (541B) |
| **Common Name** | Oxygenator, Cardiopulmonary Bypass |

## Device Class

| | |
|---|---|
| **Classification** | II |
| **Regulation Number** | 21 CFR 870.4350 |
| **Classification Panel** | Cardiovascular |
| **Product Code** | DTZ |

## Predicate Device Information

| Model | Description | Predicate 510(k) |
|---|---|---|
| 541 | Affinity NT Oxygenator and Uncoated Cardiotomy/ Venous Reservoir | Reference K191029 |
| 541B | Affinity NT Oxygenator with Balance Biosurface and Uncoated Cardiotomy/Venous Reservoir | Primary Predicate K191444 |
| NOTE: For reference, the component 1140008-503, which is the subject of this special 510(k) is cleared under K240534 for use in Bio-Medicus Life Support Catheters and Introducers | | |

## Device Description

The Affinity NT Oxygenator with /without Balance Biosurface is a sterile membrane Oxygenator with plasma resistant fiber. It is a single-use gas exchange device with integral stainless-steel heat exchanger. Models 541 and 541B include a cardiotomy/venous reservoir.

The Luer cap 1140008-503 that is the 'subject' of this special 510(k) serve as protection of the Luer Access Port. This port can be used to prime the circuit or connect to another support device with a luer connector.

## Principle of Operation

The Affinity NT Oxygenator is a single use, microporous, hollow-fiber, gas exchange device with plasma-resistant fiber and integrated heat exchanger. The Affinity NT Oxygenator is designed to be an integral part of a cardiopulmonary heart lung bypass circuit. It is used to heat and cool the blood, transfer oxygen and carbon dioxide, monitor blood temperature, remove air, and filter small emboli from the patient's blood. The primary blood-contacting surfaces the 541B Affinty NT Oxygenator are coated with Balance Biosurface to reduce platelet activation and adhesion and preserve platelet function.

The attached Affinity NT uncoated cardiotomy/venous reservoir (CVR) is a single-use device designed to collect and store blood during extracorporeal circulation. Venous blood is collected and defoamed while cardiotomy blood is collected, defoamed, and filtered before mixing with the venous blood.

There is pressure exerted on the blood-side of the device from the blood pump and patient, and 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.

## Description of Change

The purpose of this Special 510(k) submission is to notify FDA of a change in luer cap from P/N 61399400171 to P/N 1140008-503. The proposed luer cap has a different material formulation and slight dimensional changes than the existing luer cap.

## Indications for Use (Model 541)

The AFFINITY NT Integrated CVR Membrane Oxygenator with Plasma Resistant Fiber is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood, cool or warm the blood and oxygenate and remove carbon dioxide from the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

## Contraindications (Model 541)

This device used for any other purposes than for the indicated intended use is the responsibility of the user.

## Indications for Use (Model 541B)

The Affinity NT oxygenator with 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 (CPB) procedures up to 6 hours in duration.

The Affinity NT cardiotomy/venous reservoir (CVR) is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine CPB procedures up to 6 hours in duration.

## Contraindications (Model 541B)

Use the device only as indicated.

## Comparison to Predicate Devices

The modified Affinity NT Oxygenator (541, 541B) has the following similarities to the predicate Affinity NT Oxygenator which previously received FDA clearance per Primary Predicate 510(k) K191444:

- Same intended use/indications for all devices in scope
- Same finished device operating principles for all devices in scope
- Same shelf life for all devices in scope
- Patient-contacting devices are packaged and sterilized using identical materials and processes
- Did not require clinical data to verify safety and efficacy
- Did not alter the sterilization process or reduce the sterilization requirements

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

- Material Formulation (same Polymer class material -polypropylene)
- Slight Dimensional differences leading to variation in torque.

In summary, based upon the examination of the comparison with the predicate devices, and the information presented in this submission demonstrates that the modified Affinity NT Oxygenator is substantially equivalent to the legally marketed predicate devices.

## Summary of Testing

### Biocompatibility:

According to ISO 10993-1:2018, Affinity NT Oxygenator is classified as externally communicating devices with circulating blood contact and limited duration (≤ 24 hours).

Biocompatibility assessment for use of the alternate luer cap on Bio-Medicus Life Support Catheters and Introducers (BMLS) cleared K240534 has been leveraged in this submission as BMLS is categorized as external communicating, circulating blood contact devices for prolonged duration (> 24 hrs to 30 days), which is a higher risk contact classification than that of NT Oxygenator. The BMLS is demonstrated to be biocompatible as a prolonged use device in accordance with ISO 10993-1:2018 and with FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" (8 September 2023).

### Verification and Validation:

A separate design assessment of the component was conducted including dimensional comparison, torque removal test and pressure integrity test which concluded that the slight dimensional difference between the current and the proposed luer cap has no impact on the final product functionality or performance.

**Table 1 – Summary of Verification and Validation testing**

| Component | Material Change | Design Verification and Validation | Results |
|---|---|---|---|
| Luer Cap | The luer cap used on access port of the NT Oxygenator models has undergone a supplier and material formulation change. | Risk-based testing and evaluations to qualify this change included product functional testing and biocompatibility assessment. | Pass |

## Conclusion

The information included in this submission demonstrates that the modified Affinity NT Oxygenators are substantially equivalent to the legally marketed predicate devices.