



May 17, 2019

Medtronic, Inc.
Sammie Joseph-Fredericks
Sr. Regulatory Affairs Specialist
7611 Northland Drive
Minneapolis, Minnesota 55428

Re: K191029

Trade/Device Name: Affinity NT™ Oxygenator (Model 511), Affinity® NT Hollow Fiber Oxygenator with Plasma Resistant Fiber (PRF) with Trillium™ Biosurface (Model 511T), Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541), Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541-R), Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T), Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T-R), Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Model 541TT), Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Model 541TT-R), Affinity NT™ Oxygenator with Cortiva™ BioActive Surface (Model CB511), Affinity NT™ Integrated Uncoated CVR/Oxygenator with Cortiva™ BioActive Surface (Model CB541)

Regulation Number: 21 CFR 870.4350

Regulation Name: Cardiopulmonary Bypass Oxygenator

Regulatory Class: Class II

Product Code: DTZ

Dated: April 17, 2019

Received: April 18, 2019

Dear Sammie Joseph-Fredericks:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,

for Nicole Ibrahim
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

Indications for Use

510(k) Number (if known)

K191029

Device Name

Affinity NT™ Oxygenator (Model 511)

Indications for Use (Describe)

The 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 (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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Indications for Use

510(k) Number (if known)

K191029

Device Name

Affinity® NT Hollow Fiber Oxygenator with Plasma Resistant Fiber (PRF) with Trillium™ Biosurface (Model 511T)

Indications for Use (Describe)

The Affinity® NT Hollow Fiber Oxygenator with Plasma Resistant Fiber (PRF) with Trillium™ 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.

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

510(k) Number (if known)

K191029

Device Name

Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541)

Indications for Use (Describe)

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.

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

510(k) Number (if known)

K191029

Device Name

Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541-R)

Indications for Use (Describe)

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.

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

510(k) Number (if known)

K191029

Device Name

Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T)

Indications for Use (Describe)

The Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface 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.

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

510(k) Number (if known)

K191029

Device Name

Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T-R)

Indications for Use (Describe)

The Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface 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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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Indications for Use

510(k) Number (if known)

K191029

Device Name

Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Model 541TT)

Indications for Use (Describe)

The Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator 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.

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

510(k) Number (if known)

K191029

Device Name

Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator (Model 541TT-R)

Indications for Use (Describe)

The Affinity® NT Integrated Trillium™ CVR/Membrane Oxygenator 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.

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

510(k) Number (if known)

K191029

Device Name

Affinity NT™ Oxygenator with Cortiva™ BioActive Surface (Model CB511)

Indications for Use (Describe)

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 (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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Indications for Use

510(k) Number (if known)

K191029

Device Name

Affinity NT™ Integrated Uncoated CVR/Oxygenator with Cortiva™ BioActive Surface (Model CB541)

Indications for Use (Describe)

The Affinity NT™ Integrated Uncoated CVR/Oxygenator with Cortiva™ BioActive Surface 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 (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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