DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 10, 2017

Medtronic, Inc.
Harsh Dharamshi
Regulatory Operations Specialist
8200 Coral Sea Street NE
Mounds View, MN 55112

Re: K162774
Trade/Device Name: MYOtherm XP™ Cardioplegia Delivery System with Cortiva™ BioActive Surface
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchanger
Regulatory Class: Class II
Product Code: DTR
Dated: January 25, 2017
Received: January 26, 2017

Dear Mr. Dharamshi:

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)*
K162774

Device Name
MYOtherm XP Cardioplegia Delivery System with Cortiva BioActive Surface

Indications for Use *(Describe)*

The MYOtherm XP with Cortiva bioactive surface is a device intended for the mixing, warming/cooling and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration. Blood/cardioplegia solution is delivered to the patient through the cardioplegia delivery system and appropriate cannula by the operation of a single occlusive roller pump.

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. 510(k) Summary of Safety and Effectiveness

**Date Prepared:** January 25, 2017

**Submitter:** Medtronic, Inc.

Medtronic Perfusion Systems
7611 Northland Drive
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Establishment Registration Number: 2184009

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**Common Name:** Heat-Exchanger, Cardiopulmonary Bypass.

Cardiopulmonary bypass heat exchanger.

**Trade Name:** MYOtherm XP™ Cardioplegia Delivery System with Cortiva™ BioActive Surface

**Classification:** Class II

**Panel:** Cardiovascular

**Regulation:** 21 CFR 870.4240

**Product Code:** DTR

**Predicate Device:**

K003724 MYOtherm XP Cardioplegia Delivery System with Carmeda BioActive Surface

## Device Description

The MYOtherm XP cardioplegia delivery system with Cortiva bioactive surface is comprised of polycarbonate housing and comes preconnected to tubing and connector components comprised of polycarbonate, polyvinyl chloride and plastisol materials and provided in Y-type, straight, reducer and tubing configurations. The MYOtherm XP cardioplegia delivery system with Cortiva bioactive surface is available with or without an additional optional bridge, which is a preconnected independent tubing line for the delivery of additional arterial blood without the mixing with cardioplegia solution. The blood contacting surfaces of the MYOtherm XP cardioplegia delivery system with Cortiva bioactive surface and associated tubing and connector components are coated with a heparin-based non-leaching thromboresistant surface.

## Description of Change

The proposed change is to allow the use of disinfectants in the water path. The Instructions for Use (IFU) for MYOtherm XP cardioplegia delivery system with Cortiva bioactive surface will be updated to allow disinfectant use (hydrogen peroxide) in the water path. The IFU warning will change as noted below:

Current Warning: Disinfectants must not be used in the heater/cooler system when the heat exchanger is in use; if disinfectants are used in the heater/cooler system prior to use, the system must be thoroughly flushed.

New Warning: Follow institution CPB protocol when using disinfectants in the heater/cooler during bypass. The integrity of the water path has been verified with hydrogen peroxide (330 ppm). Contact Medtronic for information regarding the use of additional disinfectants.

Along with the proposed IFU warning change, the "Indications for Use" statement is also being updated as noted in the section below to **(a)** add the last sentence in the indications for use statement, i.e. “Blood/cardioplegia solution is delivered to the patient through the cardioplegia delivery system and appropriate cannula by the operation of a single occlusive roller pump”, in order to be consistent with Uncoated and Trillium biosurface MYOtherm XP cardioplegia delivery systems. **(b)** add the 6 hour duration of use specification to the indications for use statement in order to be consistent with the testing and all other cardiopulmonary bypass (CBP) devices in the CPB circuit.

## Indications for Use

The MYOtherm XP with Cortiva bioactive surface is a device intended for the mixing, warming/cooling and delivery of oxygenated blood/cardioplegia solution in a predetermined ratio during routine cardiopulmonary bypass (CPB) procedures up to 6 hours in duration. Blood/cardioplegia solution is delivered to the patient through the cardioplegia delivery system and appropriate cannula by the operation of a single occlusive roller pump.

## Contraindications

Use the device only as indicated.

## Comparison to Predicate Devices

When compared to predicate device K003724, the Medtronic MYOtherm XP cardioplegia delivery system with Cortiva bioactive surface presented in this submission have the same:

- Same Intended Use
- Same Technological characteristics and Operating principle
- Same Design Features
- Same Performance
- Same Base Materials
- Same Shelf Life

## Summary of Testing

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 |

## Conclusion

The data included in this submission is sufficient to demonstrate substantial equivalence of the subject device with proposed labeling change to the marketed predicate devices.