February 23, 2024

Medtronic
Kaitlin Cady
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55040

Re: K240190
Trade/Device Name: MYOtherm XP™ Cardioplegia Delivery System with Cortiva™ BioActive Surface, MYOtherm XP™ Cardioplegia Delivery System Uncoated
Regulation Number: 21 CFR 870.4240
Regulation Name: Cardiopulmonary Bypass Heat Exchanger
Regulatory Class: Class II
Product Code: DTR
Dated: January 17, 2024
Received: January 24, 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)*

K240190

Device Name

MYOtherm XP™ Cardioplegia Delivery System with Cortiva™ BioActive Surface

MYOtherm XP™ Cardioplegia Delivery System Uncoated

Indications for Use *(Describe)*

MYOtherm XP™ Cardioplegia Delivery System with Cortiva™ BioActive Surface_Models CBXP41, CBXP41B, A10378001

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.

MYOtherm XP™ Cardioplegia Delivery System Uncoated_Models XP41, XP41B, 61399405409

The MYOtherm XP cardioplegia delivery system 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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13.0 Attachment 13 - 510(k) Summary

Date Prepared: JAN 17, 2024

Submitter: Medtronic, Inc.

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Establishment Registration Number: 2184009

Contact Person: Kaitlin Cady

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Device Name

Trade Names	MYOtherm XP™ Cardioplegia Delivery System with Cortiva™ BioActive Surface MYOtherm XP™ Cardioplegia Delivery System Uncoated
Common Name	Heat-Exchanger, Cardiopulmonary Bypass. Cardiopulmonary bypass heat exchanger.

Device Class

Classification	II
Regulation Number	21 CFR 870.4240
Classification Panel	Cardiovascular
Product Code	DTR

Predicate Device Information

Model	Description	Predicate 510(k)
CBXP41	MYOtherm XP Cardioplegia Delivery System with Cortiva BioActive Surface	K162774
CBXP41B	MYOtherm XP Cardioplegia Delivery System with Cortiva BioActive Surface with Bridge	
A10378001	Non-Sterile MYOtherm XP™ with Cortiva™ BioActive Surface for inclusion in procedure packs (CB MYOTHERM INCONEL)	K171979
XP41	MYOtherm XP Cardioplegia Delivery System Uncoated	K162958
XP41B	MYOtherm XP Cardioplegia Delivery System with Bridge	
61399405409	Non-Sterile MYOtherm XP Cardioplegia Delivery System	K171979
NOTE: The component 61399405213 (CONNECTOR - MALE TO MALE LUER), which is the subject of this special 510(k) is a cleared component under Tubing Pack 510(k) – Reference 510(k) K171979.		

Device Description

The Cortiva coated and Uncoated MYOtherm XP™ Cardioplegia Delivery System is designed to mix arterial blood from an oxygenator with sanguineous cardioplegia solution in specific ratios, depending upon the system chosen. The patient delivery line is packaged separately to allow for ease of sterile transfer to the operative field prior to connection to the delivery outlet of the cardioplegia system. A pressure monitoring line, three-way stopcock, and gauge protector, as well as a pressure relief line with pressure relief valve are preconnected.

The Cortiva coating is a BioActive Surface that is non-leaching and provides thromboresistant blood contact surface. The A10378001, CBXP41 and the CBXP41B MYOtherm Cardioplegia Delivery Systems are identical except for the bypass loop. The XP41B and CBXP41B contains a bridge between the blood and crystalloid line allowing the physician to deliver 100% blood, if needed.

The male-to-male Luer connector component 61399405213 that is the 'subject' of this special 510(k) connects with MYOtherm via a pressure relief valve and tubing. 61399405213 gets connected to a pressure relief valve on one end, and a cap on the other end. A perfusionist can remove the cap to connect a PVC tubing of choice, during Cardioplegia intervention.

Principle of Operation

MYOtherm XP is designed to be an integral part of the cardiopulmonary bypass (CPB) circuit. It is used to mix, warm/cool and deliver oxygenated blood/ cardioplegia solution in a predetermined ratio. MYOtherm XP is connected to a heater-cooler unit, recirculation water circuit, cardio circuit, and the main blood path. These connections are made with tubing connected to barbed or luer ports. There is pressure exerted on the blood-side of the device from the blood pump, and the water-side of the device due to the flow of the heater-cooler for water.

The male-to-male luer connector which is the 'subject' of this special 510(k) is used to deliver cardioplegia solution to an extracorporeal circuit with duration of use up to six hours.

Description of Change

The purpose of this Special 510(k) submission is to notify FDA of a polycarbonate resin change to the connector component 61399405213 (Connector – Male to Male Luer).

The base material resin used in the subject component constitutes of polycarbonate resin, tint package and lubricant. The tint package and lubricant within the resin are changing. There is no change to the base polycarbonate resin.

Indications for Use

MYOtherm XP with Cortiva BioActive Surface (CBXP41, CBXP41B, A10378001):

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.

MYOtherm XP Cardioplegia Delivery Systems (XP41, XP41B, 61399405409);

The MYOtherm XP cardioplegia delivery system 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

The device used for any other purposes than for the indicated use is the responsibility of the user. Use the device only as indicated.

Comparison to Predicate Devices

The modified MYOtherm XP Cardioplegia Delivery System (which includes the subject connector component built with new resin formulation) have the following similarities to the predicate devices which previously received FDA clearance per K162958, K162774 and reference Tubing Pack 510(k) – K171979.

- 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 MYOtherm XP Cardioplegia Delivery System (which includes the subject connector component built with new resin formulation) presented in this submission have the following resin differences:

Ingredient	Current Resin Formulation	Proposed Resin Formulation
Mold Release Agent Source	Animal based	Plant based
Dye A	Yes, < 15 ppm	Not Present
Dye B	Yes, < 2 ppm	Same, no change here.
Dye C	Not Present	Yes, < 2 ppm

In summary, based upon the examination of the comparison with the predicate devices, and the information presented in this submission demonstrates that the modified MYOtherm XP Cardioplegia Delivery System (which includes the subject connector component built with new resin formulation) is substantially equivalent to the legally marketed predicate devices.

Summary of Testing

Biocompatibility testing was performed on the modified MYOtherm XP Cardioplegia Delivery System. The samples built for the testing included the connector component with proposed resin formulation. The Biocompatibility results summarized in table below demonstrate that modified MYOtherm XP Cardioplegia Delivery System (which includes the subject connector component built with new resin formulation) met acceptance criteria and that the biocompatibility test data satisfies all biological endpoints to be addressed for subject device with passing results.

Biological Endpoint / Extraction Condition	Result
ISO MEM Elution Cytotoxicity / 1x MEM with 5% serum, 2% antibiotics, and 1% L-glutamine at 37°C for 24hrs	Pass
Guinea Pig Maximization Sensitization / Normal Saline and Sesame Oil at 50°C for 72hrs	Pass
Intracutaneous Reactivity / Normal Saline and Sesame Oil at 50°C for 72hrs	Pass
In Vitro Skin Irritation / Phosphate Buffered Saline and Sesame Oil at 50°C for 72hrs	Pass
Acute Systemic Toxicity / Normal Saline and Sesame Oil at 50°C for 72hrs	Pass
Material-mediated Pyrogenicity / Sterile, Non-Pyrogenic 0.9% Normal Saline at 50°C for 72hrs	Pass
Hemolysis (extract and direct) / Calcium and Magnesium Free Phosphate Buffered Saline (CMF-PBS) at 50°C for 72hrs (extract) and at 37C for 3hrs (direct)	Pass
Complement Activation SC5b-9 / Normal Human Serum at 37°C for 60min	Pass
ASTM Partial Thromboplastin Time (PTT) / Human Plasma at 37°C for 15min	Pass

Biological Endpoint / Extraction Condition	Result
Platelet and Leukocyte Count / Pooled Whole Human Blood at 37°C for 60min	Pass

A separate design assessment was conducted which concluded that the change has no impact on the final product functionality or performance and as a result, no design verification or validation testing is warranted.

Conclusion

In conclusion, the information included in this submission demonstrates that the modified MYOtherm XP Cardioplegia Delivery System (which includes the subject connector component built with new resin formulation), are substantially equivalent to the legally marketed predicate devices.