May 15, 2024

Medtronic Cardiac Surgery
Yidi Hou
Senior Regulatory Affairs Specialist
8200 Coral Sea Street NE
Mounds View, Minnesota 55112

Re: K241053
Trade/Device Name: MVR™ Venous Reservoir Bag 800 mL; MVR™ Venous Reservoir Bag 1600 mL; MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 800 mL; MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 1600 mL
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary bypass blood reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: April 17, 2024
Received: April 17, 2024

Dear Yidi Hou:

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

MVR™ Venous Reservoir Bag 800 mL
MVR™ Venous Reservoir Bag 1600 mL
MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 800 mL
MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 1600 mL

Indications for Use *(Describe)*

MVR™ Venous Reservoir Bag, with or without Cortiva™ BioActive Surface_Models MVR800, MVR1600, CBMVR800, CBMVR1600

The MVR Venous Reservoir Bag is indicated for use during cardiopulmonary bypass surgery in an extracorporeal circuit utilizing a membrane oxygenator for up to 6 hours in duration. The MVR Holder (Model MVR-SH) is indicated for use with the MVR Collapsible Venous Reservoir Bag.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Attachment 13 - 510(k) Summary

Date Prepared: May 15, 2024

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

Contact Person: Yidi Hou
Sr. Regulatory Affairs Specialist
Medtronic Perfusion Systems
Phone: +16513990486
Email: yidi.hou@medtronic.com

Alternate Contact: Megan Schlichting
Regulatory Affairs Manager
Medtronic Perfusion Systems
Phone: +16519554743
Email: megan.schlichting@medtronic.com

Device Name

Trade Name	MVR™ Venous Reservoir Bag 800 mL MVR™ Venous Reservoir Bag 1600 mL MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 800 mL MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 1600 mL
Common Name	Cardiopulmonary bypass blood reservoir. Collapsible venous reservoir bag.

Device Class

Classification	II
Regulation Number	21 CFR 870.4400
Classification Panel	Cardiovascular
Product Code	DTN

Predicate Device Information

Model	Description	Predicate 510(k)
MVR800	MVR™ Venous Reservoir Bag 800 mL	K920774
MVR1600	MVR™ Venous Reservoir Bag 1600 mL	
CBMVR800	MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 800 mL	
CBMVR1600	MVR™ Venous Reservoir Bag with Cortiva™ BioActive Surface 1600 mL	

Device Description

The MVR Venous Reservoir Bag, with or without Cortiva bioactive surface, is a single-use, sterile, nonpyrogenic variable volume device used in conjunction with a membrane oxygenator during cardiopulmonary bypass (CPB) surgery. It is sterilized using ethylene oxide. It is designed to accommodate blood from the patient and suctioned blood from the cardiotomy reservoir. The internal screen of the venous reservoir is designed to assist in tramping air, which may enter the venous reservoir during priming or perfusion on the inlet side of the reservoir. Air trapped in the venous reservoir bag can be removed using the one-way stopcock located at the top of the reservoir.

Blood that comes from the patient flows into the reservoir and is delivered through a pump to the oxygenator and other axillary devices, and back to the patient. The oxygenator can be connected to a heater/cooler device, recirculation circuit, cardioplegia circuit, and the main blood path.

Products coated with Cortiva bioactive surface include a "CB" prefix in the model number. The primary blood-contacting surfaces of the product are coated with Cortiva bioactive surface. This coated surface enhances blood compatibility and provides a blood-contacting surface that is thromboresistant. Cortiva bioactive surface contains nonleaching heparin derived from porcine intestinal mucosa.

Principle of Operation

The MVR Venous Reservoir Bag is designed to be part of a cardiopulmonary heart lung bypass circuit. It is used to accommodate blood from the patient and suctioned blood from the cardiotomy reservoir, allows for blood temperature monitoring, and remove air from the patient's blood.

The MVR Venous Reservoir Bag is connected to cannula, suckers, vents, and other auxiliary devices to collect and filter blood from the patient, which is then delivered through a pump to an oxygenator, arterial filter or other auxiliary devices, and back to the patient. The internal screen of the Venous Reservoir Bag is designed to assist in trapping air, which may enter the venous

reservoir during priming or perfusion on the inlet side of the reservoir. Air trapped in the Venous Reservoir Bag can be removed using the one-way stopcock located at the top of the reservoir.

In the perfusion circuit, blood travels from the Venous Reservoir Bag to a pump, an oxygenator and then an arterial filter. The oxygenator transfers oxygen to the blood to support the patient's metabolic load. It also removes carbon dioxide, a product of metabolism, from the patient's blood so that the carbon dioxide levels are normal once the blood is returned to the patient.

Indications for Use

The MVR Venous Reservoir Bag is indicated for use during cardiopulmonary bypass surgery in an extracorporeal circuit utilizing a membrane oxygenator for up to 6 hours in duration. The MVR Holder (Model MVR-SH) is indicated for use with the MVR Collapsible Venous Reservoir Bag.

Contraindications

Use the device only as indicated.

Comparison to Predicate Devices

The modified MVR Venous Reservoir Bag (which includes the subject one-way stopcock component built with the same resin with an addition of a colorant) have the following similarities to the predicate device which previously received FDA clearance per K920774.

- 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
- Blood-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 device, the modified MVR Venous Reservoir Bag (which includes the subject one-way stopcock component built with the same resin with an addition of a colorant) presented in this submission have the following resin differences:

Materials within Stopcock	Current Formulation	Proposed Formulation
Stopcock Housing	100% Makrolon 3158 550115 Polycarbonate Resin Clear	96% Makrolon 3158 550115 Polycarbonate Resin Clear + 4% Teknor, 41,988WCPC BLUE Concentrate Polycarbonate
Stopcock Diverter	100% INEOC HDPE, T60-800-119 Natural White	100% INEOC HDPE, T60-800-119 Natural White
Lubricant	Dow Corning 360 Medical Fluid 350	Dow Corning 360 Medical Fluid 350

In summary, based upon the examination of the comparison with the predicate devices, and the information presented in this submission demonstrates that the modified MVR Venous Reservoir Bag (which includes the subject one-way stopcock component built with the same resin with an addition of a colorant) is substantially equivalent to the legally marketed predicate devices.

Summary of Testing

Biocompatibility evaluation has been performed to support evaluation of one-way stopcock component (M946844A001 – Female Luer to Male Luer with 2 Arrow Diverter) used with the MVR Venous Reservoir Bag after a material change in accordance with ISO 10993 and USA FDA Guidance Document on Use of ISO 10993-1.

The proposed one-way stopcock is used within Medtronic Surgical Innovations product, the Step™ Auto Suture™ Dilator and Cannula with Radially Expandable Sleeve 12mm / REF S101012. The Step™ Auto Suture™ Dilator and Cannula is used as the reference device in the biocompatibility evaluation since it is an external communicating device with limited tissue/bone contact and has undergone/passed cytotoxicity, sensitization, irritation (in vivo and in vitro), material-mediated pyrogenicity, and acute systemic toxicity testing. Since the one-way stopcock supplier, colorant, and sterilization process remain consistent for both the subject component and the reference component, the biocompatibility test data from the reference device component (Step™ Auto Suture™ Dilator and Cannula) can be applied to the subject device component (one-way stopcock of MVR® Venous Reservoir Bags). The identical contact duration ensures the consistent biocompatibility test methodology for shared tests between the subject device component and the reference device component, enabling the utilization of test data from the reference device for relevant biological endpoints.

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

The supplier provided certificate of regulatory compliance for material used in the one-way stopcock, which stated *"an identical formulation of resin with higher levels of additives and colorants was used to determine biocompatibility according to ISO 10993-1 and USP class VI. Tests conducted in accordance with 'Good Laboratory Practice' include: USP Class VI Evaluation, USP Systemic Toxicity Injection Test, USP Intracutaneous Reactivity Test, USP Muscle Implantation Test,* ***Ames Test – Saline and 95% Ethanol extracts, Blood Compatibility Evaluation (direct contact), Blood Compatibility Evaluation (saline extract)****, MEM Elution Test Evaluation, Guinea Pig Maximization, Pyrogen Test…"*, which indicates that a test article representative of the one-way stopcock body impregnated with 4% 988WCPC blue colorant underwent/passed genotoxicity and hemocompatibility testing, respectively.

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 MVR Venous Reservoir Bag (which includes the subject one-way stopcock component built with the same resin with an addition of a colorant), are substantially equivalent to the legally marketed predicate devices.