October 31, 2023

TransMedics, Inc.
Miriam Provost
VP, Global Regulatory Affairs
200 Minuteman Road, Suite 302
Andover, Massachusetts 01810

Re: K231362
Trade/Device Name: OCS Heart Leukocyte Depleting Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary bypass arterial line blood filter
Regulatory Class: Class II
Product Code: DTM
Dated: October 13, 2023
Received: October 13, 2023

Dear Miriam Provost:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231362

Device Name
OCS™ Heart Leukocyte Depleting Filter

Indications for Use *(Describe)*

The OCS™ Heart Leukocyte Depleting Filter is indicated for the reduction of leukocytes from donor blood prior to its introduction into the OCS™ Heart System for the preservation of a donor heart from the same donor.

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.

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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the **TransMedics, Inc. OCS™ Heart Leukocyte Depleting Filter** is provided below.

1. SUBMITTER

Applicant:	TransMedics, Inc. 200 Minuteman Road, Suite 302 Andover, MA 01810
Contact:	Miriam Provost, Ph.D. SVP, Global Regulatory Affairs TransMedics, Inc 978-494-7897 mprovost@transmedics.com
Date Prepared:	October 27, 2023

2. DEVICE

Device Trade Name:	OCS™ Heart Leukocyte Depleting Filter
Common Name	Blood Cardioplegia filter
Regulation Name:	Cardiopulmonary bypass arterial line blood filter
Regulation:	21 CFR 870.4260 -
Regulatory Class:	Class II
Product Code:	DTM

3. PREDICATE DEVICE

The subject device claims equivalence to the following legally marketed predicate device:

510(k) Number:	K902518
Device Name:	LeukoGuard BC2
Submitter:	Pall Biomedical
Regulation Name:	Cardiopulmonary bypass arterial line blood filter
Regulation:	21 CFR 870.4260
Regulatory Class:	Class II
Product Code:	DTM

4. REASON FOR 510(K) SUBMISSION

The OCS Heart Leukocyte Depleting Filter is a new device.

5. DEVICE DESCRIPTION

The OCS™ Heart Leukocyte Depleting Filter is a sterile, single-use filter intended for depletion of leukocytes in donor blood prior to its introduction into the OCS Heart system. The polycarbonate housing is 3.2" high and 3.0" in diameter. It has 1/4" fittings and includes a hydrophobic gas-permeable membrane and vent port to allow air to efficiently vent during priming and use. The leukocyte depleting material is a melt blown polyester media supplied by Pall Biomedical (the same material as is used in the predicate device). It has 6 layers, approximately 5 pleats per inch. It includes a polypropylene extruded diamond mesh that provides support for the polyester filter media. The priming volume is 273.5 mL and the anticipated flow rate (associated with gravity feed from a blood collection bag) is 1.9 L/min. During use, the blood enters through the inlet port, flows through the filter media to the interior of the filter element, and then exits through the outlet port. The device is sterilized by ethylene oxide and is provided in a Tyvek pouch packaged in a corrugated box.

6. INTENDED USE/INDICATIONS FOR USE

The OCS™ Heart Leukocyte Depleting Filter is indicated for the reduction of leukocytes from donor blood prior to its introduction into the OCS™ Heart System for the preservation of a donor heart from the same donor.

7. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The indication for use of the proposed device differs from the predicate device because the indication for the proposed device is specific for its use with the OCS Heart System, while the predicate device is for general use with blood cardioplegia circuits. This difference in the indication for use does not lead to a difference in intended use. Both the proposed and the predicate device are intended to filter blood for therapeutic (extracorporeal) use to reduce leukocytes. Therefore, the proposed device may be found substantially equivalent to the predicate device.

Technological Comparisons

The technological characteristics of the subject device are similar to the predicate device. The TransMedics OCS Heart Leukocyte Depleting filter and the Pall Biomedical LeukoGuard BC2 Cardioplegia filter are both sterile, single use filters intended to remove leukocytes from *ex vivo* circulating blood. Both the proposed and predicate device are comprised of a polycarbonate housing with the same melt blown polyester filter material for the reduction of leukocytes. The filter in both the proposed and predicate device is comprised of 6 layers with 5 pleats per inch and both filters include a polypropylene support screen. Both the predicate and proposed device are sterilized by ethylene oxide and are composed of biocompatible materials.

There are some minor differences between the proposed and predicate devices. The OCS Heart Leukocyte Depleting Filter is larger (273.5 mL priming volume compared to 95 mL priming

volume for the LeukoGuard BC2) and therefore removes more leukocytes and platelets than the predicate device. However, these differences in leukocyte removal are to be expected given the larger size of the proposed device. Reduction of leukocytes is beneficial because leukocytes cause inflammatory reactions which may lead to myocardial reperfusion injury in the donor heart as well as increased sensitization to human leukocyte antigens (HLA) for the intended transplant recipient. Therefore, an increased level of leukocyte depletion does not raise a different question of safety or effectiveness for the proposed intended use. There is a small increase in platelet removal from the donor blood, but this does not impact the clinical performance of the OCS Heart System. Pre-clinical performance testing with swine hearts demonstrates that the OCS Heart System has similar performance when used with the OCS Heart Leukocyte Depleting filter compared to the predicate device.

8. PERFORMANCE DATA

Biocompatibility Testing

The OCS Heart Leukocyte Depleting filters have been tested for biocompatibility according to ISO-10993-1 “Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Biocompatibility studies were conducted by NAMSA (Norwood, OH) in compliance with 21 CFR Part 58 - Good Laboratory Practice for Nonclinical Laboratory Studies (GLPs). Ethide Laboratories (West Warwick, RI) conducted the LAL endotoxin testing according to USP <85>, ANSI/AAMI ST72:2019.

The nature of contact was external communicating device, blood path indirect and the duration of contact was limited (< 24 Hours), or Category A. As such, the recommended tests are: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Acute Systemic Toxicity, Hemocompatibility.

The following additional tests were conducted: Genotoxicity, Pyrogenicity (USP Pyrogen and LAL), USP Physicochemical Test for plastics (USP <661>). All tests were passed, demonstrating the biocompatibility of the materials used in the OCS Heart Leukocyte Depleting Filter.

Sterilization and Shelf Life

The OCS Heart Leukocyte Depleting filter is sterilized using Ethylene Oxide (ETO) to a sterility assurance level of 10^{-6}. It is labeled with a 12 month shelf life.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable. The device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Software Verification and Validation Testing

Not applicable. The device contains no software.

Bench Testing

Bench performance testing was done to verify that OCS Heart Leukocyte Depleting Filter met its specifications and is equivalent to the predicate device. Testing included:

- Leukocyte and platelet depletion
- Filtration time
- Hold-up volume, priming volume and pressure drop
- Maximum flow rate when used with OCS Heart system
- Structural integrity testing
- Hemolysis
- Pre-Clinical Validation using the OCS Heart Leukocyte Depleting Filter with the OCS Heart System to preserve swine hearts.

The testing demonstrated that the OCS Heart Leukocyte Depleting filter met all specifications and was shown to be equivalent to the predicate device.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

9. CONCLUSION

The information provided in this submission demonstrates that the subject device is substantially equivalent to the predicate device in both indications for use and technological characteristics. The minor technological differences do not raise new or different questions of safety and effectiveness. Bench testing has demonstrated acceptable performance of the device, that it meets all acceptance criteria and that the OCS Heart Leukocyte Depleting Filter is acceptable for clinical use.