November 18, 2022

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

Re: K222535
Trade/Device Name: OCS Lung Donor Flush Set
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated Kidney Perfusion And Transport System and Accessories
Regulatory Class: II
Product Code: MSB
Dated: August 19, 2022
Received: August 22, 2022

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 (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/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 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 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,

Jade M. Noble -S
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for
Gema Gonzalez, M.S.
Acting Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology 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)*
K222535

Device Name
OCS™ Lung Donor Flush Set

Indications for Use *(Describe)*
The OCS™ Lung Donor Flush Set is a single-use device indicated for hypothermic flushing and replacement of residual blood in donor lungs with a legally marketed organ preservation solution at the time of organ removal from the donor during the preparation of these organs for transplantation.

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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In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the **TransMedics, Inc. OCS™ Lung Donor Flush Set** is provided below.

1. SUBMITTER

Applicant:	TransMedics, Inc. 200 Minuteman Road, Suite 302 Andover, MA 01810
Contact:	Miriam Provost, Ph.D. VP, Global Regulatory Affairs TransMedics, Inc 978-494-7897 mprovost@transmedics.com
Date Prepared:	August 18, 2022

2. DEVICE

Device Trade Name:	OCS™ Lung Donor Flush Set
Common Name	Organ perfusion cannula and tubing
Regulation Name:	Isolated kidney perfusion and transport system and accessories
Regulation:	21 CFR 876.5880
Regulatory Class:	Class II
Product Code:	MSB

3. PREDICATE DEVICE

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

510(k) Number:	K203262
Device Name:	Cannula for Organ Perfusion
Submitter:	Bridge to Life Ltd.
Regulation Name:	Isolated kidney perfusion and transport system and accessories
Regulation:	21 CFR 876.5880
Regulatory Class:	Class II
Product Code:	KDN, MSB

4. REASON FOR 510(K) SUBMISSION

The OCS Lung Donor Flush Set is a new device.

5. DEVICE DESCRIPTION

The OCS Lung Donor Flush Set is a sterile single-use device indicated for hypothermic flushing and replacement of residual blood in donor lungs with a legally marketed organ preservation solution at the time of organ removal from donor during the preparation of these organs for transplantation. It is comprised of an already 510(k) cleared cannula (K132811, Sarns Soft-Flow Extended Aorta Cannula) along with the donor flush lines subassembly. The donor flush line assembly consists of silicone tubing, clamps and two spike connectors to enable connection between donor lungs and bags of organ preservation solution. The clamps are used to control the gravity flow of solution from bags to the donor organ.

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 Lung Donor Flush Set is a sterile single-use device indicated for hypothermic flushing and replacement of residual blood in donor lungs with a legally marketed organ preservation solution at the time of organ removal from donor during the preparation of these organs for transplantation.

7. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The OCS Lung Donor Flush Set has an indication for use statement that is identical to the predicate device (Bridge to Life Ltd Cannula for Organ Perfusion) with the exception of additional explanatory text at the end of the predicate device indication, which is not necessary for an indication for use statement and the limitation that the OCS Lung Donor Flush Set is indicated for donor lungs, while the predicate device is indicated for general donor organs.

Like the predicate device, the OCS Lung Donor Flush Set is indicated for hypothermic flushing and replacement of residual blood in donor organs with a legally marketed organ preservation solution at the time of organ removal from donor during the preparation of these organs for transplantation.

Technological Comparisons

The technological characteristics of the subject device are nearly identical to the predicate device. The main difference is that the OCS Lung Donor Flush Set includes the donor flush lines subassembly to facilitate connection between the preservation solution and the donor lung, while the user must utilize off-the-shelf tubing and connectors for the predicate device. This difference is simply an added convenience for the user and does not impact on safety or substantial equivalence.

8. PERFORMANCE DATA

Biocompatibility Testing

The OCS Lung Donor Flush Set consists of components and materials that were either PMA-approved or were 510(k)-cleared, therefore, biocompatibility testing is not necessary to demonstrate substantial equivalence.

Sterilization and Shelf Life

The OCS Lung Donor Flush Set is sterilized using Ethylene Oxide (ETO) to a sterility assurance level of 10^{-6}. The OCS Lung Donor Flush Set is labeled with a 26 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

Performance testing was done to verify that OCS Lung Donor Flush Set meets all of its product requirements. The testing demonstrated that all acceptance criteria were met and that the OCS Lung Donor Flush Set was acceptable for clinical use.

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 substantial equivalence 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 Lung Donor Flush Set is acceptable for clinical use.