July 29, 2021

TransMedics, Inc.
℅ Christy Foreman, M.B.E.
Senior Consultant, Medical Devices
Biologics Consulting Group, Inc.
1555 King Street, Suite 300
Alexandria, Virginia 22314

Re: K211314
Trade/Device Name: OCS™ Lung Solution
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: II
Product Code: MSB
Dated: April 29, 2021
Received: April 30, 2021

Dear Christy Foreman:

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,

Carolyn Y. Neuland, Ph.D.
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)*
K211314

Device Name
OCS™ Lung Solution

Indications for Use *(Describe)*
OCS™ Lung Solution is intended for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

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™ Lung Solution** is provided below.

1. SUBMITTER

Applicant: TransMedics, Inc.
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Date Prepared: April 29, 2021

2. DEVICE

Device Trade Name:	OCS™ Lung Solution
Common Name	Organ perfusion and preservation solution
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:	K000881
Device Name:	Perfadex®
Submitter:	VitroLife Sweden AB (now distributed by the subsidiary Xvivo Perfusion AB)

Regulation Name:	Isolated kidney perfusion and transport system and accessories
Regulation:	21 CFR 876.5880
Regulatory Class:	Class II
Product Code:	MSB

4. DEVICE DESCRIPTION

The OCS Lung Solution is a colorless, sterile, pyrogen-free solution for cold flushing, storage and transport of donor lungs for transplantation. The OCS Lung Solution is a colloid-based extracellular low potassium solution for cold flushing and storage of donor lungs for transplantation. The OCS Lung Solution is used to flush and store a lung after removal from the donor. Administration of the solution at the recommended temperature will effectively cool the organ to reduce its metabolic requirements.

The subject 510(k) involves the class II use of the OCS Lung Solution. More specifically, the OCS Lung Solution is indicated for hypothermic flushing, storage and transportation of donor lungs for transplantation (21 CFR 876.5880, Class II Product Code MSB). The OCS Lung Solution is identical to the device approved as a component of the OCS Lung System, approved under P160013. However, as a class II device, the OCS Lung Solution is a stand-alone medical device.

5. INTENDED USE/INDICATIONS FOR USE

OCS™ Lung Solution is intended for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

6. SUBSTANTIAL EQUIVALENCE

Comparison of Indications

The OCS Lung Solution has an indication for use statement that is identical to the predicate device (Perfadex). Like the predicate device, the OCS Lung Solution is indicated for flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

Technological Comparisons

The OCS Lung Solution is substantially equivalent to the Perfadex Solution cleared under K000881. The chemical composition is nearly identical between the two products in terms of electrolytes and Dextran 40. Both products are adjusted to the same pH prior to use by 1 mmol THAM/TRIS or bicarbonate. The differences are the addition of one more gram of glucose in the OCS Lung solution, and the use of a polypropylene bag compared to a PVC bag for the predicate device.

7. PERFORMANCE DATA

Biocompatibility Testing

Biocompatibility testing for the OCS Lung Solution was performed in accordance with the guidance, "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing." The duration of contact with the lung for the subject device is less than 24 hours. The level of contact was considered direct since the OCS Lung Solution is in direct contact with the donor lung. The testing to support the substantial equivalence included cytotoxicity testing, sensitization, intracutaneous reactivity, acute systemic toxicity, pyrogenicity (material mediated and bacterial endotoxin) and in vitro hemolysis. As the OCS Lung Solution in its final finished form (both solution and solution bag) is identical to the previously marketed device in formulation, processing, sterilization, and geometry and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents), biocompatibility of the OCS Lung Solution has been established.

Sterilization and Shelf Life

After formulation and filling, the OCS Lung Solution bags are terminally sterilized using a steam sterilization process to a SAL of $\leq 10^{-6}$. Each lot (or batch) of the OCS Lung Solution is tested for endotoxins prior to lot release and the product is labeled as pyrogen-free.

This OCS Lung Solution is labeled with a 24-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 testing consisted of chemical analyses of the OCS Lung Solution.

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.

8. 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.