November 26, 2024

Traferox Technologies Inc.
Nicole Baker
Official Applicant
3505 Laird Rd. Unit 16
Mississauga, ON L5L5Y7
Canada

Re: K240650
Trade/Device Name: LungProtect
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated Kidney Perfusion And Transport System And Accessories
Regulatory Class: Class II
Product Code: KDN
Dated: November 1, 2024
Received: November 1, 2024

Dear Nicole Baker:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Maura Rooney -S

Maura Rooney
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240650

Device Name

LungProtect

Indications for Use *(Describe)*

LungProtect is indicated for the flushing, cold static 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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"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."

510(k) #: K240650

510(k) Summary

Prepared on: 2024-11-01

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Traferox Technologies Inc.
Applicant Address	3505 Laird Rd. Unit 16 Mississauga ON L5L5Y7 Canada
Applicant Contact Telephone	416-788-2253
Applicant Contact	Ms. Nicole Baker
Applicant Contact Email	nbaker@traferox.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	LungProtect
Common Name	Isolated kidney perfusion and transport system and accessories
Classification Name	System, Perfusion, Kidney
Regulation Number	876.5880
Product Code(s)	KDN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K091989	PERFADEX AND PERFADEX WITH THAM	KDN

Device Description Summary

21 CFR 807.92(a)(4)

LungProtect is an organ preservation solution used for flushing, static cold storage, and the perfusion and preservation of lungs intended for transplantation. LungProtect is a clear, sterile, non-pyrogenic, colloid based, lightly buffered extracellular low potassium dextran solution.
During use, the solution is cooled to 4-8°C and is used to perfuse the isolated organ immediately before its removal from the donor and/or immediately after its removal. The solution is then left in the organ vasculature during storage and transportation.
The solution is slightly acidic (pH 5.4) to permit long shelf life and is adjusted shortly before use to pH 7.4 by the addition of THAM solution.
The solution is packaged in one-liter (1000 ml) or two-liter (2000 ml) EVA bags, permanently and integrally connected to one (for 1L) or two (for 2L) PVC bags each containing 25 ml (1 mmol) THAM.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

LungProtect is indicated for the flushing, cold static storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Indications are the same for that of LungProtect and its predicate.

Technological Comparison

21 CFR 807.92(a)(6)

LungProtect and the predicate device are both indicated for the flushing, cold static storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient. LungProtect and its predicate are substantially equivalent, as they have the same intended use, ingredients, composition, and other technological characteristics. The subject and predicate device have a different method of sterilization; however, both devices are provided sterile and have been validated per ISO standards. Primary packaging material is different; however, the bag material has been demonstrated to provide stability over the declared lifetime. The minor differences between the subject and predicate devices do not raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non clinical tests submitted to demonstrate biological safety are:
1) Cytotoxicity
2) Sensitization
3) Intracutaneous Irritation
4) Acute Systemic & Pyrogenicity
5) Hemolysis

Packaging validation tests submitted demonstrates that the packaging of solution is safe. The following tests were performed on real-time aged samples:
1) Shipping and Distribution tests
2) Environmental conditioning
3) Compression testing

Compositional analysis and microbiological testing (sterility and endotoxin) were performed to verify the stability of the solution over the defined shelf life.

The physical and chemical analysis of the LungProtect solution was completed to demonstrate that the LungProtect is substantially equivalent to its predicate.

Non-clinical testing was sufficient to demonstrate substantial equivalence to the predicate device. The non-clinical data supports the safety and effectiveness of the LungProtect.

The LungProtect (subject device) and Perfadex with THAM (predicate device) have the same indications for use and are substantially equivalent in technological characteristics and performance (same composition).

The non clinical tests submitted demonstrates that LungProtect does not raise any questions on the safety and effectiveness and is equivalent to the predicate device. The non clinical data supports and demonstrates the safety of the LungProtect.