May 1, 2025

Traferox Technologies Inc.
Anuradha Iyer
Regulation Affairs Manager
3505, Laird Rd. Unit 16
Mississauga, ON L5L 5Y7
Canada

Re: K243870
Trade/Device Name: X Port Lung Preservation System; X Port Lung Preservation Solution
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: Class II
Product Code: KDN
Dated: March 31, 2025
Received: March 31, 2025

Dear Anuradha Iyer:

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
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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)*

K243870

Device Name

X°Port Lung Preservation System;
X°Port Lung Preservation Solution

Indications for Use *(Describe)*

X°Port Lung Preservation System
The X°Port Lung Preservation System is intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient. The X°Port Lung Preservation System is intended to be used with the X°Port Lung Preservation Solution.

The intended organ storage time for the X°Port Lung Preservation System is up to 8 hours.

When clinically accepted static hypothermic preservation times are exceeded, the lungs should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.

X°Port Lung Preservation Solution
The X°Port Lung Preservation Solution 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.

TRAFEROX

510(k) Summary

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR §807.92.

Date Prepared: March 31, 2025

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Device Details:

First Device Trade Name:	X°Port Lung Preservation System
Regulation Name:	Isolated kidney perfusion and transport system and accessories.
Classification name:	System, Perfusion, Kidney
Common name:	Lung Preservation and Transport System
Regulation Number:	876.5880
Product Code:	KDN

Second Device Trade Name:	X°Port Lung Preservation Solution
Regulation Name:	Isolated kidney perfusion and transport system and accessories.
Classification name:	System, Perfusion, Kidney
Common name:	Solution for lung preservation
Regulation Number:	876.5880
Product Code:	KDN

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Predicate Devices

First Device Predicate Name: SherpaPak™ Lung Preservation System

510(k) Number:	K192869
Regulation Name:	Isolated kidney perfusion and transport system and accessories.
Classification name:	System, Perfusion, Kidney
Common Name:	Organ Preservation and transport device
Regulation Number:	876.5880
Product Code:	KDN

Second Device Predicate Name: LungProtect

510(k) Number:	K240650
Regulation Name:	Isolated kidney perfusion and transport system and accessories.
Classification name:	System, Perfusion, Kidney
Common Name:	Solution for lung preservation
Regulation Number:	876.5880
Product Code:	KDN

Reference Device:	Perfadex Plus
510(k) Number:	K170826
Regulation Name:	Isolated kidney perfusion and transport system and accessories.
Classification Name:	System, Perfusion, Kidney
Common Name:	Solution for lung preservation
Regulation Number:	876.5880
Product Code:	KDN

Device Description:

X°Port Lung Preservation System

The X°Port Lung Preservation System is an organ preservation system. It is designed to store, preserve, and transport human lungs donated for transplantation at 4°C-10°C.

The X°Port Lung Preservation System consists of an insulated chamber, phase-change cooling packs, a cradle to hold the lung bag, and a temperature probe and logger. The X°Port Lung Preservation System is designed to be mobile, with wheels and a telescopic handle to maneuver the device throughout its travel. The device is designed to protect the lungs during transport and to display and log the internal temperature on an external screen. Additionally, the internal temperature may be monitored via an application running on a mobile device.

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X°Port Lung Preservation Solution

The X°Port Lung Preservation Solution is an organ preservation solution used for flushing, static cold storage, and the perfusion and preservation of lungs intended for transplantation. X°Port Lung Preservation Solution 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 hypothermic storage and transportation at 4-10°C.

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 must be supplemented with 0.5 mmol/l Calcium Chloride prior to use.

Indications for Use:

X°Port Lung Preservation System:

The X°Port Lung Preservation System is intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient. The X°Port Lung Preservation System is intended to be used with the X°Port Lung Preservation Solution.

The intended organ storage time for the X°Port Lung Preservation System is up to 8 hours.

When clinically accepted static hypothermic preservation times are exceeded, the lungs should be evaluated by the transplant surgeon to determine transplantability in accordance with accepted clinical guidelines and in the best medical interest of the intended recipient.

X°Port Lung Preservation Solution

The X°Port Lung Preservation Solution 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.

Technological Characteristics:

X°Port Lung Preservation System:

The proposed X°Port Lung Preservation System has the same indications for use, fundamental technology, system components, and mode of operation as its predicate, SherpaPak Lung

Preservation System (K192869). X°Port Lung Preservation System and SherpaPak Lung Preservation System (K192869) both are intended to be used for the static hypothermic preservation of lungs during transportation and eventual transplantation into a recipient. The subject device is recommended to be used with X°Port Lung Preservation Solution to maintain an organ storage temperature of 4°C to 10°C.

The difference in the storage temperature between subject device (4°C to 10°C) and predicate device (4°C to 8°C) has been validated and is supported by non-clinical and clinical performance data which is part of this submission. The differences between the subject device and predicate device do not raise new questions of safety or effectiveness. Based on the information submitted, the X°Port Lung Preservation System is considered substantially equivalent to SherpaPak Lung Preservation System (K192869).

X°Port Lung Preservation Solution

The proposed X°Port Lung Preservation Solution has the same indications for use, composition and technological characteristics as its predicate, LungProtect (K240650). X°Port Lung Preservation Solution and predicate device solutions are both cooled to 4°C to 8°C and are indicated for flushing, cold static storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient. The difference between the X°Port Lung Preservation Solution and LungProtect (K240650) is in the usage temperature.

The X°Port Lung Preservation Solution is intended to be used for hypothermic storage and transportation of lungs at 4°C to 10°C and the predicate device is intended to be to be used for hypothermic storage and transportation of lungs at 4°C to 8°C. The difference in the usage temperature between subject device (4°C to 10°C) and predicate device (4°C to 8°C) has been validated and is supported by the clinical performance data which is part of this submission.

It is also required to add 0.5 mmol/l of Calcium Chloride to the subject device prior to use. Calcium is required to ensure the solution composition is suitable for use at 10°C and aligns with supporting clinical data provided in this 510(k).

The differences between the subject device and predicate device do not raise new questions of safety or effectiveness. Based on the information submitted, the X°Port Lung Preservation Solution is considered substantially equivalent to LungProtect (K240650).

Summary of Non Clinical Performance Data:

X°Port Lung Preservation System:

Non-clinical performance testing has been performed on the proposed X°Port Lung Preservation System to demonstrate the device's substantial equivalence:

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Non-clinical validation testing includes:

- Basic Safety (electrical, mechanical, thermal)
- Electromagnetic Compatibility
- Physical Testing
- Functional Validation (thermal performance)
- Software and Cybersecurity Testing
- Software Workflow Validation
- Packaging and Shipping Testing
- Lifetime Testing
- Human Factors Testing

X°Port Lung Preservation Solution:

Non-clinical performance testing has been performed on the proposed X°Port Lung Preservation Solution to demonstrate the device's substantial equivalence.

Non clinical tests submitted to demonstrate biological safety are:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic & Pyrogenicity
- Hemolysis

Packaging validation tests submitted demonstrate that the packaging of solution is safe. The following tests were performed on real-time aged samples:

1) Environmental conditioning
2) Shipping and Distribution tests
3) Compression testing

Compositional analysis and microbiological testing (sterility and endotoxin) were performed on three samples to demonstrate that the solution can be consistently manufactured to meet all required test specifications.

Summary of Clinical Performance Data:

X°Port Lung Preservation System and X°Port Lung Preservation Solution:

The clinical evaluation supporting this submission includes two retrospective, single-arm studies with historical controls, conducted outside of the United States. These studies assess the safety and

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effectiveness of controlled hypothermic lung preservation using temperature-controlled devices, including a portable hypothermic preservation device and a temperature-regulated incubator set to 10°C.

The objectives of the first clinical study were to evaluate the use of a portable 10°C hypothermic preservation device (X°Port Lung Transport Device) on lung transplant outcomes when compared to transplants performed using conventional ice storage methods. Baseline characteristics were similar in both groups (X°Port: Average Age 45, 44.9% Female, 55.1% Male, 69.5% Caucasian, 30.5% Non-Caucasian; Control: Average Age 48, 43.1% Female, 56.9% Male, 67.2% Caucasian, 32.8% Non-Caucasian). In total, 118 study patients were included in the study group and 538 in the controls. No noticeable difference was observed in results based on demographic subgroups.

The objectives of the second clinical study were to evaluate the long-term outcomes of transplant patients receiving lungs preserved at 10°C in a temperature-controlled incubator compared to lungs preserved using conventional ice storage methods. Baseline characteristics were similar in both groups (Incubator: Average Age 48, 43.5% Female, 56.5% Male, 75.4% Caucasian, 24.6% Non-Caucasian; Control: Average Age 48, 43.1% Female, 56.9% Male, 67.4% Caucasian, 32.6% Non-Caucasian). In total, 138 study patients were included in the study group and 538 in the controls. No noticeable difference was observed in results based on demographic subgroups.

The study results show that controlled hypothermic lung preservation at 10°C led to the safe use of donor lungs (reducing (S)AEs), while using higher risk organs (i.e., longer preservation times, lungs procured from more donation after cardiac death donors). Controlled hypothermic lung preservation at 10°C showed improved long-term Chronic Lung Allograft Free Dysfunction survival and lower infection rates when compared to ice preservation. When comparing the clinical performance data to published post-market registry data from the predicate device, there was no statistically significant difference in rates of grade 3 primary graft dysfunction or 1-year survival.

The clinical data demonstrate that lung storage and preservation at 10°C results in equivalent short and mid-term outcomes when compared with the standard practice of cold preservation and when compared to the predicate device. Therefore, we can conclude that lung preservation at 10°C does not add any additional risks to patients receiving a lung transplant.

Conclusion:
The non-clinical testing conducted as well as clinical data demonstrates that the proposed device is substantially equivalent to the predicate device.