June 1, 2026

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

Re: K260456
Trade/Device Name: VIPort™ Liver Preservation System
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated Kidney Perfusion And Transport System And Accessories
Regulatory Class: Class II
Product Code: KDN
Dated: April 30, 2026
Received: April 30, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

ANTHONY LEE -S

Anthony C. Lee, Ph.D., M.B.A.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260456

Please provide the device trade name(s).

VI°Port™ Liver Preservation System

Please provide your Indications for Use below.

The VI°Port™ Liver Preservation System is intended to be used for the static hypothermic preservation of livers during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with the livers.

The intended organ storage time for the VI°Port™ Liver Preservation System is up to 15 hours.

When clinically accepted static hypothermic preservation times are exceeded, the livers 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.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) #: K260456

510(k) Summary

Prepared on: 2026-04-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Traferox Technologies Inc.
Applicant Address	3505 Laird Rd. Unit 16 Mississauga ON L5L 5Y7 Canada
Applicant Contact Telephone	+1 437-983-8971
Applicant Contact	Ms. Anuradha Iyer
Applicant Contact Email	aiyer@traferox.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	VI°Port™ Liver Preservation System
Common Name	System, Perfusion, Kidney
Classification Name	Isolated kidney perfusion and transport system and accessories
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
K192869	SherpaPak™ Liver Transport System	KDN

Device Description Summary

21 CFR 807.92(a)(4)

The VI°Port Liver Preservation System is designed to store, preserve, and transport human livers donated for transplantation. The target temperature range maintained during storage is 4°C to 8°C. The VI°Port Liver Preservation System is designed to protect the livers during transport and to display and log the internal device temperature on an external screen. Additionally, the internal temperature may be monitored via an optional mobile application. The system is designed to be mobile, with wheels and a telescopic handle to maneuver the device throughout its travel.

The system consists of an insulated chamber, specialized phase-change material with a transition temperature of approximately 5°C, an internal support for the organ, and a temperature probe and logger. The temperature logger has Bluetooth connectivity. The system is a non-sterile single use device and does not contact the organ. The VI°Port Liver Preservation System is intended to be used with cold storage solutions indicated for use with the liver.

VI°Port Liver Preservation System principle of operation is in the pre-conditioning and use of specialized phase change material cooling packs. The cooling packs are preconditioned in a freezer (at least -20°C) for a minimum of 48 hours before setting up the VI°Port Liver Preservation System.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The VI°Port™ Liver Preservation System is intended to be used for the static hypothermic preservation of livers during transportation and eventual transplantation into a recipient, using cold storage solutions indicated for use with the livers.

The intended organ storage time for the VI°Port™ Liver Preservation System is up to 15 hours.

When clinically accepted static hypothermic preservation times are exceeded, the livers 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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device has the same indications for use as its predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The proposed VI°Port™ Liver Preservation System is substantially equivalent to its predicate SherpaPak™ Liver Transport System (K192869) with regards to:

- Intended use/Indications for use
- Technological characteristics (Fundamental scientific technology); and
- Safety and effectiveness.

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

The following non-clinical bench testing has been performed for the VI°Port Liver Preservation System to demonstrate the device's safety and effectiveness.

- Software and Cybersecurity Testing
- Basic Safety (electrical, mechanical, thermal)
- Electromagnetic Compatibility
- Transportation Testing
- Thermal Qualification Testing
- Human Factors Testing
- Packaging and Shipping Testing
- Lifetime Testing

Not Applicable

The non-clinical testing conducted demonstrates that the proposed device does not raise any new issues of safety and effectiveness and is substantially equivalent to the predicate device.