July 23, 2026

Xvivo Perfusion AB
Petra Rosen
Regulatory Affairs Manager
Entreprenörsstråket 10
Mölndal, SE-431 53
Sweden

Re: K261644
Trade/Device Name: Perfadex Plus
Regulation Number: 21 CFR 876.5880
Regulation Name: Isolated kidney perfusion and transport system and accessories
Regulatory Class: Class II
Product Code: KDN
Dated: July 21, 2026
Received: July 22, 2026

Dear Petra Rosen:

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,

Gema Gonzalez -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

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.	K261644; K261644/S

Please provide the device trade name(s).

Perfadex Plus

Please provide your Indications for Use below.

Perfadex Plus is indicated for the flushing, static cold storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a 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) #: K261644

510(k) Summary

Prepared on: 2026-07-23

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	XVIVO Perfusion AB
Applicant Address	Entreprenörsstråket 10 Mölndal SE-431 53 Sweden
Applicant Contact Telephone	+46730259244
Applicant Contact	Ms. Petra Rosen
Applicant Contact Email	petra.rosen@xvivogroup.com

Device Name

21 CFR 807.92(a)(2)

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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K170826	Perfadex Plus	KDN

Device Description Summary

21 CFR 807.92(a)(4)

Perfadex® Plus is a sterile, single-use organ preservation solution indicated for the flushing, cold static storage, and transportation of isolated donor lungs prior to transplantation. The product is supplied in flexible sterile containers for use in professional healthcare settings.

During organ procurement, the solution is used to flush the donor lung and provide hypothermic preservation prior to implantation. Perfadex® Plus functions as an extracellular preservation solution intended for ex vivo use during the transplantation process. The device does not contain software or electrical components and operates through its solution-based preservation properties.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Perfadex Plus is indicated for the flushing, static cold 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)

Perfadex Plus has the same indications for use as the predicate device, Perfadex Plus (K170826).

Technological Comparison

21 CFR 807.92(a)(6)

Perfadex Plus has the same technological characteristics as the predicate device, Perfadex Plus (K170826). It is a sterile, ready-to-use extracellular low-potassium dextran lung preservation solution supplied in sterile flexible Ecobag containers (1000 mL and 3000 mL). The

device is terminally sterilized by moist heat and functions through its solution composition during flushing and cold static preservation of donor lungs.

The formulation, chemical composition, sterilization method, packaging configuration, and principle of operation are unchanged from the predicate device. The differences are limited to labeling updates expanding the preservation temperature range from 2–8 °C to 2–10 °C and extending the labeled shelf life from 12 months to 18 months.

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

No new bench or animal testing was required to support the labeling change increasing the upper preservation temperature limit from 8 °C to 10 °C. The modification does not alter the intended use, formulation, technological characteristics, sterilization method, packaging configuration, or performance specifications. Therefore, no additional nonclinical performance testing was necessary.

The extension of labeled shelf life from 12 months to 18 months is supported by stability data generated using established and previously validated methods. Stability testing demonstrates continued compliance with product specifications throughout the proposed 18-month shelf life.

Collectively, the supporting stability data demonstrate that the modified storage temperature and extended shelf life maintain compliance with established product specifications. The device continues to meet all performance requirements and remains safe and effective for its intended use.

No new clinical investigations were conducted for this submission. To support the labeling change increasing the upper preservation temperature limit to 10 °C, published clinical literature was reviewed. This approach was previously discussed with FDA in December 2025 (refer to Attachment B04). The identified studies, including prospective and retrospective clinical analyses of lung transplantation procedures, demonstrated comparable safety and performance outcomes at preservation temperatures up to 10 °C. Baseline demographic and clinical characteristics were comparable between the 10 °C and control cohorts. Across the reviewed studies, median recipient age ranged from 57 to 64 years in the 10 °C cohorts and from 49 to 64 years in the control cohorts. Female recipients comprised 43% to 54% of the 10 °C cohorts and 27% to 43% of the control cohorts. Demographic information regarding race or ethnicity was not reported in the reviewed literature. Overall, the available clinical evidence supports the safety and effectiveness of Perfadex Plus at the revised temperature range.

Based on the available nonclinical and clinical evidence, including published literature supporting the revised preservation temperature, Perfadex Plus is as substantially equivalent to the legally marketed predicate device. The labeling modification increasing the upper preservation temperature limit to 10 °C does not adversely affect device safety or performance and supports a determination of substantial equivalence.