July 15, 2026

Traferox Technologies, Inc.
Nicole Baker
VP - Quality & Regulatory
3505 Laird Rd., Unit 16
Mississauga, ON L5L 5Y7
Canada

Re: P250025
Trade/Device Name: TorEx Lung Perfusion System
Product Code: PHO
Filed: July 7, 2025
Amended: April 14, 2026

Dear Nicole Baker:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the TorEx Lung Perfusion System. This device is indicated for use in continuous normothermic machine perfusion of donor lungs, initially deemed unsuitable for transplantation, during which time the ex vivo function of the lungs can be reassessed for transplantation in adults. The TorEx Lung Perfusion System includes a mobile cart with embedded software, single-use sterile Organ Chamber and Cannulae set and is used with TorEx Lung Perfusate solution to perform ex vivo lung perfusion for up to 6 hours. Note: The TorEx System is used to evaluate the quality of donated lungs, but the final determination of the suitability of the lungs for transplant remains with the transplanting surgeon.

Based upon the information submitted, the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to all other applicable requirements, including those governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved at 10 years of use life for the mobile cart, 1 year for the perfusion kit containing organ chamber and perfusion cannulae, and 1 year for the TorEx Lung Perfusate.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the CDRH Portal. The Annual Report should indicate the beginning and ending date of the period covered by the report and must include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, under 21 CFR 814.82(a)(9), the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You must obtain approval of your post-approval study (PAS) protocol(s) within 60 days from the date of this order. Within 30 days of your receipt of this letter, you must submit PMA supplements that include complete protocols of your post-approval studies described below. Your PMA supplements should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted to the CDRH Portal. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below.

1. The "*TorEx Study Continuation Long-Term Post-Approval Study*" is an observational, dual-arm, single-center continuation study designed to evaluate the long-term safety and effectiveness of the TorEx Lung Perfusion System in subjects previously enrolled in the premarket TorEx Study submitted in support of the P250025 PMA. The purpose of this study is to obtain long-term post-transplant follow-up data for up to 5 years for all subjects enrolled in the premarket TorEx Study (n = 221 in the TorEx group; n = 379 in the control group). The TorEx group consists of subjects who underwent lung transplantation at Toronto General Hospital and received donor lungs evaluated using the TorEx Lung Perfusion System between December 6, 2022, and November 7, 2025. The control group consists of subjects who underwent lung-only transplantation using conventional cold static preservation (without EVLP) at the same site during the same calendar period. The study is a closed-enrollment retrospective continuation of the premarket study population. The study will follow all enrolled subjects through November 7, 2030 (five years post-transplant for the last enrolled subject). Data completeness will be reviewed at least annually, with particular focus on survival status, chronic lung allograft dysfunction (CLAD), and airway complications. The primary endpoint is patient survival at 1-year post-transplantation. Secondary endpoints include: patient survival at 2, 3, 4, and 5 years post-transplantation; pulmonary function (FEV1) at 1, 2, 3, 4, and 5 years; chronic lung allograft dysfunction (CLAD)-free survival at 1, 2, 3, 4, and 5 years; incidence of Bronchiolitis Obliterans Syndrome (BOS) at 1, 2, 3, 4, and 5 years; and incidence of airway anastomotic complications (including airway ischemia, bronchial anastomotic stricture requiring intervention,

bronchial dehiscence, and bronchial necrosis) within 12 months of transplantation. As the study is a retrospective continuation of the premarket study population, all analysis will be considered descriptive in nature. The draft protocol for the "*TorEx Study Continuation Long-Term Post-Approval Study*" was received via email by FDA from the sponsor on June 30, 2026.

PAS Progress Reports must be submitted every six (6) months for the first year and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA. The Final PAS Report should be submitted no later than three (3) months after study completion (i.e., last subject's last follow-up date).

2. The "*TorEx Lung Perfusion System Post-Approval Study*" is a prospective, observational, single-arm, multi-center, all-comers study designed to evaluate the long-term safety and effectiveness of the TorEx Lung Perfusion System under real-world clinical conditions following PMA approval. The purpose of this study is to collect longitudinal outcome data on lung transplant recipients receiving donor lungs evaluated using the TorEx Lung Perfusion System at all United States transplant centers that receive the device. The study will enroll all consecutive, eligible transplant recipients receiving TorEx-evaluated donor lungs at participating centers during a 5-year enrollment period following PMA approval. An external concurrent control cohort of contemporaneous lung transplant recipients receiving donor lungs preserved using conventional cold static preservation (without EVLP) will be derived from the Organ Procurement and Transplantation Network (OPTN) Standard Transplant Analysis and Research (STAR) database for purposes of benchmarking and contextualizing primary endpoint outcomes; this comparator is not intended to establish direct equivalence between populations. The estimated enrollment is approximately 300 transplant recipients in the TorEx cohort over the 5-year enrollment period; the external OPTN STAR control cohort is expected to include more than 1,000 subjects. No specific targets for ensuring diversity with respect to sex, age, race, or ethnicity were established in the protocol; FDA notes this as a gap that should be addressed during PAS protocol finalization. All enrolled subjects will be followed for 5 years post-transplantation (total study duration approximately 10 years). Data completeness will be reviewed at least quarterly, with particular focus on survival status, CLAD, airway complications, and major adverse events. Post-transplant clinical follow-up assessments of pulmonary function and long-term outcomes will be conducted at 1, 2, 3, 4, and 5 years post-transplantation. The primary endpoint is patient survival at 1 year post-transplantation. Secondary endpoints include: patient survival at 3 and 5 years; pulmonary function (FEV1) at 1, 2, 3, 4, and 5 years; CLAD-free survival at 1, 2, 3, 4, and 5 years; incidence of BOS at 1, 2, 3, 4, and 5 years; incidence of airway anastomotic complications (airway ischemia, bronchial anastomotic stricture requiring intervention, bronchial dehiscence, and bronchial necrosis) within 12 months of transplantation; EVLP-to-transplant conversion rate; duration of mechanical ventilation; ICU length of stay; hospital length of stay; and requirement for extracorporeal membrane oxygenation (ECMO). A safety endpoint of TorEx-related serious adverse events (SAEs) from the time of transplantation through 30 days post-transplantation or initial hospital stay, whichever is longer, will also be assessed. The primary statistical analysis will evaluate 1-year post-transplant patient survival using a non-inferiority framework compared to the OPTN STAR benchmark. Finally, as another example of an issue that will need to be addressed with the draft PAS protocol (i.e., before PAS protocol finalization within a future PMA supplement), FDA notes that the "*TorEx Lung Perfusion System Post-Approval Study*" does not include collection of "grade 3 primary graft dysfunction (PGD3) at 72 hours," and we emphasize that this is an important information to include in the PAS protocol to confirm safety as demonstrated by PGD3 rates. The draft protocol for the

"*TorEx Lung Perfusion System Post-Approval Study*" was received via email by FDA from the sponsor on June 9, 2026.

From the date of study protocol approval, you must meet the following timelines for the "*TorEx Lung Perfusion System Post-Approval Study*:"

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of the "*TorEx Lung Perfusion System Post-Approval Study*" as follows:

- PAS Progress Reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every 3 months in addition to your periodic (6-month) PAS Progress Reports, until FDA notifies you otherwise.
- Submit the Final PAS Report three (3) months from study completion (i.e., last subject's last follow-up date).

Each PAS report should be submitted to the CDRH Portal identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including initiation, enrollment, and completion requirements outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post-Approval Studies Program Database Webpage, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

In addition, the results from any post approval study should be included in the labeling as these data become available. Under 21 CFR 814.39, any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled,

"Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order" (https://www.fda.gov/media/71327/download).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. Additional information about changes that may require a PMA supplement are provided in the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/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).

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR Part 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products.

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR Part 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted to the CDRH Portal and should reference the above PMA number to facilitate processing. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

If you have any questions concerning this approval order, please contact Biniyam Taddese, Ph.D., at (240) 402-6570 or Biniyam.Taddese@fda.hhs.gov.

Sincerely,

GLENN B. BELL -S

Glenn B. Bell, Ph.D.
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