July 7, 2026

Mirion Technologies (Capintec), Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K253942
Trade/Device Name: Pulmonex II Xenon System (132-503)
Regulation Number: 21 CFR 892.1390
Regulation Name: Radionuclide rebreathing system
Regulatory Class: Class II
Product Code: IYT
Dated: June 5, 2026
Received: June 5, 2026

Dear Prithul Bom:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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.	K253942

Please provide the device trade name(s).

Pulmonex II Xenon System (132-503)

Please provide your Indications for Use below.

The Pulmonex II Xenon System is intended for the safe delivery and trapping of Xe-133 gas. The device is indicated for patients requiring lung ventilation studies. It is shielded for patient and operator safety.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

K253942

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92

Date Prepared: 2026-07-07

Contact Details

Applicant Name: Mirion Technologies (Capintec), Inc.

Applicant Address: 7 Vreeland Road Florham Park NJ 07932 United States

Applicant Contact Telephone: 412-805-3305

Applicant Contact: Ms. Mary Anne Yusko

Applicant Contact Email: myusko@mirion.com

Device Name

Device Trade Name: Pulmonex II Xenon System (132-503)

Common Name: Radionuclide Rebreathing System

Classification Name: Radionuclide Rebreathing System

Regulation Number: 21 CFR §892.1390

Product Code(s): IYT

Legally Marketed Predicate Devices

Predicate #: K810819

Predicate Trade Name: Medi/Nuclear #XE-102 Xenon/Master

Product Code: IYT

Device Description Summary

The Pulmonex II Xenon System consists of an A/C powered console and disposable components used to connect the patient to the unit. The console controls airflow through a Hans Rudolph Valve, two operator controlled adjustable blowers, two rebreathing bags, airflow control valve, and two charcoal traps, and tubing. The first bag traps breath during Phase 1 (open loop), which is rebreathed again in Phase 2 (closed loop). During Phase 2, after the patient is given Xe-133, the patient's lungs are imaged on a gamma camera. In Phase 2, the air is recycled through a disposable Litholyme cartridge to remove CO2. In Phase 3 (open loop) the patient breaths in new air and exhalation is captured in the exhalation breathing bag and cycled through the desiccant cartridge (Drierite) which removes moisture before entering the charcoal traps. The charcoal traps remove the radioactive Xe-133 before releasing the air back into the room. The system includes two glass viewing windows, so that the operator can monitor the bag inflation and adjust the blower speed accordingly to assure resistance free breathing for the patient in each phase of the process. The process can run using ambient room air and/or user facility supplied compressed O2. The entire process typically takes about 6-8 minutes. The console includes lead shielding for operator protection. The system is mobile, with interlocking casters, and contained in a stainless-steel powder coated enclosure and small convenience tray.

Convenience kits are available with the most commonly used disposable groups, which include either a face mask or mouthpiece and nose clip, tubing, disposable Litholyme cartridge and bacterial/viral filters. The Xe-133 can be added through a port on the system or through injection ports on the face masks or tubing. Individual disposable components are available should the user choose to configure their kits individually.

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92

Intended Use/Indications for Use:

The Pulmonex II Xenon System is intended for the safe delivery and trapping of Xe-133 gas. The device is indicated for patients requiring lung ventilation studies. It is shielded for patient and operator safety.

Indications for Use Comparison:

Pulmonex and predicate device indications for use are the same.

Technological Comparison

Both the Pulmonex and Xenon Master #Xe-102 have the same intended use, same principles of operation, same control type mechanism, same airflow pattern, same basic design, similar console components, and use the same basic disposable components and disposable convenience kits. Thus, the two units are equivalent in design, operation, and performance. The Pulmonex has the following enhancements which are not available in the Xenon Master: two lead glass viewing windows to allow visual monitoring of bag inflation, automatic 15 minute shut off, air speed control mechanism for better operator control, thicker lead shielding for improved operator protection, two blowers for improved resistance free breathing, and stainless-steel convenience side tray. These enhancements improve safety and effectiveness when compared to predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

Verification testing was conducted on the Pulmonex II Xenon System to confirm that all critical design elements and functional requirements were satisfied. The objective of this verification effort was to ensure that the system performs safely, effectively, and consistently under expected conditions of use, including integration with accessories and supporting components. Validation demonstrated that the Pulmonex II Xenon System satisfies user requirements for safety, mobility, usability, operations, intended performance, and serviceability. The device and its accessories were found to meet intended use conditions, supporting confidence in its safe and effective operation in clinical settings. The Pulmonex was tested and found to be in compliance with the following standards:

-ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]

-60601-1-2:2014 [Including AMD 1:2021]

-60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION

-ISO 10993

-ISO 18562 series

In conclusion, the Pulmonex II Xenon System was found to be as safe and effective as the predicate device.