February 13, 2026

Pulmonx Corporation
Terry Solomon, PhD
Principal Regulatory Affairs Specialist
700 Chesapeake Dr.
Redwood Citry, California 94063

Re: K253096
Trade/Device Name: Chartis Precision Catheter
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: January 4, 2026
Received: January 13, 2026

Dear Terry Solomon:

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 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 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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.	K253096

Please provide the device trade name(s).

Chartis Precision Catheter

Please provide your Indications for Use below.

The Chartis System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information.

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

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510k Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807 and in particular 21 CFR §807.87, the following summary of information is provided:

A. Submitted by:

Leah Andre
Principal Regulatory Affairs Specialist
Pulmonx Corporation
700 Chesapeake Drive
Redwood City, California 94063
Email: regulatory@pulmonx.com
Date Prepared: November 4, 2025

B. Device Name

Trade or Proprietary Name:	*Chartis Precision Catheter*
Common Name:	Tracheal/bronchial differential ventilation tube
Classification Name: (W/Wo Connector)	Tube, Tracheal/Bronchial, Differential Ventilation
Device Class:	Class II
Regulation Number:	21 CFR § 868.5740
Product Code:	CBI

C. Predicate Devices

The subject Chartis Precision Catheter is substantially equivalent to the predicate device Pulmonx Chartis Precision Catheter cleared in K222340.

D. Device Description

The Chartis Precision Catheter is a single-use, sterile balloon catheter designed for use with the Chartis Pulmonary Assessment System (Chartis System), which consists of the Chartis Catheter and the Chartis Console. The catheter is introduced through a bronchoscope, and once positioned, the distal balloon is inflated to temporarily occlude the target airway. The console measures pressure and airflow through the catheter to calculate resistance and quantify collateral ventilation, providing clinicians with information to guide lung volume reduction procedures. The catheter is constructed of biocompatible materials and incorporates a distal balloon, a lumen for airflow and pressure measurements, and a proximal connector to interface with the console. The

subject device, Chartis Precision Catheter, incorporates modifications limited to the sterilization method and labeled shelf life. There are no changes to the device's indications for use, intended use, principles of operation, contact materials, or packaging configuration compared to the predicate device (K222340). Despite the changes introduced to predicate Chartis Catheter (K222340) , the subject device Chartis Precision Catheter is substantially equivalent to the predicate as demonstrated by verification and validation testing performed using well established and FDA-recognized standards.

E. Indications for Use

The Chartis System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information.

The indications for use for the subject device Chartis Precision Catheter are identical to the originally cleared predicate Chartis Precision Catheter (K222340).

F. Technological Comparison

The introduction of subject device, Chartis Precision Catheter, includes change in sterilization method and extension of shelf-life. However, applicable verification and validation testing was performed using well-established test methods and FDA recognized standards demonstrating that the subject device's performance is substantially equivalent to the legally marketed predicate device, Chartis Precision Catheter (K222340).

The following table describes the summary comparison of technological characteristics of the subject device with the predicate devices:

Attribute	**Chartis Precision Catheter (Subject Device)**	**Chartis Precision Catheter (K222340 Predicate Device)**
Product Code	CBI	CBI
Regulation Number	868.5740	868.5740
Device Classification	Class II	Class II
Review Panel	Anesthesiology	Anesthesiology
Common Name	Tube, tracheal/bronchial, differential ventilation (w/wo connector)	Tube, tracheal/bronchial, differential ventilation (w/wo connector)

Attribute	Chartis Precision Catheter (Subject Device)	Chartis Precision Catheter (K222340 Predicate Device)
Intended Use	The Chartis G4 Catheter is part of the Chartis Pulmonary Assessment System, designed to measure pressure and flow in order to detect the presence of collateral ventilation in isolated lung compartments.	The Chartis G4 Catheter is part of the Chartis Pulmonary Assessment System, designed to measure pressure and flow in order to detect the presence of collateral ventilation in isolated lung compartments.
Indications for Use	The Chartis System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information.	The Chartis System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information.
Target Population	Adult patients with Chronic Obstructive Pulmonary Disease (COPD) and emphysema.	Adult patients with Chronic Obstructive Pulmonary Disease (COPD) and emphysema.
Use	Single Use, Disposable	Single Use, Disposable
Method of Use	The Chartis Catheter contains a balloon at its distal tip. It is advanced through a standard, previously positioned Bronchoscope. The balloon is advanced to the desired target airway location in the bronchus. The balloon is inflated in order to isolate the lung segment while pressure and flow measurements are being made using the Chartis Console.	The Chartis Catheter contains a balloon at its distal tip. It is advanced through a standard, previously positioned Bronchoscope. The balloon is advanced to the desired target airway location in the bronchus. The balloon is inflated in order to isolate the lung segment while pressure and flow measurements are being made using the Chartis Console.
Anatomical Site	Bronchial anatomy	Bronchial anatomy
Environment of Use	Bronchoscopy suite or operating room	Bronchoscopy suite or operating room
Compatibility	Compatible with Chartis Console	Compatible with Chartis Console
Inflation Volume	4 mL (cc)	4 mL (cc)
Airway Diameter Range	5-13 mm	5-13 mm
Catheter Length	145 cm	145 cm
Working Length	72 cm	72 cm
Connector Set Length	149.86 +/- 12.7 cm	149.86 +/- 12.7 cm
Balloon	Pellethane 2363 80AE, natural	Pellethane 2363 80AE, natural
Packaging Configuration	Catheter provided with Connector Set, integrated stopcocks and syringes	Catheter provided with Connector Set, integrated stopcocks and syringes
Shelf Life	36 months (3 years)	18 months
Biocompatibility	Tested per ISO 10993-1 standard;	Tested per ISO 10993-1 standard;

Attribute	Chartis Precision Catheter (Subject Device)	Chartis Precision Catheter (K222340 Predicate Device)
	Passes Cytotoxicity at time zero and at end of shelf-life (36 months), Sensitization, Irritation or Intracutaneous Reactivity (adopted into previous testing from predicate device, K222340) Gas Pathway Testing, including: Particulate Matter, Volatile Organic Compounds, Toxicological Risk Assessment	Passes Cytotoxicity at time zero and at end of shelf-life (18 months), Sensitization, Irritation or Intracutaneous Reactivity, Gas Pathway Testing, including: Particulate Matter, Volatile Organic Compounds, Toxicological Risk Assessment
Sterilization	Provided sterile Ethylene Oxide SAL 10^{-6}	Provided sterile E-beam radiation SAL 10^{-6}

G. Performance Data

The following performance testing was completed to demonstrate safety and efficacy in support of substantial equivalence determination which included functional testing of the subject device, Chartis Precision Catheter, to support the change in sterilization method (EO) and extension of shelf-life. The Chartis Precision Catheter completed the following functional testing after being subjected to sterilization, conditioning and distribution. In addition, the Chartis Precision Catheter successfully completed repeated functional testing and pouch seal tensile strength testing after sterilization and accelerated aging to validate its shelf-life in accordance with ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

H. Conclusion

The Chartis Precision Catheter has the same intended use as the predicate device. In addition, it has similar technological characteristics; performance data demonstrates that any differences in sterilization method and shelf-life claim do not raise different questions of safety or effectiveness. Therefore, the subject device, Chartis Precision Catheter, is substantially equivalent to the cleared predicate device, Chartis Precision Catheter (K222340).