December 1, 2022

Pulmonx Corporation
Aniket Khakhadiya
Principal Regulatory Affairs Specialist
700 Chesapeake Road
Redwood City, California 94063

Re: K222340
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: October 27, 2022
Received: October 28, 2022

Dear Aniket Khakhadiya:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

James J. Lee -S

James J. Lee, Ph.D.
Division Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222340

Device Name
Chartis Precision Catheter

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

K222340

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

Applicant Information:

Pulmonx Corporation
700 Chesapeake Drive
Redwood City, California 94063

Contact Person:

Aniket Khakhadiya
Email: akhakhadiya@pulmonx.com
Phone: (650) 216-0168 Ext. 268

Device Information:

Trade Name:	Chartis Precision Catheter
Regulation Name:	Tube, tracheal/bronchial, differential ventilation (w/wo connector)
Device Class:	II
Product Code:	CBI

Predicate Device:

Chartis Catheter, K111522, Pulmonx

Date Prepared:

July 29, 2022

Device Description:

The Chartis Precision Catheter is a single use, sterile, disposable device designed to be inserted into the working channel of a standard video or fiber bronchoscope during a diagnostic bronchoscopy procedure. After the target lung segment is accessed by the bronchoscope, the distal tip of the Chartis Precision Catheter can be introduced through the bronchoscope directly into the target airway. Inflation of the compliant balloon on the distal tip of the Chartis Precision Catheter causes the airway to become sealed and isolated. Air can then flow out of the isolated lung compartment into the environment only through the central lumen of the Chartis Precision Catheter. Assessment is accomplished by measuring air flows and pressures exiting the Chartis Precision Catheter lumen during spontaneous respiration or air flow during mechanical

ventilation. The Chartis Precision Catheter is designed for use in conjunction with the Chartis Console. The Chartis Console is a previously cleared device (under K180011) and the subject 510(k) is solely for the Chartis Precision Catheter.

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.

Comparison of Intended Use and Technological Characteristics with the Predicate Device:
The subject and the predicate devices have the same intended use in measuring pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments.

The subject and predicate device are based on the following same technological elements:

- Both devices operate with the Chartis Console as the Chartis System and have the same principles of operation.
- Both devices have the same general device description and are single use, sterile, disposable devices designed to be inserted through a 2.8 mm working channel of a standard video bronchoscope during a diagnostic bronchoscopy procedure.

The subject and predicate device have minor differences that do not raise new types of safety or effectiveness questions:

- The subject device is sterilized using E-beam radiation whereas the predicate device is sterilized using ethylene oxide.
- The subject device is packaged with the 3 mL and 10 mL syringes together in the same package whereas the predicate device does not include the 3 mL and 10 mL syringes.
- In the subject device, the 1-way stopcock and 3-way stopcock have been integrated into the Chartis handle and the Chartis Connector set, respectively. In the predicate device, the 1-way and 3-way stopcocks were provided separately.
- The subject device has a balloon working volume of up to 6 mL, airway diameter range of 5-15mm and burst requirement of at least 9 mL whereas the predicate device has a working volume of up to 3 mL, airway diameter range of 5-12mm and burst requirement of at least 6 mL. The balloon material is identical for the subject and predicate device.
- The subject device has a shorter overall length, longer connector set length and reduced catheter profile when compared to the predicate device.

- Material changes do not introduce new risks and have been shown to be biocompatible.

Non-clinical Testing / Performance Data:
Verification and validation tests have been performed in accordance with Design Controls as per 21 CFR §820.30. The following performance testing was completed to demonstrate safety and efficacy in support of substantial equivalence determination:

- Functional testing
- Shelf-life testing
- Packaging validation testing
- Biocompatibility testing
- Sterilization validation testing

Functional Testing
The Chartis Precision Catheter completed the following functional testing after being subjected to sterilization, conditioning and distribution:

- Balloon inflation, deflation and balloon burst testing
- Tensile testing of all fittings and joints of catheter, obturator, and connector set
- Airway resistance testing
- Bronchoscope deflection angle testing
- Obturator removal force testing
- Torque transmission and kink testing
- Leak testing
- Catheter insertion and withdrawal force testing
- Dimensional and visual inspection verifications
- Simulated use testing

Shelf-life Testing
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 F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Packaging Validation Testing
The Chartis Precision Catheter successfully completed packaging validation testing including visual inspection, bubble leak testing and pouch seal tensile strength testing after sterilization, conditioning and distribution in accordance with the following standards:

- ASTM D4332-2014, Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing

- ASTM D4169-2016, Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F2096-11(R19), Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)
- ASTM F88/F88M-2021, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1886/F1886M-2016 Standard Test Method for Determining Integrity of Seal for Flexible Packaging by Visual Inspection
- ISO 11607-1:2019, Packaging for Terminally Sterilized Medical Devices, Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2019, Packaging for Terminally Sterilized Medical Devices, Part 2: Validation requirements for forming, sealing and assembly processes

Biocompatibility Testing

The Chartis Precision Catheter is categorized per ISO 10993-1: 2018, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing*, as a surface device with limited (≤ 24 hours) mucosal membrane contact. Based on the device categorization, the following biological effects were evaluated for the Chartis Precision Catheter:

- Cytotoxicity at time zero and at end of shelf-life
- Sensitization
- Irritation or Intracutaneous Reactivity
- Gas Pathway Testing, including:
    - Particulate Matter
    - Volatile Organic Components
    - Toxicological Risk Assessment

The results of these evaluations support the conclusion that the Chartis Precision Catheter is biocompatible for its intended use.

Sterilization Validation Testing

The Chartis Precision Catheter is sterilized using electron beam radiation. A three lot validation study substantiated the sterilization dose for the electron beam irradiation process at a sterility assurance level (SAL) of 10^{-6} per validation method VD_{max}^{25} from the ISO 11137 series. The sterilization validation testing was successfully completed in accordance with the standards below:

- ANSI/AAMI/ISO 11137-1:2006(R2015) & A1:2013 & A2:2019, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices
- ANSI/AAMI/ISO 11137-2:2013(R2019), Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose

- ANSI/AAMI/ISO 11137-3:2017, Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects of development, validation and routine control
- ANSI/AAMI/ISO 11737-1:2018, Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
- ANSI/AAMI/ISO 11737-2:2019, Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Summary:

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 technological characteristics 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 Catheter.