July 13, 2018

Pulmonx Corporation
Ms. Sherry Kim
Sr. Regulatory Affairs Specialist
700 Chesapeake Drive
Redwood City, California 94063

Re: K180011
Trade/Device Name: Pulmonx Chartis Tablet Console
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: June 12, 2018
Received: June 13, 2018

Dear Ms. Kim:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180011

Device Name
Pulmonx Chartis Tablet Console

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.

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510(K) SUMMARY

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:

Sherry Kim
Email: skim@pulmonx.com
Phone: (650) 216-0189

Device Information:

Trade Name:	Pulmonx Chartis Tablet Console
Regulation Name:	Diagnostic Spirometer
Regulation Number:	21 CFR 868.1840
Device Class:	II
Product Code:	BZG

Predicate Device:

Chartis Console, K111764

Date Prepared:

June 7, 2018

Device Description:

The Chartis Tablet Console is a two-part spirometry system comprised of a touchscreen computer and sensor enclosure designed for use in the bronchoscopy suite in conjunction with the Chartis Catheter. The Chartis Catheter is a previously cleared device (under K111522) and the subject 510(k) K180011 is solely for the Chartis Tablet Console. The proximal end of the Chartis Catheter is attached to a polymer tube with a filter whose opposite end is attached to an input fitting on the Chartis Console. The balloon on the Chartis Catheter isolates the lung compartment of interest. The hardware components of the Tablet Console translate airflow and pressure detected through the Chartis Catheter into electrical signals. The Tablet Console analyzes and displays airflow and pressure from the isolated lung compartment in real time.

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 Tablet 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 as spirometry systems in measuring pressure and/or flow to detect the presence of 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 Catheter as the Chartis System and have the same principles of operation.
- Both devices have the same general device description. Both devices are comprised of a touchscreen computer, patient interface board and software.
- Both devices display air pressure, airflow, resistance and total volume of expired air.

Whereas the predicate device is indicated for all adult patients, the indications for use for the subject device specify the intended patient population as adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD). The computer and patient interface board of the predicate device are integrated into a single unit; in the subject device they are two physically separate components. The subject device allows segmental level assessments.

The subject device additionally provides a second display option called the Ventilator Mode. The Ventilator Mode provides a display option that may be preferred when the physician selects to perform the bronchoscopy and Chartis assessment on a patient under general anesthesia with mechanical ventilation. For clarification, the term “Ventilator Mode” does not signify it is intended for use in patients that are ventilator dependent outside of the procedure. The Standard Mode, which is available in both the predicate device and the subject device, provides a display option that may be preferred when the physician selects to perform the bronchoscopy and Chartis assessment on a patient under conscious sedation with spontaneous breathing. Both modes display the flow graphs, and both modes can be used to detect the presence of collateral ventilation in isolated lung compartments. The main difference in the display of the two modes is that the Ventilator Mode does not display inspiratory pressure and resistance since these measurements are not generated when mechanical ventilation is used during the procedure.

Performance Data:
The following performance data were provided to demonstrate safety and efficacy in support of substantial equivalence determination:

Test	**Results and Conclusions**
Software verification and validation	Test samples passed all acceptance criteria. PASS
Electrical safety per applicable requirements of AAMI ANSI ES60601-1 and IEC 60601-1-6.	Test samples passed all acceptance criteria. PASS
Electromagnetic compatibility per applicable requirements of IEC 60601-1-2	Test samples passed all acceptance criteria. PASS
Hardware Verification Testing	Test samples passed all acceptance criteria. PASS

Hardware Review	Test samples passed all acceptance criteria. PASS
Operational Temperature and Humidity Conditioning	Test samples passed all acceptance criteria. PASS
Stress Cycling Testing	Test samples passed all acceptance criteria. PASS
Repeated Cleaning and Tablet Stand Cycling Testing	Test samples passed all acceptance criteria. PASS
Usability Evaluation per IEC 62366	Test samples passed all acceptance criteria. PASS
Packaging Validation per applicable requirements of ASTM D4332, ASTM 4169	Test samples passed all acceptance criteria. PASS

Summary:

The Pulmonx Chartis Tablet Console 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 Pulmonx Chartis Tablet Console is substantially equivalent to the cleared predicate device.