510 (k) Summary K 111764 NOV 10 2011

Proprietary Name: Chartis™ Console

Classification Name: Spirometer, Diagnostic
21 CFR 868.1840 Class II
Classification: BZG

Common Name: Spirometer, Diagnostic

Manufacturer: Pulmonx, Inc.
700 Chesapeake Drive
Redwood City, CA 94063
650-364-0400 (phone)
650-364-0403 (fax)

Contact: Rich Ferrick
VP, Regulatory Compliance and Quality Assurance

Preparation Date: June 22, 2011

Predicate Device:

The Chartis Console is substantially equivalent to the following currently marketed predicate device:

Chartis Console (K083199, cleared on June 25, 2009, product code BZG, regulation number 868.1840)

Device Description:

The Chartis Console is an integrated, self-contained, 12 VDC powered system designed to be used in the bronchoscopy suite in conjunction with the Chartis Catheter. 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 Cathter isolates the lung compartment of interest. The hardware components of the Console translate air flow and pressure detected through the Chartis Catheter into electrical signals. The Console analyzes and displays airflow and pressure from the isolated lung compartment in real time.

Intended Use:

The Chartis System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients 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 a re-useable piece of capital equipment that displays the patient information.

Technological Characteristics:

The modified Chartis Console is substantially equivalent to the predicate Chartis Console with regard to technological characteristics. The minor changes to graphic display, hardware, software, packaging and service/calibration do not raise new types of safety or effectiveness questions.

Performance Data:

Verification and validation test results support the performance characteristics of the modified device and show equivalence to the currently marketed predicate device.

Conclusion:

The Chartis Console is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Hans Schulz
Director, Quality Assurance
Pulmonx, Incorporated
700 Chesapeake Drive
Redwood City, California 94063

NOV 10 2011

Re: K111764
Trade/Device Name: Chartis™ Console
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: October 10, 2011
Received: October 12, 2011

Dear Mr. Schulz:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number Not known K111764

Device Name Chartis Console

Indications for Use The Chartis System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients 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 a re-useable piece of capital equipment that displays the patient information.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____
(Per CFR 801.109)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111764