510(k) SUMMARY

JUN 25 2009

Proprietary Name: Chartis™ Catheter

Classification Name: Tube, tracheal/bronchial, differential ventilation (w/wo connector)
21 CFR §, 868.5740 Class II
Classification: CBI

Common Name: Tube, tracheal/bronchial, differential ventilation (w/wo connector)

Manufacturer: Pulmonx, Inc.
1047 Elwell Court
Palo Alto, CA, 94303

Contact: Hans Schulz
Director, Quality Assurance

Preparation Date: June 16, 2009

Predicate Devices:

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

(1) Endobronchial Blocker marketed by Cook. (K021920, cleared August 14, 2002, product code CBI, regulation number 868.5740)

Device Description:

The Chartis Catheter consists of two components which are pouched separately and provided to the user in a single shelf carton with the Instructions for Use. These two components are the Chartis Catheter and the Connector Set. The Catheter is the patient contact component while the Connector Set acts to connect the Chartis Catheter to the Chartis Console (which is documented in a concurrent 510(k) submission). The system is designed to be used by experienced bronchoscopists during a diagnostic bronchoscopy in a hospital bronchoscopy suite for functional assessment of air pressures and flows in isolated lung compartments.

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 of Substantial Equivalence:

The Chartis Catheter is substantially equivalent to the Endobronchial Blocker marketed by Cook. (K021920, cleared August 14, 2002, product code CBI, regulation number 868.5740) with regard to materials, safety, efficacy and lung isolation.

Performance Data:
Bench test results support the performance characteristics of the device and show equivalence to the currently marketed predicate device. Design durability was tested in the laboratory and animal studies were used to validate performance of the system in a simulated clinical environment, as well as verify the performance to design specifications and the durability of the device.

Conclusion:
The Chartis Catheter does not raise new questions of safety or effectiveness when compared to the legally marketed predicate device, and is substantially equivalent to the referenced predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 2009

Mr. Hans Schulz
Director of Quality Assurance
Pulmonx, Incorporated
1047 Elwell Court
Palo Alto, California 94303

Re: K083883
Trade/Device Name: Chartis ™ Catheter
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: June 16, 2009
Received: June 24, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

510(k) Number (if known): K083883

Device Name: Chartis™ Catheter

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.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page __ of ___

(POSTED)

L Schulte

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

510(k) Number: K083883