K112051

OCT 1 2 2011

510(k) Summary

1. Date of Summary

June 30, 2011

2. 510(k) Applicant

Broncus Technologies, Inc.
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3. Device Overview

Trade Name: LungPoint™ Planning and Virtual Bronchoscopic Navigation (VBN) Software

Common Name: Picture Archiving and Communications Systems

Classification Name: System, Image Processing, Radiological
21 CFR 892.2050
Product Code LLZ

4. Predicate Device

The predicate devices identified are as follows:

Trade Name	510(k) Submitter	510(k) Number
LungPoint Planning and Virtual Bronchoscopic Navigation (VBN) System	Broncus Technologies, Inc	K091160, cleared to market on May 5, 2009
inReach System	SuperDimension	K110093, cleared to market on February 11, 2011, (and K071473, K092365, and K102604, by reference)

5. Device Description

The LungPoint Software is a device that guides a bronchoscope and commercially available endoscopic tools to a prespecified target in or adjacent to the bronchial tree by providing a path, which is displayed on a 3D reconstruction of a CT scan. The Software allows visualization of the interior of the bronchial tree; placement of catheters in the bronchial tree; visualization of a prespecified target in lung tissue; and placement of markers into soft lung tissue to guide radiosurgery and thoracic surgery. The FlexNeedle is an aspiration needle. When used together with the LungPoint Software, the needle can be guided to a prespecified targeted area within the respiratory organs.

The software is installed on an off-the-shelf PC computer system, and is intended to be used with commercially-available flexible bronchoscopes with CT scans that are saved in DICOM format.

6. Intended Use

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

7. Comparison to Predicate Device

The LungPoint Software with FlexNeedle has the same intended use and technological characteristics as the predicate devices.

8. Performance Data

The existing risk analysis for the LungPoint Software was reviewed to assess whether guidance of the FlexNeedle adds any new hazards. No new risks were identified as the use of endoscopic tools, like the FlexNeedle, is inherent to the design and intended use of the existing LungPoint Software. Additionally, no new verification and validation testing was performed as the software was not modified in any way to allow for the use of the FlexNeedle.

9. Safety and Effectiveness

The labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the software. Risk management is ensured via a hazard analysis and FMECA, which are used to identify potential hazards. These potential hazards are controlled via software development, verification testing and/or validation testing.

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

Broncus Technologies, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

OCT 12 2011

Re: K112051
Trade/Device Name: LungPoint™ Planning and Virtual Brochoscopic Navigation (VBN) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: October 3, 2011
Received: October 6, 2011

Dear Mr. Job:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 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/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112051

Device Name: LungPoint™ Planning and Virtual Bronchoscopic Navigation (VBN) Software

Indications for Use: Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112051