510(k) Summary
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Proprietary or Trade Name: LungVision System

Common/Usual Name: System, image processing, radiological

Classification Name: Picture archiving and communications system
LLZ, Class II, CFR 892.2050

Predicate Device: BodyVision – LungVision – K163622

Reference Device: Covidien - superDimension™ Navigation System V7.2
K173244

Device Modification

1. Virtual Bronchoscopy
    a. A standard technology in the field of pulmonology. This is a visualization technique showing the same information already available in the CT scan.
2. Software upgrades
    a. C-Arm based Tomography – visual aid. Collecting a number of successive images produced by a standard C-Arm which are digitally "stacked" together to form an additional alternative visualization of imaging information sourcing from standard C-Arm.
    b. Multi view Setup - an algorithm improvement. Same airway based registration algorithm, extended to multiple C-Arm angles. previous was limited to one angle (AP, LAO, RAO or other C-Arm position)
3. Real time compensation
    a. Predicate displays a static target overlay on the fluoroscopic image, whereas the proposed modification performs small adjustments related to the tool movement on the fluoroscopic screen to the target overlay.
4. 3D Guidance
    a. Predicate calculates the tool position with respect to pre-operative CT. The proposed modification provides 3D visualization for those calculations in addition to the existing screen.
5. Use of a Tablet in addition to PC
    a. The Tablet image displayed is not for diagnostic purposes.

None of these modifications changes the indications for use, environment of use or patient population.

Description:
The LungVision System (K163622) is designed to enable users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with live X-ray images of the same anatomy in order to support catheter/device navigation during pulmonary procedures.

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The LungVision System is designed to assist the physician in guiding endobronchial tools towards the target area of interest inside the patient lungs. Prior to the endoscopic procedure the system allows planning the target location and the path to the target area on the CT scan. During the endoscopic procedure the system overlays planned data over fluoroscopic images to support endobronchial tool navigation towards the area of interest. The system does not include the Fluoroscope, Bronchoscope or the external monitor.
LungVision system includes a main unit and a tablet vs. the previous PC based hardware platform. Image processing algorithms are executed on the main unit and the tablet is used as a primary method of interacting with the system. The Tablet is for planning but is not for diagnostic purposes. Both can perform the following functions:

- segment previously acquired DICOM 3D CT image data,
- register DICOM 3D CT image data with live fluoroscopic X-ray image
- overlay the segmented 3D CT dataset over a live fluoroscopic X-ray image of the same anatomy, obtained on a Fluoroscopic system.

System Components Overview
The following is a list of the LungVision System's main components:
LungVision Main Unit
LungVision Tablet
LungVision Router
LungVision Board (passive device)
LungVision Software

Tablet is off-the-shelf information technology equipment powered from the medical grade power supply. The system has been evaluated to AAIM ANSI ES 60601-1 2005+ A1:2012 and IEC 60601-1-2: 2014.

Indications for Use:
The LungVision System is intended to enable users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with fluoroscopic live X-ray images of the same anatomy in order to support catheter/device navigation during pulmonary procedures.

Contraindications:
None

Device Comparison

Table 1 compares the subject device to the predicate

Feature	Proposed Device LungVision	Primary Predicate K163622 Body Vision-LungVision
Indications for Use	The LungVision System is intended to enable users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with fluoroscopic live X-ray images of the same anatomy in order to support catheter/device navigation during pulmonary procedures.	The LungVision System is intended to enable users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with fluoroscopic live X-ray images of the same anatomy in order to support catheter/device navigation during pulmonary procedures.
Classification	Picture archiving and communications system 21CFR 892.2050	Picture archiving and communications system 21CFR 892.2050

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Feature	Proposed Device LungVision	Primary Predicate K163622 Body Vision-LungVision
	Product Code: LLZ	Product Code: LLZ
Target anatomy	Lungs	Lungs
Anatomy access	Bronchial airways	Bronchial airways
Windows OS	Windows 10	Windows 10
Medical imaging software	Yes	Yes
General Image 2D/3D review	Yes	Yes
3D rendering view	Yes	Yes
Multi-modality Support	Yes	Yes
Image registration	Yes	Yes
Multi-planar reformatting (MPR)	Yes	Yes
DICOM import	Yes	Yes
Fluoroscopic video	Yes	Yes
Standard Image viewing tools	Yes	Yes
Segmentation tool	Yes	Yes
Video capture	Yes	Yes
Live Image overlays	Yes	Yes
Import prior plans	Yes	Yes
Point marking/ tagging	Yes	Yes
Navigation type	Visual	Visual
Modifications		
Virtual bronchoscopy	Yes	No Reference Covidien - superDimension™ Navigation System V7.2 - K173244
C-Arm based Tomography	Yes	No
Multi-view set-up	Yes	No
Real-time compensation	Yes – software upgrade	No
3D Guidance	Yes – software upgrade	No

Substantial Equivalence Discussion

We will discuss the table above.

Indications for Use / Patient Population / Environment of Use: As in comparison of Indications For Use above, we can conclude that the indications for use for the LungVision and the predicate are substantially equivalent.
Discussion: The differences in proposed indications for use are minor. The minor differences do not raise new risk or safety concerns, and the subject device can be found substantially equivalent.

Prescriptive: Both the LungVision and predicate are prescription devices.

Discussion: There are no differences.

Design and Technology: The LungVision utilizes the same technological characteristics as the predicate and reference devices. Both include:

- software applications that provide 2D and 3D medical image acquisition including real-time video image acquisition and visualization of the anatomy
- allow co-registration of real-time images to previously created 3D image sets based on previously collected DICOM CT images
- include image enhancements such as contrast and brightness, zoom and pan capabilities
- addition of a Tablet to the PC but not to be used for diagnostic purposes

For the Virtual Bronchoscopy feature the reference device - Covidien - superDimension™ Navigation System V7.2 - K173244 has the same feature and intended use.

Discussion: The software modifications including virtual bronchoscopy, C-arm based Tomography, 3D Guidance, and Real-time compensation are similar to the reference device.

Performance and Specifications:
The performance and specifications demonstrate that the LungVision and predicate devices perform the same functions using the same technologies thus can be found substantially equivalent.
Discussion: There are no differences, thus the subject device can be found substantially equivalent.

Compliance with Standards:
LungVision includes hardware and complies with ANSI/AAMI/ES 60601-1:2005(2012) and IEC 60601-1-2:2014.
Discussion: The proposed device complies with the latest standards and thus can be found substantially equivalent.

Performance Testing:

Nonclinical / Bench: We have performed bench tests and found that the LungVision met all requirements specifications and was found to be equivalent in comparison to the predicate. Testing includes verification testing of the requirements, testing of hazards mitigations) and performance testing of the system.

Testing has also been performed with pig lungs to test accuracy in deformable tissue.

Biocompatibility: There are no patient contacting parts of the LungVision System

Animal: No animal testing was performed

Clinical: No clinical testing was performed

Substantial Equivalence Conclusion
Based upon the foregoing performance testing and comparison to the legally marketed predicate devices for indications for use, technology, and performance we believe we have demonstrated that the LungVision System is substantially equivalent in safety and effectiveness to the predicate device.