

LungVision

Category:

Best Medical Technology

Company Name:

Body Vision Medical

Product/Solution Name:

LungVision

Compound/Tech Name:

AI-driven real-time imaging

Trade Name:

AI Tomography

Corporate Name:

LungVision

Date of Approval:

2024-10-01

Indications:

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.

Therapeutic Areas:

Localized, minimally-invasive lung cancer therapy delivery

General Information File Document upload:

K183593 LungVision System Gen 2.pdf

Background information and need for drug / device:

Lung cancer is the leading cause of cancer-related deaths worldwide, with an estimated 1.8 million deaths (18%) in 2020. Unfortunately, lung cancer is often diagnosed at advanced stages when treatment options are limited. Therefore, there is a growing need for efficient patient screening to allow early detection and improve survival rates. There are two popular ways to diagnose lung cancer. The first is transthoracic needle aspiration (TTNA), usually conducted under ultrasound, computed tomography (CT), or fluoroscopic guidance. This method is an effective way to diagnose the primary tumor mass and establish a diagnosis of lung cancer. However, the procedure has a high complication rate and can lead to pneumothorax, hemorrhage, and air embolism. The alternative technique is transbronchial biopsy. The method involves inserting a flexible bronchoscope through a patient's mouth to collect several pieces of lung tissue. The procedure is less invasive and creates fewer complications; however, it also has a lower diagnosis success rate than TTNA generally not exceeding 70%.

LungVision® uses a proprietary AI algorithm can to transform 2D X-ray images from any conventional C-arms into real-time CT scans. During diagnostic bronchoscopy procedures, bronchoscopists can visualize the lung lesion and its exact location, leading to a higher chance of an early and definitive diagnosis for potential lung cancer patients, improving the probability of timely treatment and patient survival. Recent clinical data confirmed LungVision® AI-driven intraoperative imaging can achieve a remarkable 89% diagnostic yield when used standalone for navigation and real-time imaging, 91.1% diagnostic yield in conjunction with the Ethicon Monarch™ Robot-Assisted Bronchoscopy (RAB) platform, and 94.5% diagnostic yield in conjunction with the Ion by Intuitive RAB platform.

Key Features and Benefits:

1. AI-powered intraoperative imaging: LungVision uses AI to transform standard C-arm X-ray images into real-time, intraoperative CT scans.
2. 3D imaging: The system provides a 3D view of the lungs, allowing for better visualization of lesions and their relationship to the surrounding airways.
3. Enhanced navigation: LungVision provides real-time image guidance, helping bronchoscopists accurately navigate to and biopsy lung lesions.
4. Improved biopsy accuracy: The system enables more precise and accurate bronchoscopic biopsies, leading to more confident diagnoses.
5. Minimally invasive procedures: LungVision supports minimally invasive procedures for lung cancer diagnosis and treatment.
6. Cost-effectiveness: The system offers potential radiation exposure benefits and reduced total cost of ownership compared to 3D C-arms.

Impact and Applications:

1. Early-stage lung cancer diagnosis: LungVision enables earlier and more accurate diagnosis of lung cancer, potentially leading to improved patient outcomes.
2. Smaller lesion access: The system allows for biopsy of smaller, more difficult-to-access lung lesions, which were previously difficult to diagnose.
3. Improved patient outcomes: By enabling more accurate and efficient diagnosis, LungVision contributes to improved patient outcomes and reduced need for additional procedures.
4. Global impact: Body Vision Medical has made LungVision available in various countries including the US and most EU countries and is working to expand access to this technology globally.

Background File Document upload:

**Frost and Sullivan Technology Innovation Leadership Award 2023
Body Vision Medical.pdf**

History of the development of the solution/product:

Body Vision Medical, founded in 2014 by Dorian Averbuch, has significantly advanced lung cancer diagnostics through the development of the LungVision® system. Recognizing the limitations of electromagnetic navigation bronchoscopy (ENB), particularly the CT-to-body divergence issue, Averbuch aimed to create a more reliable, real-time imaging solution for pulmonary lesion diagnosis. This led to the development of C-Arm-Based Tomography (CABT), which transforms 2D fluoroscopic images into 3D tomographic scans using artificial intelligence (AI), enabling real-time visualization of pulmonary lesions during bronchoscopy procedures .

Key Milestones in LungVision® Development:

May 2017: The U.S. Food and Drug Administration (FDA) granted clearance for the LungVision® system, allowing real-time navigation and lesion localization during bronchoscopic procedures. This system integrates intraoperative fluoroscopy with pre-operative high-resolution imaging, such as computed tomography (CT), to enhance diagnostic accuracy .

April 2018: FDA clearance was obtained for the LungVision Tool, a navigation catheter designed to work with standard bronchoscopes and the LungVision system, facilitating access to small pulmonary nodules .

May 2019: The FDA cleared LungVision® 2.0, which introduced real-time tool-in-lesion confirmation and seamless integration with the LungVision Tool. This version enhanced the system's ability to visualize fluoroscopically "blind" lesions during biopsy sampling using any conventional C-Arm .

September 2023: The LungVision® system achieved EU-MDR certification as a Class IIa

medical device, making it the first lung navigation and real-time imaging platform to obtain this certification under the new European Medical Device Regulation .

October 2024: A new FDA 510(k) clearance encompassed significant enhancements to the LungVision® system. Notably, the LungVision® v2.27 software update introduced the latest AI Tomo® imaging algorithm, which offers a larger field of view. This advancement improves the reach and fidelity of virtual bronchoscopy in peripheral airways and provides an enhanced pathway planning experience. These improvements are designed to assist bronchoscopists in navigating to and accurately sampling small pulmonary lesions, thereby increasing diagnostic yield and facilitating earlier-stage cancer detection.

Development File Document upload:

N/A

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

Lung cancer is the leading cause of cancer mortality worldwide. Despite advances in therapy, overall, 5-year survival is approximately 18 percent in the US and as low as 10 percent globally. Five-year survival using clinical staging ranges from 92 percent (stage IA1) to less than 2 percent (stage IVB). The key to improving survival is early diagnosis of malignant tumors. Data from multiple clinical studies demonstrates that screening high-risk patients increases early-stage diagnosis and reduces lung cancer-related mortality. As more small nodules are found during lung cancer screening or incidentally on a chest image, the need to biopsy these nodules in order to obtain a definitive diagnosis will increase.

Lung nodule biopsies are obtained through surgical resection, trans-thoracic needle aspiration (TTNA), or navigational bronchoscopy, all of which have their shortcomings. Surgical resection and TTNA, while having high diagnostic yield rates, also have comparatively high complication rates. Conversely, navigational bronchoscopy is relatively safe but, historically, has had, at best, a roughly 70% success rate in yielding a definitive diagnosis.

Due to surgical resection and TTNA's poor risk-benefit profile, and navigational bronchoscopy's lack of diagnostic accuracy, patients with small lung nodules are often sent home for "watchful waiting." Thus, not only do limitations of existing diagnostic methodologies currently prevent the diagnosis of lung cancer early in the patient journey, but the lack of an effective diagnostic pathway for lung patients with suspicious pulmonary nodules (SPNs) hinders existing lung cancer screening programs from realizing their full potential.

Body Vision Medical's LungVision® platform addresses this diagnostic gap by providing the real-time imaging needed in bronchoscopy biopsies to achieve diagnostic yields approaching, if not exceeding, 90%, regardless of nodule size. LungVision® technology turns any conventional C-arm, a commodity present in every bronchoscopy suite, into a real-time intraoperative advanced imaging device. LungVision® provides the most accurate, least expensive approach to diagnosing small lung nodules in the market, enabling global lung cancer screening and early-stage lung cancer diagnosis a reality.

Innovation File Document upload:

[Current Challenges in Lung Cancer Care Body Vision Medical.pdf](#)

Please provide appropriate references (PubMed, Abstract, Website):

See attached.

References File Document upload:

[MSM00047 Rev 01 FAQ Clinical Evidence in Support of LungVision.pdf](#)

[MSM00048 Rev 02 LungVision Clinical and Financial Impact.pdf](#)

[Radiation in the bronchoscopy suite_Tsai.pdf](#)

[Roshen Mathew paper.pdf](#)

[Grady BV Abstract from CHEST 2022.pdf](#)