BodyVision Ltd.
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

October 1, 2024

Re: K240943
Trade/Device Name: LungVision
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 30, 2024
Received: August 30, 2024

Dear Paul Dryden:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

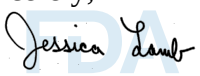
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,



Jessica Lamb, Ph.D.
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240943

Device Name

LungVision

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
30-Aug-24

Official Contact: Benny Krauz – VP RA/QA
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Submission Correspondent: Paul Dryden
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St. Petersburg, FL 33704

Proprietary or Trade Name: LungVision System

Common/Usual Name: System, image processing, radiological

Classification Name: Automated radiological image processing software
QIH, CFR 892.2050
Picture archiving and communications system
LLZ, CFR 892.2050

Predicate Device: BodyVision – LungVision – K183593
Picture archiving and communications system
LLZ, CFR 892.2050

Description:
The LungVision System 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.

The System is intended to assist the guidance of endobronchial tools to areas of interest inside a patient's lungs. The System allows the user to mark lesion locations and pathways to marked lesions using a patient's CT scan. During the endoscopic procedure, the System overlays planning information on real-time fluoroscopic images to guide endobronchial tool navigation. The System also provides tomographic images for lesion identification, as well as 3D views for understanding tool and lesion proximity and orientation. The System is designed to be integrated with fluoroscopic imaging systems and external displays.

The LungVision system includes a main unit and a tablet. Image processing algorithms are executed on the main unit and the tablet is used as a primary method of interacting with the 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

The submission includes claims of:
- Transform 2D X-ray images into intraoperative tomographic scans
- AI-driven intraoperative tomographic imaging

- We find that this reflects the functionality of AI TOMO feature. The system receives CABT output and transform them into tomographic imaging.
- CABT is a limited angle tomography based on the SIRT algorithm

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 K183593 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	Automated radiological image processing software QIH, CFR 892.2050 Picture archiving and communications system LLZ, CFR 892.2050	Picture archiving and communications system LLZ, CFR 892.2050
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

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Feature	Proposed Device LungVision	Primary Predicate K183593 Body Vision LungVision
Point marking/ tagging	Yes	Yes
Navigation type	Visual	Visual

Feature	Proposed Device LungVision	Primary Predicate K183593 Body Vision LungVision
Modifications		
Virtual bronchoscopy	Yes	Yes
C-Arm based CT	Yes	Yes
Multi-view set-up	Yes	Yes
Real-time compensation	N/A	Yes
3D Guidance	Yes	Yes

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 similar technology as the predicate. This includes:

- 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

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.

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Discussion: The proposed device complies with the latest standards and thus can be found substantially equivalent.

Non-clinical / Bench Performance Testing:
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 on physical and simulated lung models representing deformable tissue.

For AI-Tomo the clinical validation was performed by physicians with data that was recorded from historical LungVision clinical cases. Cases were selected to include a representative range of lesion sizes, types, and locations, as well as a range of tools.

Simulated cases: synthetically simulated test cases, based on real human's CT scans. With this method we can simulate a lot of different use cases, and use diverse data. This method uses simulated data in a simulated environment, and therefore measures the registration error only, without additional real-world inaccuracies: CT to body divergence, jig estimation errors, fluoroscope distortion etc.

The mean accuracy calculated for 500 cases is 3.15 mm with 3.2 mm std.

Rigid body model cases: Laboratory test cases recordings and analysis in a patient simulated environment with a rigid lung model under real-time fluoroscopy.

This method provides a lower amount of test cases, as it uses only one lung anatomy with one ground truth transform. It is closer to a real-world scenario as it is influenced by jig estimation errors and fluoroscope distortion, but still does not include CT to body divergence.

The mean accuracy calculated for 93 cases is 3.64 mm with 1.57 mm std.

CBCT scans cases: test cases based on real human's CT scans and real human's CBCT scans taken in real procedures. This method is based on real cases data and therefore represents a real-world scenario and influenced by real-world inaccuracies: CT to body divergence, jig estimation errors, fluoroscope distortion etc.

The mean accuracy calculated for 191 cases is 5.34 mm with 3.32 mm std

The clinical validation of AI Tomo confirmed that lesion marking accuracy was comparable when using CABT and AI Tomo images. Therefore, regardless of the imaging modality used, the accuracy of the registration process remains consistent.

The images are CABTs collected from real cases performed by physicians using the LungVision system in the USA, Italy, and Israel. The CABTs are used as input data to the AI-Tomo post processing, and the output is evaluated using the ground truthing methodology.

Ground Truth methods included:
- Geometry test
- Lesion contrast on real data tests (with and without tool)

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

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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.