DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Body Vision Medical Ltd. May 16, 2017
% Mr. Paul Dryden
Consultant
PROMEDIC, LLC
24301 Woodsage Drive
BONITA SPRINGS FL 34134

Re: K163622
Trade/Device Name: LungVision System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: April 13, 2017
Received: April 14, 2017

Dear Mr. Dryden:

This letter corrects our substantially equivalent letter of May 11, 2017.

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. 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.

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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

For
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K163622

Device Name

LungVision System

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)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Official Contact: Dorian Averbuch
Body Vision Medical Ltd.
34 Sokolov St.
Ramat Hasharon Israel
Tel: 646- 863-7848 (US)

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: Philips EP-Navigator K062650

Device Description:
The LungVision System is designed enabling 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 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 image processing algorithms are executed on a PC based hardware platform, which 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:

- Laptop with a mouse and DVD reader
- Video Capture Box
- IEC 60601-1compliant Isolation Transformer
- LungVision Board (passive device)
- LungVision Software

The laptop mouse and DVD reader are off-the-shelf information technology equipment powered from the isolation transformer. The video capture box is manufactured by BodyVision and is also powered from the isolation transformer. The system above has been evaluated to AAIM ANSI ES 60601-12005+ A1:2012 and IEC 60601-1-2: 2014. The system connects to customer supplied imaging and display devices.

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	Predicate K062650 Philips EP-Navigator	Proposed Device LungVision	Comments
Indications for Use	EP-Navigator is intended to enable users to segment previously acquired 3D CT datasets and overlay and register these 3D segmented data sets with live fluoro X-ray images of the same anatomy in order to support catheter/device navigation during specified 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.	Substantially equivalent
Classification	Picture archiving and communications system 21CFR 892.2050 Procut Code: LLZ Class II	Picture archiving and communications system 21CFR 892.2050 Procut Code: LLZ Class II	Similar
Target anatomy	Heart	Lungs	Different anatomy same process
Anatomy access	Cardiac vessels	Bronchial airways	Different anatomy same process
Windows OS	Yes (Windows 7)	Yes (Windows 10)	LungVision uses latest version of Windows OS
Medical imaging software	Yes	Yes	equivalent
General Image 2D/3D review	Yes	Yes	equivalent
3D rendering view	Yes	Yes	equivalent
Multi-modality Support	Yes	Yes	equivalent
Image registration	Yes	Yes	equivalent
Multi-planar reformatting (MPR)	Yes	Yes	equivalent

Feature	Predicate K062650 Philips EP-Navigator	Proposed Device LungVision	Comments
DICOM import	Yes	Yes	equivalent
Fluoroscopic video	Yes	Yes	equivalent
Standard Image viewing tools	Yes	Yes	equivalent
Segmentation tool	Yes	Yes	equivalent
Video capture	Yes	Yes	equivalent
Live Image overlays	Yes	Yes	equivalent
Import prior plans	Yes	Yes	equivalent
Point marking/ tagging	Yes	Yes	equivalent
Navigation type	Visual	Visual	equivalent

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 devices.
Both:

- are PC based software applications that provide 2D and 3D medical image acquisition including real-time video image acquisition arid visualization of the anatomy
- use Windows operating systems
- 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

Discussion: Same design and technology.

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 IEC 60601-1:2005 and IEC 60601-1-2:2014. The EP Navigator includes hardware and complies with IEC 60601-1:2005 and IEC 60601-1-2:2007
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 BodyVision 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.

The device was also tested to the requirements of ANSI AAMI ES 60601-1 and IEC 60601-1-2.

Biocompatibility:
There are no patient contact 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.