April 26, 2018

Body Vision Medical Ltd.
% Paul Dryden
Consultant
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, FL 33704

Re: K172955
Trade/Device Name: LungVision Tool
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: March 22, 2018
Received: March 23, 2018

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 (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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172955

Device Name
LungVision Tool

Indications for Use *(Describe)*
LungVision Tool is an instrument designed as a working channel intended to be used with standard bronchoscopes, endotherapy accessories and ultrasound probe to guide the endotherapy accessories or ultrasound probe to the target area, specifically within the respiratory system.

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.

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510(k) Summary

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

Date Prepared: April 19, 2018

Proprietary or Trade Name: LungVision Tool

Common/Usual Name: Bronchoscope (flexible or rigid) and accessories

Classification Name: Bronchoscope (flexible or rigid) and accessories
EOQ, Class II, CFR 874.4680

Predicate Device: K060243 - Olympus Sheath Guide
Reference Device: K151315 - Boston Scientific Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle ("EPEUTAN")

Device Description:
LungVision Tool is an instrument designed as a working channel intended to be used with standard bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasound probe to the target area, specifically within the respiratory system.

LungVision tool is designed to be used by pulmonologists or thoracic surgeons during pulmonary procedures.

The LungVision Tool is designed to be connected to a standard Bronchoscope Instrument Port.

The LungVision Bronchoscope Adaptor is used to connect the LungVision Handle to the Bronchoscope *instrument port / working channel entrance,* and to allow the physician to release the tool from the bronchoscope. The current adaptor is for the Olympus Bronchoscope Model BF-1T160.

More types of Bronchoscope Adaptors for other bronchoscopy brands and models.

LungVision Tool Sheath can accommodate endo-therapy accessories and ultrasound probes with an outer diameter up to 1.9 mm.

Indications for Use:
LungVision Tool is an instrument designed as a working channel intended to be used with standard bronchoscopes, endotherapy accessories and ultrasound probe to guide the endotherapy accessories or ultrasound probe to the target area, specifically within the respiratory system.

Patient Population
Patients undergoing endoscopic procedures.

Contraindications
Contraindications are limited to those of the use of a bronchoscope of the endotherapy instruments that the clinician may desire to use.

510(k) Summary

Environments of use
Anywhere a patient may undergo a bronchoscopy procedure, e.g., hospital, sub-acute care or physician office settings.

Device Comparison

The following tables compare the subject device to the predicate and reference devices.

Feature	**Predicate K060243 Olympus Guide Sheath**	**Reference K151315 Boston EPEUTAN**	**Subject device K172955 LungVision Tool**
Intended Use	To be used with bronchoscopes and endo-therapy accessories	To be used with bronchoscopes and endo-therapy accessories	To be used with bronchoscopes and endo-therapy accessories
Anatomical location	Respiratory organs	Respiratory organs	Respiratory organs
Components			
Handle	Handle-like	Yes	Yes
Connector / Adaptor to attach to working channel	Stopper	Yes	Yes
Sheath	Yes	Yes	Yes
Wire / stylet to stiffen or protect the sheath	No	Yes	Yes
Works with endo-therapy instruments	Yes	Yes	Yes

As can be seen the predicate, reference and subject device have similar intended uses, conditions of use, and components.

510(k) Summary

Feature	Predicate K060243 Olympus Guide Sheath	Reference K151315 Boston EPEUTAN	Subject Device K172955 LungVision Tool
Indications for Use	This instrument has been designed to be used with Olympus bronchoscopes, endo-therapy accessories and ultrasound probe to guide the endo-therapy accessories or ultrasound probe to the target area within the respiratory organs.	The Expect™ Pulmonary Endobronchial Ultrasound Transbronchial Aspiration Needle is designed to be used with endobronchial ultrasound endoscopes for ultrasound guided fine needle aspiration (FNA) of the submucosal and extramural lesions of the tracheobronchial tree. Do not use this instrument for any purpose other than its intended use.	LungVision Tool is an instrument designed as a working channel intended to be used with standard bronchoscopes, endotherapy accessories and ultrasound probe to guide the endotherapy accessories or ultrasound probe to the target area, specifically within the respiratory system.
Classification	Bronchoscope (flexible or rigid) and accessories. 21CFR 874.4680 Procut Code: EOQ	Bronchoscope (flexible or rigid) and accessories. 21CFR 874.4680 Procut Code: EOQ	Bronchoscope (flexible or rigid) and accessories. 21CFR 874.4680 Procut Code: EOQ
Target anatomy	Respiratory Organs	Respiratory Organs	Respiratory Organs
Anatomy access	Bronchial airways	Bronchial airways	Bronchial airways
Patient Population	Not specified but for patients undergoing endoscopic procedures	Not specified but for patients undergoing endoscopic procedures	Patients undergoing endoscopic procedures
Environment of use	Not specified but where endoscopic procedures are performed: hospitals, sub-acute and physician office settings	Not specified but where endoscopic procedures are performed: hospitals, sub-acute and physician office settings	Not specified but where endoscopic procedures are performed: hospitals, sub-acute and physician office settings
Single Use	Yes	Yes	Yes
Sterile	Yes	Yes	Yes
Mechanism of action	Manual attachment	Manual attachment	Manual attachment
Number of device passes during a procedure	Multiple passes	Multiple passes	Multiple passes
Echogenic	No	Yes	No
X-ray detection	Yes	No	Yes
Components	Handle-like Stopper (Connector) Sheath	Handle Adaptor / Connector Sheath Wire / Stylet	Handle Adaptor / Connector Sheath Wire
Sheath Max Outer Diameter	2.7 mm	N/A	2.72 mm
Sheath Min Inner Diameter	2.1 mm	N/A	2.08 mm

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Feature	Predicate K060243 Olympus Guide Sheath	Reference K151315 Boston EPEUTAN	Subject Device K172955 LungVision Tool
Working Length Length extended beyond the scope	900 mm 27.5 mm	N/A	1000 mm 17 mm
Sheath length adjustable	Yes	Yes	Yes
Recommended Channel Size	2.8 mm	2.0 mm (this device is inserted into a sheath	2.8mm
Curved distal tip	No, but endotherapy instruments do	N/A	Yes
Performance – Non-clinical			
Biocompatibility	Surface Contact Skin and Breached Limited duration (<24 hours)	Surface Contact Skin and Breached Limited duration (<24 hours)	Surface Contact Skin and Breached Limited duration (<24 hours)
Testing			Cytotoxicity Sensitization Irritation or Intracutaneous Reactivity Acute Systemic Toxicity Material Mediated Pyrogenicity – no claim of non-pyrogenic
Bench testing	Not listed	Passability Tensile strength - Stylet (wire) Durability Removal Force Rotation	Bronchoscope Compatibility Test Simulated Use Fluoroscopy Tensile Test for Sheath and Wire Tensile Test for Wire Distal End Repeatability Use Sheath Insertion/Withdrawal Twisting Test Drop Test Accelerated Aging Verification Test Package integrity Test Package Stability Test

510(k) Summary

Substantial Equivalence Discussion

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 Tool and the predicate are substantially equivalent.
Discussion -The differences in proposed indications for use relate to associating the specific sheath to that bronchoscope manufacturer's own instrument of scope. The subject device is intended for use with the compatible bronchoscopes with equivalent working channel and instrument diameters.

This difference does not raise new risk or safety concerns, and the subject device can be found substantially equivalent.

Prescriptive:
Both the LungVision Tool and predicate are prescription devices.
Discussion -There are no differences.

Design and Technology:
The LungVision Tool is constructed of similar materials and components to both the predicate and reference.
Discussion -There are no differences in design, technology, or principle of operation which would raise new safety or effectiveness concerns thus the subject device can be found substantially equivalent.

Performance and Specifications:
We performed the equivalent tests and used the predicate for reference of acceptance criteria.
Discussion -There are no differences which would raise safety or effectiveness concerns compared to the predicate, thus the subject device can be found substantially equivalent.

Performance Testing:

Nonclinical / Bench
We have performed bench tests and found that the LungVision Tool met all requirements specifications and can be found to be substantially equivalent to the predicate.

- Bronchoscope Compatibility Test
- Simulated Use
- Fluoroscopy
- Tensile Test for Sheath and Wire
- Tensile Test for Wire Distal End
- Repeatability Use
- Sheath Insertion/Withdrawal
- Twisting Test
- Drop Test
- Accelerated Aging Verification Test

510(k) Summary

Biocompatibility

- We assessed the patient contact type and performed the applicable ISO 10993 tests which included:
    - Cytotoxicity
    - Sensitization
    - Irritation or Intracutaneous Reactivity
    - Acute Systemic Toxicity
    - Material Mediated Pyrogenicity but no claim the device is non-pyrogenic

The test results supported the materials as non-cytotoxic, non-sensitizers, and non-irritants.

Sterilization and Packaging

- We have performed Single Lot Release validation which includes the following tests:
    - Bioburden
    - Bioburden Validation
    - Fractional Cycle – BI show no growth
    - Fractional Cycle – Sterility Test
    - Sterility Validation
    - Full Cycle – BI show no growth
    - Full Cycle – ETO Residual
    - Bacterial Endotoxin test as per LAL method
    - Package integrity Test
    - Package Stability Test
- The results confirm that the single lot Ethylene Oxide sterilization process capability has achieved SAL of at least 10^{-6}

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 device for indications for use, technology, and performance we believe we have demonstrated that the LungVision Tool is substantially equivalent in safety and effectiveness to the predicate device.