ETView Ltd.
% Yoram Levy
Qsite General Manager
Qsite
31 Haavoda St.
Binyamina, 3054431 Il

Re: K181886
Trade/Device Name: VivaSight-DL System
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: Class II
Product Code: CBI
Dated: October 26, 2018
Received: October 30, 2018

Dear Yoram Levy:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; 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 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,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181886

Device Name
VivaSight-DL System

Indications for Use *(Describe)*
The ETView VivaSight-DL is intended to isolate the left or right lung of a patient for intensive care or surgery, one lung ventilation or one lung anesthesia. The VivaSight-DL System is indicated for verifying tube placement and repositioning.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

VivaSight-DL™ System

510(k) Number K181886

Applicant's Name: ETView Ltd.
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Binyamina, Israel 3054431
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Yoram@qsitemed.com

Trade Name: ***VivaSight-DL*™ System**

Preparation Date: November 10, 2018

Classification: **Regulatory Name**: Tracheal/bronchial differential ventilation tube
Product Code: CBI
Regulation No: 21 CFR 868.5740
Class: II
Panel: Anesthesiology

Device Description:

The ETView ***VivaSight-DL™ System*** functions as a standard endobronchial tube that additionally has an embedded video imaging device in its tracheal lumen. The system provides a video image of the patient's bronchus, which is displayed on the monitor, for as long as the ***VivaSight-DL***™ is inside the patient's bronchus. Visualization of the bronchus is used to verify placement and repositioning of the endobronchial tube during the intubation procedure or throughout surgery.

Intended Use Statement:

The ETView ***VivaSight-DL™*** is intended to isolate the left or right lung of a patient for intensive care or surgery, one lung ventilation or one lung anesthesia. The ***VivaSight-DL™*** System is indicated for verifying tube placement and repositioning.

Intended users: The device is intended to be used only on Adult and by trained personnel only.

Predicate Devices:

Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
VivaSight-DL™ System	K123853	April 15, 2013

The following table summarizes the similarities and differences between the ***VivaSight-DL™*** and its predicate device VivaSight-DL™ System (K123853):

Characteristics	Proposed *VivaSight-DL™* System	VivaSight-DL System (K123853)
Indications for Use	The ETView ***VivaSight-DL™***) is intended to isolate the left or right lung of a patient for intensive care or surgery, one lung ventilation or one lung anesthesia. The ***VivaSight-DL™*** System is indicated for verifying tube placement and repositioning.	Same
Product Code	CBI	Same
Regulation No.	21 CFR 868.5740	Same
Basic Structure	Standard EBT	Same
Use	Single use	Same
Method of sterilization	Ethylene Oxide	Same
Performance Tests	Non clinical, laboratory performance testing was performed according to ISO 5361 and ISO 16628	Same
EBT Material	Thermo-sensitive flexible medical grade Poly Vinyl Chloride (PVC)	Same
Imaging Sensor	CMOS video camera	Same
Tube Dimensions	35FR, 12.5x13.5mm 37FR: 13.0x14.0mm 39FR, 13.5x14.5mm 41FR, 14.0x15.0mm	Same
Video Transfer	Real time image acquisition on a continuous or intermittent basis without disconnection the patients from the mechanical ventilator	Same
System Display	VivaSight display system available in the following configurations:	VivaSight display system available in the following configurations:

Characteristics	Proposed *VivaSight-DL™* System	VivaSight-DL System (K123853)
	• VivaSight- Max Monitor- 7" monitor • VivaSight Direct- RCA cable configuration for connection to external medical display. • **Ambu aView monitor (not part of ETView product) - VivaSight is provided with an adapter cable to integrate the DL tubes to Ambu aView Monitor.**	• VivaSight- Max Monitor- 7" monitor • VivaSight Direct- RCA cable configuration for connection to external medical display.
Shelf life	3 years from date of sterilization	5 years from date of sterilization
Packaging	Pouch, complies with EtO sterilization	Same
Operation Environment	Temperature: 0 ÷ 42°C Humidity: 10 ÷ 100% RH Atmospheric pressure: 7.5 ÷ 15.5 PSI	Same
Storage Environment	Temperature: 0 ÷ 42°C Humidity: 10 ÷ 100% RH Atmospheric pressure: 7.5 ÷ 15.5 PSI	Same

Table No. 1: Comparison between the modified ETView *VivaSight-DL*™ and the FDA cleared ETVIEW VivaSight-DL System (K123853)

Performance Standards:

VivaSight-DL™ was tested and complies with the following standards:

- IEC 60601-1 "Medical Electrical Equipment, General Requirements for Safety"
- IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Safety, Collateral Standard: Electromagnetic Compatibility"
- IEC 60601-2-18 Medical Electrical Equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment
- ISO 10993-1 "Biological Evaluation of Medical Devices, Evaluation and Testing"
- ISO 14971 "Medical devices - Application of risk management to medical devices"
- ISO 5361 Anesthetic and respiratory equipment -- Tracheal tubes and connectors
- ISO 16628 Tracheobronchial Tubes – Sizing and marking.
- ISO 11135 Sterilization Of Health-Care Products Ethylene Oxide - Requirements For The Development, Validation And Routine Control of Sterilization Process For Medical Devices.
- IEC 60601-2-18 Medical Electrical Equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment

Principle of Operation:

The operation principle of ***VivaSight-DL*** **System** is similar to the use of standard endotracheal tubes. The use of the device should be performed according to the currently accepted medical technique.

The ETView ***VivaSight-DL* System** enables visual navigation of the airway during intubation. Once the ***VivaSight-DL*** is in position, the airways can be inspected for accumulation of secretions and for efficacy of suctioning.

The aView adapter cable is an integrated single use video/power cable with connector between VivaSight-DL and Ambu's aView monitor. VivaSight-DL displays images of the airway onto the Ambu's aView monitor, for as long as the device remains in place during intubation.

Performance Testing

ETView performed a set of performance tests in order to demonstrate that the device met its specifications. Performance testing demonstrated that the ***ETView VivaSight-DL™*** is substantially equivalent to the cleared predicate device. The addition of the new cable adapter for connection to Ambu aView Monitor was tested through electrical safety and EMC testing and demonstrates that this addition is substantially equivalent to the predicate device.

In addition, bench tests were conducted in order to demonstrate the compatibility of the proposed adapter and Ambu aView monitor with the ***ETView VivaSight-DL™***. The bench tests include: Video signal test, time restriction test, electronics test, image quality, IP rating and mechanical test.

Biocompatibility:

Materials of the ***ETView VivaSight-DL™*** system that are in contact with the human body, are identical to the predicate (K123853) and were tested and found to be biocompatible in accordance with ISO 10993-1.

Conclusion:

ETView believes that, based on the information provided in this submission, the proposed ETView ***ETView VivaSight-DL™*** System is substantially equivalent to its predicate device (K123853) and does not raise different questions of safety and/or effectiveness.