ETView Ltd.
% Yoram Levy
Qsite General Manager
Qsite
31 Haavoda St.
Binyamina, 30500 Il

Re: K181880
Trade/Device Name: VivaSight-SL (TVT) system
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
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)*
K181880

Device Name
VivaSight-SL

Indications for Use *(Describe)*
The ETView VivaSight-SL (TVT) is intended for intubation procedures. The ETView VivaSight-SL (TVTTM) is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral intubations.
The VivaSight-SL (TVT) System is indicated for viewing during non-difficult and difficult intubation procedures, for verifying endotracheal tube and endobronchial blocker placement and repositioning, for viewing during suctioning and for general inspection of the airway.

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)*

510(K) SUMMARY

ETVIEW VIVASIGHT-SL SYSTEM (TVT™)

510(k) Number K181880

Applicant's Name: ETView Ltd.
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Trade Name: ***ETView VivaSight-SL System (TVT™)***

Device Type: Tracheal tube
Preparation Date: November 7, 2018
Classification and Classification Name:

Name: Tracheal tube
Product Code: BTR
Regulation No: 21 868.5730
Class: II
Panel: Anesthesiology

Indications for Use Statement:

The ETView ***VivaSight-SL (TVT^{TM})*** is intended for intubation procedures.
The ETView ***VivaSight-SL (TVT^{TM})*** is indicated for use as a temporary

artificial airway in adults requiring mechanical ventilation. It is intended for oral intubations.

The ***VivaSight-SL (TVT™)*** System is indicated for viewing during non-difficult and difficult intubation procedures, for verifying endotracheal tube and endobronchial blocker placement and repositioning, for viewing during suctioning and for general inspection of the airway.

Device Description:

The ETView ***VivaSight-SL (TVT™)*** is a single use, cuffed device that functions as a standard endotracheal tube (ETT) and additionally has an embedded video imaging device embedded in a dedicated lumen. The system provides a video image of the patient's trachea, which is displayed on the monitor, for as long as the ***VivaSight-SL (TVT™)*** is inside the patient's trachea.

Predicate Device: Substantially equivalent to the following predicate devices:

Device Name	Manufacturer	510k No	Date of Clearance
VivaSight-SL (TVT™)	ETView	K121028	June 21, 2012

Substantial Equivalence to Predicate device

Characteristics	Proposed ETView VivaSight-SL(TVT) system	ETView VivaSight-SL(TVT) system (K121028)
Indication for Use	The ***ETView VivaSight-SL (TVT™)*** is intended for intubation procedures. The ETView ***VivaSight-SL (TVT™)*** is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral intubations. The ***VivaSight-SL (TVT™)*** System is indicated for viewing during non-difficult and difficult intubation procedures, for verifying endotracheal tube and endobronchial blocker placement and repositioning, for viewing during suctioning and for general inspection of the airway.	The ETView ***VivaSight-SL (TVT™)*** is intended for intubation procedures. The ETView ***VivaSight-SL (TVT™)*** is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral **and nasal** intubations. The ***VivaSight-SL (TVT™)*** System is indicated for viewing during non-difficult and difficult intubation procedures, for verifying endotracheal tube and endobronchial blocker placement and repositioning, for viewing during suctioning and for general inspection of the airway.
Product Code	BTR	Same
Regulation No.	21 CFR 868.5730	Same
Classification	Class II	Same
Supplied/use	Single use	Same
Method of Sterilization	EtO	Same

Characteristics	Proposed ETView VivaSight-SL(TVT) system	ETView VivaSight-SL(TVT) system (K121028)
Basic structure	Standard ETT	Same
ETT Material	Medical grade Polyvinyl Chloride (PVC)	Same
Imaging sensor	CMOS video camera	Same
Tube Dimensions: Internal Diameter	Three models: • ID 7.0 mm • ID 7.5 mm • ID 8.0 mm	Same
Tube Dimensions: Outer Diameter	• OD 10.0 mm • OD 10.5 mm • OD 11.0 mm	Same
Cuff	Medical grade PVC, High volume, low pressure	Same
Bevel	Opening to the bottom with the camera on the top	Same
Video transfer	Video transfer: Colored real time image acquisition from the aperture of the tracheal lumen on a continuous or intermittent basis without disconnecting the patient from the mechanical ventilator	Same
Video Format	Composite Video Baseband Signal (CVBS)-NTSC	Same

Characteristics	Proposed ETView VivaSight-SL(TVT) system	ETView VivaSight-SL(TVT) system (K121028)
Display system	VivaSight display system available in the following configurations: • 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 SL tubes to Ambu aView monitor.	VivaSight display system available in the following configurations: • VivaSight- Max Monitor- 7" monitor • VivaSight Direct- RCA cable configuration for connection to external medical display.
Number of Murphy Eyes	2	2
Shelf life/life cycle	3 years	5 years
Packaging	EtO pouch	Same
Electrical Safety	Electrical Safety and Electromagnetic Compatibility data demonstrates that the system (tube and display system) is compliance with IEC 60601-1 and IEC 60601-1-2	Same
Performance tests	Nonclinical laboratory performance testing was performed according to ISO 5361	Same

Performance Standards

ETView *VivaSight-SL (TVT™)* was tested and complies with the following standards:

- ISO 5361 Anesthetic and respiratory equipment -- Tracheal tubes and connectors
- ISO 11135 Sterilization of health care products — Ethylene oxide
- ISO 14971-1 Risk management for medical devices
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing
- 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

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, reducing the need for direct laryngoscopy and providing absolute verification of tube position, while enabling uninterrupted ventilation. 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 test according to ISO5361 requirements. Performance testing demonstrated that the ***ETView VivaSight-SL (TVT™)*** is substantially equivalent to the cleared predicate device.

The addition of the new adapter for connection to Ambu aView Monitor was tested through electrical safety and EMC testing and demonstrates that this addition does not raise different questions of safety or effectiveness.

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

Technological Characteristics

Both the proposed ETView ***VivaSight-SL (TVT™)*** device and its predicate device (ETView VivaSight-SL K121028) function as a standard endotracheal tube (ETT) that additionally has an embedded video imaging device in a dedicated lumen. The system provides video image of patient's trachea that is displayed for as long as the ETT is inside the patient's trachea.

Biocompatibility:

Materials of the ETView ***VivaSight-SL (TVT™)*** system that are in contact with the human body, are identical to the predicate

(K121028) 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 ***VivaSight-SL (TVT™)*** System is substantially equivalent to its predicate device without raising different questions of safety and/or effectiveness.