DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 25, 2016

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

Re: K152438
Trade/Device Name: ETView VivaSight-SL System (TVT™)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: January 19, 2016
Received: January 27, 2016

Dear Mr. 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. 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" (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.

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 yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
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Office of Device Evaluation
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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152438

Device Name
ETView VivaSight-SL System (TVT)

Indications for Use *(Describe)*
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. VivaSight-SL (TVT) System is compatible for use with Laryngeal Mask Airway (LMA).

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.

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510(K) SUMMARY

ETVIEW VIVASIGHT-SL SYSTEM (TVT™) WITH LMA

510(k) Number K152438

Applicant's Name: ETView Ltd.
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Yoram@qsitemed.com

Trade Name: ***ETView VivaSight-SL System (TVT™)***

Device Type: Tracheal tube
Preparation Date: August 18, 2015

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 and nasal intubations.

The ***VivaSight-SL (TVT^{TM})*** 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. ***VivaSight-SL (TVT^{TM})*** System is compatible for use with standard Laryngeal Mask Airway (LMA).

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^{TM})*** 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	October 8, 2008
IntubaidFlex	EZC Medical	K090777	August 04, 2009

Standards Compliance

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

- ISO 5361 Anesthetic and respiratory equipment -- Tracheal tubes and connectors
- ISO 14971-1 Risk management for medical devices

Testing in accordance with the following standards were conducted with the **VivaSight-SL (TVT™)** K121028 which is identical to the subject device with the applicable parameters:

- ISO 11135 Sterilization of health care products — Ethylene oxide
- 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

Performance Testing

Performance tests were conducted on **ETView *VivaSight-SL (TVT™)***'s predicate (K121028) and provided in that submission. The two devices are identical; therefore the tests are applicable to both devices.

A performance test was conducted in order to demonstrate that ***ETView VivaSight-SL (TVT™)*** is compatible for use with a Laryngeal Mask Airway (LMA) with a minimum ID (Inside Diameter according to VivaSight-SL IFU). The performance test includes inspections of the insertion of VivaSight-SL tube through the LMA tube; the ability to operate the VivaSight-SL tube and the LMA according to their specifications (while the device is inserted through LMA tube); resistance to tube collapse; and the ability to safely remove the LMA, while the VivaSight-SL tube remains in place.

Determination of Cuff Resting Diameter, Cuff Leak Resistance Integrity, Resistance to Cuff Herniation, Cuff symmetry, Air Flow Resistance, Thermal Safety, Camera EtO Durability and Camera Imaging Performance were conducted for the K121028 which is identical for these parameters.

The performance testing demonstrated that the ***ETView VivaSight-SL (TVT™)*** is substantially equivalent to the cleared predicate device.

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. The proposed ***VivaSight-SL (TVT™)*** device and its predicate device (EZC Medical, **IntubaidFlex** K090777) are compatible for use with a standard Laryngeal Mask Airway (LMA).

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. The tests were provided in K121028 submission.

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 any new safety and/or effectiveness concerns.