APR 15 2013

ETVIEW *Airway Management*

510(K) SUMMARY

VivaSight-DL™ System
510(k) Number K123853

Applicant's Name: ETView Ltd.
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Trade Name: ***VivaSight-DL™ System***

Preparation Date: **November 11, 2012**

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.

The ***VivaSight-DL***™ is a modification of ETView cleared DLVT™, which was cleared on May 18, 2012 under K113576 (the name changed for marketing reasons). The only difference between the ***VivaSight-DL***™ and the market-cleared DLVT™ system is an addition of three new endobronchial tube sizes (35FR, 39FR and 41FR).

The device is indicated for non-MRI environments only.

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.

Predicate Devices:

Substantial equivalence to the following predicate device is claimed:

Device Name	510k No	Date of Clearance
Double Lumen Ventilation Tube (DLVT™)	**K113576**	**May 18, 2012**
Weal lead Endobronchial tube	**K092886**	**Mar 11 2011**
Silbroncho tubes (Double Lumen tube)	**K051522**	**Aug 17 2005**

Performance Standards:

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

- ISO 5361:1999 Anesthetic and respiratory equipment -- Tracheal tubes and connectors
- ISO 16628:2008 Tracheobronchial Tubes – Sizing and marking
- ANSI/AAMI/ISO 11135-1:2007 Sterilization of health care products — Ethylene oxide
- ISO 14971-1:2007 Risk management for medical devices
- ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing
- EN 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems.
- IEC 60601-1-2 Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

A detailed description appears in **Section 14**.

Technological Characteristics

The ***VivaSight-DL***™ System functions as a standard endobronchial tube (EBT) that has an additional embedded video imaging device in its tracheal lumen. The modified device has the same technological characteristics as the cleared predicate device. The system provides a video image of the patient's bronchus, which is displayed on the monitor, for as long as the ETView ***VivaSight-DL***™ is inside the patient's bronchus.

Visualization of the bronchus is used to verify placement and repositioning of the EBT during intubation procedure.

Technological Characteristics	Proposed *VivaSight-DL™* System	Double Lumen Video Tracheoscope (DLVT™) (K113576)
Basic Structure	Standard EBT	Same
Use	Single use	Same
Method of sterilization	Ethylene Oxide	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	37FR: 13.0x14.0mm
Video Transfer	Real time image acquisition on a continuous or intermittent basis without disconnection the patients from the mechanical ventilator	Same
System Display	Standard NTSC TV Screen	Same

Performance Testing

Performance tests were performed in order to demonstrate that the new tube dimension of the ***VivaSight-DL™*** is as safe and effective as the market-cleared ETView ***DLVT™*** system.

The following performance tests were conducted:

- Determination of Cuff Resting Diameter
- Cuff Leak Resistance Integrity
- Cuff Symmetry
- Resistance to tube collapse
- Determination of effective inside diameter
- Determination of the bronchial segment
- Resistance to cuff herniation
- Air flow resistance
- Thermal safety
- Tracheal seal

Comparison to Predicate Device:

The ETView ***VivaSight-DL™*** is a modification to its predicate device, the market-cleared ETView ***DLVT™*** (K113576).

The ETView ***VivaSight-DL™*** has the same intended use and indication for use, utilizes the same technology and is made of the same material as the market-cleared ETView DLVT™.

The only difference between the ***VivaSight-DL™*** and the market-cleared DLVT™ system is an addition of three new endobronchial tube sizes (35FR, 39FR and 41FR).

The modification was validated successfully.

The new tube's sizes of the VivaSight-DL are equivalence to the market-cleared and well established in the market endobronchial tubes devices: The ETView VivaSight's 41FR is equivalent to Weal lead Endobronchial tube (K092886). The ETView VivaSight 35 FR and 39FR are equivalent the Silbronco tubes Double Lumen tube (K051522) system.

The results of the performance tests clearly demonstrate that the ETView ***VivaSight-DL™*** device is as safe and effective as its predicate without raising any new safety and/or effectiveness concerns.

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

April 15, 2013

ETView Limited
C/O Mr. Yoram Levy
General Manager
Qsite
31 Haavoda Street
Binyamina, Israel 30500

Re: K123853
Trade/Device Name: VivaSight-DL™ System
Regulation Number: 21 CFR 868.5740
Regulation Name: Tracheal/Bronchial Differential Ventilation Tube
Regulatory Class: II
Product Code: CBI
Dated: March 13, 2013
Received: March 18, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ETVIEW *Airway Management*

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K123853

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

Indications for Use: The ETView ***VivaSight-DL™*** System 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.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123853