OCT 0 8 2008

K082420

510(K) SUMMARY

ETVIEW TRACHEOSCOPIC VENTILATION TUBE (TVT™)

510(k) Number K_____

Applicant's Name: ETView Ltd.
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Binyamina, Israel 30500
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Trade Name: ETView Tracheoscopic Ventilation Tube (TVT™)

Classification and Classification Name:

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

Indications for Use Statement:

The ETView Tracheoscopic Ventilation Tube (TVT™) is intended for intubation procedures.

The ETView Tracheoscopic Ventilation Tube (TVT™) is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral and nasal intubations.
The TVT™ System is indicated for viewing during non-difficult and difficult intubation procedures, for verifying tube placement and repositioning, for viewing during suctioning and for general inspection of the airway.

Device Description:

The ETView TVT™ is a single use, cuffed, endotracheal tube with an embedded video imaging device, and light source at its tip and integrated cable with connector to transfer the video signal to the display. The video image is displayed for as long as the Endotracheal tube (ETT) is inside the patient's trachea. The video image can be displayed on ETView's display or on most other TV/VCR displays.
The ETView Tracheoscopic Ventilation Tube (TVT™) system consists of:

- Endotracheal tube (ETT) with:
  - Embedded Video camera
  - Embedded Light source
  - Integrated cable with connector
- Monitor

Predicate Device: ETView Tracheoscopic Ventilation Tube (TVT™); cleared under k052233.

Technological Characteristics

Both the modified ETView Tracheoscopic Ventilation Tube (TVT™) device and its predicate device (ETView Tracheoscopic

Ventilation Tube (TVT); k052233) are endotracheal tubes with a tiny video camera and a light source embedded in their wall. Both devices generate a video image of the patient's trachea as long as the tube is inside the patient airways.

Technological Modifications from Predicate Device

The main modifications between the proposed ETView Tracheoscopic Ventilation Tube (TVT™) and its predicate device ETView Tracheoscopic Ventilation Tube (TVT); k052233 are:

- New generation of camera.
- Standard NTSC signal output for direct display (no need for dedicated software).

Substantial equivalence:

The modified ETView Tracheoscopic Ventilation Tube (TVT™):

- has the same intended use
- incorporates the same technology
- the tube is made from the same material (as its predicate device).

ETView Ltd. believes that the ETView Tracheoscopic Ventilation Tube (TVT™) device is substantially equivalent to its predicate device without raising any new safety and/or effectiveness concerns.

Performance Validation:

Performance Testing – bench tests

Series of bench tests were performed to ensure that the device performs as intended.

Tests were done according to ISO 5361:1999 Anaesthetic and respiratory equipment – Tracheal tubes and according to ISO 10933-1:2003 (for surface device-mucosal membrane-prolonged duration). All testing results demonstrated satisfactory performance.

Materials:

Materials of the ETView Tracheoscopic Ventilation Tube (TVT™) device system that are in contact with the human body were tested and found to be biocompatible in accordance with ISO 10993-1.

Conclusion: ETView Ltd. believes that, based on the information provided in this submission, the modified ETView Tracheoscopic Ventilation Tube (TVT™) System is substantially equivalent to its predicate devices without raising any new safety and/or effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

ETView Limited
C/O Mr. Yoram Levy
QSite
31 Haavoda Street
Binyamina,
ISRAEL 30500

Re: K082420
Trade/Device Name: ETView Tracheoscopic Ventilation Tube (TVT™)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: September 24, 2008
Received: September 30, 2008

Dear Mr. Levy:

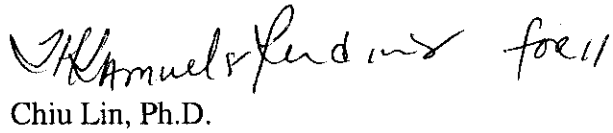
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: ETView Tracheoscopic Ventilation Tube (TVT™)

- **Indications for Use:** The ETView Tracheoscopic Ventilation Tube (TVT™) is intended for intubation procedures.
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Prescription Use _x_ AND/OR (Part 21 CFR 801 Subpart D)

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 Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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