DEC 1 3 2005

K052233

ETView Endotracheal Management

510(k) Summary

Applicant's Name Yoram Levy
Consultant

ETView Ltd.
Misgav Technological Center
6 Kahol Street,
Teradion Industrial Park
ISRAEL 20179
Telephone: (972)4-999-1996
Fax: (972)4-999-1901

Contact Person:

Yoram Levy, QSite
31 Haavoda St.
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

A. Trade Name:

Tracheoscopic Ventilation Tube (TVT) System

B. Manufacturer:

ETView Ltd.
Misgav Technological Center
6 Kahol Street,
Teradion Industrial Park
ISRAEL 20179
Telephone: (972)4-999-1996
Fax: (972)4-999-1901

C. Classification: **Classification name:** (1) Tracheal Tube, adult, cuffed
(2) Bronchoscope, flexible
Common/usual name: (1) Tracheal Tube (or Endotracheal Tube) with (2) image transmission, (3) integral video imager (4) external monitor, (5) Integral light source
Class II device
Product Code: BTR
Regulation No.: 868.5730

D. Contract Sterilizer:

Mediplast Israel Ltd.
7 Hayarkon St.,
P.O.B. 13214 Yavne 81227

ETView Endotracheal Management

Tel (972)8-932-7766
Fax (972)8-932-7992

E. Reason for the Premarket Notification Submission:

New device
ETView intends to market the Tracheoscopic Ventilation Tube (TVT) System as an endotracheal tube that enables intubation and at the same time viewing of the airways during non-difficult and difficult intubation procedures, for verifying tube placement and repositioning, for viewing during suctioning and for general inspection of the airway.
The TVT System provides higher video resolution and thus accuracy compared to the existing cleared device.

F. Identification of Legally Marketed Predicate Devices:

Pulmonx Visualized Endotracheal Tube (VETT) (K973191)
Parker Medical Flex -Tip Endotracheal Tube (K984528)

G. Performance Standards or Special Controls:

The ETView TVT conforms to ISO 5361 (Dated December 15, 1999) and to Anaesthetic and Respiratory Equipment - Tracheal Tubes and Connectors.
This standard replaces ASTM F 1242-96, "Standard Specification for Cuffed and Uncuffed Tracheal Tubes for the same devices, except where stated

The TVT conforms to ANSI/AAMI/ISO 11135 (Medical devices - Validation and routine control of ethylene oxide sterilization).

H. Indications for Use:

The ETView Tracheoscopic Ventilation Tube (TVT) is intended for oral and nasal intubation.

The ETView Tracheoscopic Ventilation Tube (TVT) System has the following specific indications:

- Temporary artificial airway in adults requiring mechanical ventilation, for oral and nasal intubation.
- 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.

I. Technological Characteristics:

The ETView Tracheoscopic Ventilation Tube (TVT) System is a visualized endotracheal tube system same as the cleared Pulmonx VETT System (K973191), except that the ETView device uses a tiny CMOS video camera and light source and the Pulmonx device uses fiberoptic components.

J. Performance Testing

Bench testing demonstrated that the Tracheoscopic Ventilation Tube (TVT) System is at least as safe and effective as the cleared Pulmonx VETT System for oral and nasal intubation and in providing visualization of the airway.

The following performance tests have been done and the results are attached to this submission: Determination of Cuff Resting Diameter, Resistance to Tube Collapse, Resistance to Cuff Herniation, Cuff Symmetry, Air Flow Resistance, Thermal Safety, Imaging Performance, Cuff Leak Resistance Integrity, Mechanical Integrity (Fatigue, Burst, and Cuff Compliance as part of the Mechanical Integrity test), Efficacy of Selective Suctioning, Software Validation.

K. Comparison to the Predicate Device

The ETView Tracheoscopic Ventilation Tube (TVT) System has the same intended use, general and specific indications and principles of operation as the cleared Pulmonx Visualized Endotracheal Tube (VETT) System.

In addition, the TVT employs similar technology as the cleared VETT except for the different type of camera and illumination.

The TVT has two Murphy eyes like the Parker Medical Flex -Tip Endotracheal Tube (K984528), and an additional lens clearing lumen. The inherent radiopacity of the TVT obviates the need for a radiopaque strip.

The minor differences between the TVT and the VETT do not raise any new questions of safety or efficacy. Moreover, bench testing of the TVT System (bench testing is provided in **Attachments 6B, and 6C**) demonstrated that the TVT is as safe and effective as the VETT. Thus, the ETView TVT System is substantially equivalent to the already cleared VETT System.

ETView Ltd., Misgav Technological Center, Teradion Industrial Zone, 20179 Israel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2005

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

Re: K052233
Trade/Device Name: Tracheoscopic Ventilation Tube (TVT)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: II
Product Code: BTR
Dated: November 28, 2005
Received: December 7, 2005

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.

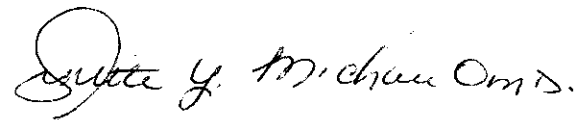
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 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,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ETView Endotracheal Management

510(k) Number (if known): K052233

Device Name: Tracheoscopic Ventilation Tube (TVT)

- **Indications for Use:**

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.

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 of Cardiovascular, Respiratory and Neurological Devices
510(k) Number

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
(510(k) Number K052233

ETView Ltd., Misgav Technological Center, Teradion Industrial Zone, 20179 Israel