FEB 13 1998

K973191

Pulmonx

Vision in Airway Management

510(k) - Premarket Notification

Visualized Endotracheal Tube System

Appendix 1; 510(k) Summary, page 1 of 3:

Submission Date: August 21, 1997

Submitter: Pulmonx, Inc.
1047 Elwell Ct.
Palo Alto, CA 94303

Contact Person: Tony Wondka
Director, Product Development
ph.: (650) 934-2606; fax.: X-2601

1. **Device Trade Name:** Pulmonx Visualized Endotracheal Tube System, or, VETT System (includes Pulmonx VETT and Pulmonx Compact Video System).

2. **Device Common Name:** (1) Tracheal Tube (or Endotracheal Tube) with (2) integral Fiberoptic Flexible Bronchoscope. Also, (3) Fiberoptic Light Source/Carrier and (4) Video Display.

3. **Device Classification Name:**
   (1) Tracheal Tube, Adult, Cuffed
   (2) Bronchoscope, Flexible
   (3) Fiberoptic Light Source and Carrier

4. **Device to which this device is substantially equivalent:**

   (1) Mallinckrodt Hi-Lo Tracheal Tube with Cuff
   (2) Olympus LF1/LF2 Tracheal Intubation Fiberscope, A.O. LS6A/LS7 Fiberoptic Laryngoscope.
   (3) Welch Allyn Hi-Lux HLS-24W Illuminator
   (4) UroHealth Integrated Visualization System, END-101

5. **Description of Device**

   The Pulmonx Visualized Endotracheal Tube (VETT) with Cuff utilizes the fiberoptic components of a bronchoscope and integrates them into the wall of a standard endotracheal tube. Real-time endoscopic visualization from the distal end of the tracheal tube is possible on a continuous or intermittent basis without disconnecting the patient from the mechanical ventilator.

   The VETT is made with biocompatible materials. The device is supplied with a pre-formed arc, pre-cut to length and with depth markings and a full length radiopaque stripe. The distal tip is a hooded bevel with a Murphy's eye. The cuff is a low pressure-high volume cuff. The inflation system has a self sealing valve. The airway connector is a standard 15mm connector. The device is sterilized by ethylene oxide and is designed for single use. The sizes are 7.0, 7.5 and 8.0 mm ID.

   The VETT works in conjunction with the Pulmonx Compact Video System which includes a 5 inch LCD display, an integral Light Source and a Remote Handpiece and Cable. A Head Mounted Display is provided as a supplement to the primary display.

Appendix 1; 510(k) Summary, continued, page 2 of 3:

6. Intended Use of the Device:

The Pulmonx Visualized Endotracheal Tube (VETT) is indicated for use as a temporary artificial airway in adults requiring mechanical ventilation. It is intended for oral and nasal intubations.

The VETT System is indicated for viewing during difficult intubation procedures, for verifying tube placement and repositioning, for viewing during suctioning and for general inspection of the airway.

7. Technical Characteristics, Comparison to Predicate Device(s)

CHARACTERISTIC	PULMONX VISUALIZED ENDOTRACHEAL TUBE SYSTEM	(1) Mallinckrodt Medical HI-LO Tracheal Tube, (2) Olympus LF-1/LF-2 Tracheal Intubation Fiberscope and American Optical LS-6A / LS-7 Fiberoptic Laryngoscope (3) Welch Allyn HI-LUX HLS-24W Light Source (4) UroHealth END-101 Video Display
Cannula material	Thermosensitive Medical Grade PVC	Thermosensitive Medical Grade PVC (1)
Cuff design and material	Compliant Medical Grade PVC, high volume-low pressure	Compliant Medical Grade PVC, high volume-low pressure (1)
Endoscope Type	Flexible	Flexible (2)
Field and direction of View	70° minimum forward looking.	60° forward looking (2, LS-6A)
Illumination method	Light Guide system	Light Guide system (2)
Lamp Type	Welch Allyn Hi-Lux (Metal Halide) or equivalent.	Welch Allyn Hi-Lux (Metal Halide) (3)
Color Temp	5000 °K	5000 °K (3)
Fiber Optic Bundle Interface	Custom LEMO Fiberoptic Connector	ACMI (2,3)
Intensity Control System	Mechanical Shutter (0% - 100%)	Mechanical Shutter (20% - 80%) (3)
Display Type	LCD	LCD (4)
Camera Format	High resolution	High resolution (4)
Video Format	NTSC or PAL	NTSC (4)

Appendix 1; 510(k) Summary, continued, page 3 of 3:

8. Performance Data

The VETT cannula flexibility has been tested by means of measuring forces to conform to patient anatomy. The force is substantially equivalent to the predicate Mallinckrodt Medical Hi-Lo EndoTracheal Tube. The Pulmonx VETT cannula lumen patency has been tested by means of passing a steel ball (ASTM1242, A1.2) and the device passes the lumen patency test. The cannula of the VETT (with regard to lumen patency and ability to conform to patient anatomy) is demonstrated to be safe and effective.

The VETT cuff has been tested for symmetry about the tube, herniation over the distal tip of the tube, compliance, and leak resistance integrity (ASTM1242). All of these properties meet the ASTM requirement. Minimum tracheal sealing pressure, fatigue and burst performance are also evaluated and these properties meet or exceed that of the Mallinckrodt Hi-Lo Tracheal Tube. The cuff of the VETT is demonstrated to be safe and effective.

All applicable biocompatibility testing is acceptable.

The fiberoptic system of the VETT and the Compact Video System is tested for image quality and light output. All samples show good performance and are substantially equivalent to the predicate devices. This aspect of the device is demonstrated to be safe and effective.

9. Conclusions

Based on the data described above, the Pulmonx VETT is safe and effective and it is substantially equivalent to the Mallinckrodt Hi-Lo Tracheal Tube in design and performance. Also, the design and performance of the Pulmonx VETT fiberoptic system and the Pulmonx Compact Video System is substantially equivalent to the predicate device(s) and is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 13 1998

Mr. Robert Kotmel
V.P., Research and Development
Pulmonx, Inc.
1049 Elwell Court
Palo Alto, CA 94303

Re: K973191
Visualized Endotracheal Tube System
Regulatory Class: II (two)
Product Code: BTR
Dated: January 22, 1998
Received: January 26, 1998

Dear Mr. Kotmel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973191

Device Name: Visualized Endotracheal Tube System

Indications for Use:

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The VETT System is indicated for viewing during difficult intubation procedures, for verifying tube placement and repositioning, for viewing during suctioning and for general inspection of the airway.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Pugh

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K973191

Prescription Use ✓ OR Over-the-Counter Use _____

(Optional Format 1-2-96)