3/26/99

K990556

WOLFE TORY MEDICAL, INC.

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510(K) Summary
Summary of Safety and Effectiveness

Company and Submission Information

Applicant	Wolfe Tory Medical, Inc. 79 West 4500 South, Suite 21 Salt Lake City, UT 84107 (801) 281-3000
Contact	Dr. Tim Wolfe
Date Prepared	2/17/99
Classification Name	Tube, tracheal – accessory (73 BTR II 868.5730)
Common/Usual Name	Esophageal Detector Device (EDD)
Proprietary Name and Legally Marketed Device	Esophageal Intubation Device (EID®) Bulb Model – K942628 Syringe Model – K930741
Device Description	A device that relies on anatomical differences between the trachea and the esophagus. By applying negative pressure to the endotracheal tube, the rigid trachea remains open allowing free aspiration of air into the EDD, whereas the fibromuscular esophagus collapses around the endotracheal tube and thus prevents aspiration of air.
New Intended Use	To assist verification of placement of the endotracheal tube or esophageal/tracheal double lumen airway tube.

Summary of Technological Characteristics of the Endotracheal Tube and the Esophageal/Tracheal Double Lumen Airway Tube

Endotracheal Tube	Esophageal/Tracheal Double Lumen Airway Tube
Non-collapsible single lumen hollow tube	Non-collapsible double lumen hollow tube
Outside diameter of distal lumen = 13mm (For inner diameter of 9.0 mm)	Outside diameter of distal lumen =14mm (For 41 French size tube)
Distal end lumen opens out the tip with inflatable/deflatable balloon proximal to tip.	Distal end lumen opens out the tip with inflatable/deflatable balloon proximal to tip.
15mm standard adapter at proximal end for ventilation	15mm standard adapter at proximal end for ventilation
	Second lumen opens on side of tube through fenestrated openings.
	A second balloon exists above fenestrated openings.
Requires clinical judgement to assure proper placement.	Requires clinical judgement to assure proper placement.
Requires distal end placement in the trachea for ventilation of the lungs.	Distal end placement may be located in the trachea or the esophagus, but knowing location is required for ventilation of the proper lumen.

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Summary of Research Findings

Sayre MR, Salkes J, Mistler A, et al: "Teaching basic EMTs endotracheal intubation: Can basic EMTs discriminate between endotracheal and esophageal intubation?" Prehosp Disast Med 1994; 9: 234-237.

Hunt RC, Sheets CA, Whitley TW: "Pharyngeal Tracheal Lumen airway training: Failure to discriminate between esophageal and endotracheal modes and failure to confirm ventilation." Ann Emerg Med 1989; 18: 947-952.

Using a mannequin model and an endotracheal tube, basic EMTs were unable to identify an esophageal intubation 27% of the time. Using the same model and an esophageal/tracheal double lumen airway tube (Pharyngeal Tracheal Lumen), 21% of basic EMTs were unable to determine which lumen to ventilate.

Wafai Y, Czinn E, Salem MR, et al: "Proper placement of the esophageal tracheal Combitube." Anesthesiology 1995; 82: 1304-1305 (letter).

The Combitube (esophageal/tracheal double lumen airway tube) was placed into 20 tracheas and 38 esophagi of patients undergoing elective surgery. The EDD was then used to determine which tube to ventilate. The EDD was always attached to the distal lumen and if no air returned into the EDD, the proximal lumen was ventilated. If air immediately returned, then the distal lumen was ventilated. Using this technique, the location of the distal lumen was correctly identified 100% of the time.

Conclusions

Based on the evidence supplied and studies conducted, the Esophageal Intubation Detector safely and effectively assesses the location of the distal lumen of the esophageal/tracheal double lumen airway tube. Use of this device to determine location of the distal end of the esophageal/tracheal double lumen airway tube is substantially equivalent to using this device to determine the location of an endotracheal tube.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 1999

Tim Wolfe, M.D.
Wolfe Tory Medical, Inc.
79 West 4500 South, Suite 21
Salt Lake City, UT 84107

Re: K990556
Esophageal Intubation Device (EID)
Regulatory Class: II (two)
Product Code: 73 BTR
Dated: February 17, 1999
Received: February 22, 1999

Dear Dr. Wolfe:

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 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). 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/dsma/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): K990556

DEVICE NAME: Esophageal Intubation Detector (EID)

INDICATIONS FOR USE:

To assist verification of placement of the endotracheal tube or esophageal/tracheal double lumen airway tube.

Anil K. Gavlovski

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format