OCT 2 7 1999

POLAMEDCO, INC.
4054 GLENCOE AVENUE
MARINA DEL REY, CA 90592-5608
PHONE: (310) 577-1422
(800) 227-7578
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510 (K) SUMMARY
POLAMEDCO Tracheostomy Tube for Emergency Cricothyrotomy

Date: June 25,1999

Owner/Operator: Polamedco, Inc.
4054 Glencoe Avenue
Marina del Rey, CA 90292
Registration # 2020839

Device Trade Name: Tracheostomy Tube for Emergency Cricothyrotomy
Common Name: Tracheostomy Tube for Emergency Cricothyrotomy
Classification Name: Class 2

Regulatory Reference: K 983000

Predicate Device: Kendall Argyle Tracheostomy tube "substantially equivalent t devices introduced into interstate commerce prior to May 28, 1976", Ref:K 831720

Description:

- Polamedco's Tracheostomy Tube for Emergency Cricothyrotomy is designed for use by EMT's, Paramedics, E.R. Physicians, Anesthesiologists and R.N.'s
- The length of the device is longer than a tracheostomy tube with comparable internal diameter/outside diameter
- The device features a beveled smooth rounded tip that minimizes trauma
- The device is made of flexible medical grade PVC
- Features full radiopaque line for tube depth visualization
- Packaged Sterile and single use
- Latex Free
- The device is made with heavy metal free materials that are safe incinerate and autoclave
- Available in: 5.5 mm., 6.0 mm and 6.5 mm. ID sizes

Intended Use:

• The intended use of this device is to permit conventional ventilation, suctioning, and spontaneous ventilation on the part of an adult patient after insertion of the device in an incision at the cricothyriod space.

Physical/Technical Comparison:

Similarities:

- have the same intended use which is to establish ventilation or airway
- both devices are for use on adult patients and children above 8 years of age
- are both latex free
- are both safe to incinerate and or autoclave
- both are preconnected to 15 mm connectors
- the POLAMEDCO device has a full radiopaque line for tube depth visualization; the Arglye device is radiopaque.
- both packaged sterile and disposable for single use
- the devices feature a beveled smooth rounded tip that minimizes trauma
- both devices are for use in children and adults
- both devices do not include or require stylets for use
- both are flexible
- both are unshortened

DIFFERENCES:

• The length of the device is longer than a tracheostomy tube with comparable internal diameter/ outside diameter

Performance Summary:

The following tests are to assure safety and effectiveness of Polamedco, Inc. Tracheostomy Tube for Emergency Cricothyrotomy:

- In-house inflation and deflation test
- Functional test during manufacturing
- Sterilization validation
- Other applicable qualifying tests

Reference Standards:

- Federal Register 43June 1978 Proposed Residual Limits for ETO, ECH and ETG.
- Sterilization Exposed to sub process Treatment, ISO 11737-97 Appendix 1-4
- 21 CFR 821 June 23,1978 and ANSI/AAMI/ISO 10993-7: 1995
- ANSI/AAMI/ISO 11135: 1994 Guideline for Industrial Ethylene Oxide Sterilizatior Medical Devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 1999

Gerald S. Linder, M.D.
Polamedco, Inc.
4054 Glencoe Avenue
Marina Del Rey, CA 90292-5608

Re: K983000
Cricothyrotomy Tube
Regulatory Class: II (two)
Product Code: 73 BTO
Dated: July 1, 1999
Received: August 26, 1999

Dear Dr. Linder:

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,

Jeanne H Weckerschaus for,

Wolf Sapirstein, M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indication For Use Form

510(k) Number K983000

Indication For Use:

The Tracheostomy Tube for Emergency Cricothyrotomy is intended for emergency surgical cricothyrotomy.

✓ Prescription use per 21 CFR 801.109

OR

___ Over-the-Counter Use

(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 Neu
510(k) Number K983000