NOV 13 1998

K970811

SECTION 13: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

13.1 SUBMITTER INFORMATION

a.	Company Name:	PneumoCare, Inc.
b.	Company Address:	P.O. Box 7811 Laguna Niguel, CA 92607-7811
c.	Company Phone:	(714) 643-2306
d.	Contact Person:	Joseph Bales President
e.	Date Summary Prepared:	January 10, 1997

13.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	Disposable Cannula Tracheostomy Tube Disposable Cannula Fenestrated Tracheostomy Tube
b.	Classification Name:	Tracheostomy Tube and Tube Cuff

13.3 IDENTIFICATION OF PREDICATE DEVICE

Company	Device	510(k) No.	Date Cleared
Mallinckrodt	Disposable Cannula Trach Tubes	K811447	June 26, 1981
Concord Portex	D.I.C. Tracheostomy Tubes	K903730	September 25,1990

13.4 DEVICE DESCRIPTION

The PneumoCare Disposable Cannula Tracheostomy Tube is constructed of a soft inner and outer cannula and incorporates a soft flange which is attached to the outer cannula. The tracheostomy tubes are available in both the fenestrated and standard configuration. Both configurations are available in 6.0, 7.0, 8.0 and 9.0mm sizes, where the size of the tube is determined by the inner diameter of the inner cannula. The tracheostomy tubes incorporate a swivel connection and a rotating angled elbow. The features allow for increased chin movement and patient comfort.

13.5 SUBSTANTIAL EQUIVALENCE

The PneumoCare Disposable Tracheostomy Tube is substantially equivalent to other tracheostomy tubes currently in commercial distribution by Mallinckrodt and Concord Portex in terms of the intended use of achieving a safe and effective airway for breathing or ventilation in adult tracheostomy patients.

The fundamental technical characteristics are similar to those of the predicate devices and are listed on the comparison chart provided in this 510(k) submission.

13.6 INTENDED USE

The PneumoCare Disposable Cannula Tracheostomy Tubes are designed to provide adult tracheostomy patients with an effective airway for breathing or ventilation.

13.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed devices is provided in this submission.

13.8 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 13 1998

Mr. Joseph H. Bales
PneumoCare Inc.
P.O. Box 7811
Laguna Niguel, CA 92607-7811

Re: K970811
Disposable Cannula Tracheostomy Tubes
Regulatory Class: II (two)
Product Code: 73 JOH
Dated: November 4, 1998
Received: November 9, 1998

Dear Mr. Bales:

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

SECTION 7: INDICATIONS FOR USE (Separate Page)

510(k) Number: To Be Assigned By FDA

Device Name: PneumoCare Disposable Cannula Tracheostomy Tube

Indications For Use: The Disposable Cannula Tracheostomy Tubes are designed to provide an adult tracheostomy patient with an effective airway for breathing and/or ventilation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K970811

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)