510(k) Summary

Non-Confidential Summary of Safety and Effectiveness
Page 1 of 2
18-Apr-07

Engineered Medical System, Inc.
2055 Executive Dr.
Indianapolis, IN 46241

Tel - (317) 246-5500
Fax - (317) 246-5501

Official Contact:	Jeff Quinn - President
Proprietary or Trade Name:	Talking Trach
Common/Usual Name:	Tracheostomy tube
Classification Name:	Tube, tracheostomy and tube cuff
Device:	Traceostomy tube with inner cannula
Predicate Devices:	Passy Muir – K962714 Portex – Trach Talk – K972385 Shiley – Trach tubes – K962173

Device Description -- The proposed EMS Talking Trach is a tracheostomy tube which allows patients who are ventilator dependent or spontaneously breathing to speak or phonate. It can be used with patients on ventilators while the cuff is "up" or inflated. It is offered in sizes from 4.0 to 10.0 mm with disposable standard and speaking inner cannula.

Indications for Use -- The EMS Talking Trach tracheostomy tube, cuffed, is intended to provide tracheal access for airway management of tracheostomized patient. The device allows tracheostomy patients with a functional larynx and an unobstructed upper airway to vocalize / phonate. The Inner Speech cannula allows vocalization with the tracheostomy tube's cuff to remain inflated for ventilator dependent patients.

Patient Population -- For adult patients > 30 kg.

Environment of Use -- Home, hospital, and sub-acute care settings

Contraindications -- Do not use this tracheostomy tube with abnormal upper airway anatomy or pathology as this may result in partial or total airway obstruction.

Non-Confidential Summary of Safety and Effectiveness
Page 2 of 2
18-Apr-07

Device Attributes:

	EMS Talking Trach
Attributes	
Intended use General	To provide tracheal access for airway management of tracheostomized patient.
Intended use Specific	Can allow a patient to phonate with cuff up while on a ventilator as well be used with a standard inner cannula or as a standard tracheostomy tube
Environments of use	Home, hospital, sub-acute care settings
Patient Population	For adult patients > 30 kg.
Contraindications	Not for abnormal airway anatomy
Prescription	Prescription
Design	
Outer tube	Sizes 4 to 10 with or without fenestration
Inner cannula	Standard disposable Speech inner cannula
Materials	
Components in air pathway	PVC, Silicone
Performance	
Ventilator performance	Substantially equivalent to predicate when testing • Peak Pressure as measured by the ventilator at various flow rates • Peak Pressure – intra-pulmonary at various flow rates • Expiratory Flow (average) • Expiratory Flow (Peak)
Standards	Comply with ISO 5366-1, 5366-3

Differences between Other Legally Marketed Predicate Devices

The EMS Talking Trach is viewed as substantially equivalent to the following predicate devices – Passy Muir – K962714, Portex – Trach Talk – K972385, and Shiley – Trach tubes – K962173.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Engineered Medical Systems, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court #102
Bonita Springs, Florida 34134-2015

APR 20 2007

Re: K062104
Trade/Device Name: EMS Talking Trach
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: BTO
Dated: March 23, 2007
Received: March 26, 2007

Dear Mr. Dryden:

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,

Brigette Y. Michaud M.D.

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: **K062104**

Device Name: EMS Talking Trach

Indications for Use:
The EMS Talking Trach tracheostomy tube, cuffed, is intended to provide tracheal access for airway management of tracheostomized patient. The device allows tracheostomy patients with a functional larynx and an unobstructed upper airway to vocalize / phonate. The Inner Speech cannula allows vocalization with the tracheostomy tube's cuff to remain inflated for ventilator dependent patients. For adult patients > 30 kg.

Prescription Use XX or **Over-the-counter use** __
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Suzette Y. Michau MD.
General Hosp...,
...ion Control, ... Devices
...k) Number K062104