JUL 3 0 2002

K013728

Non-Confidential Summary of Safety and Effectiveness

April 30, 2002

Engineered Medical Systems
2055 Executive Dr.
Indianapolis, IN 46241

Tel (317) 246-5500
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Official Contact: Bonnie Holly – Quality Manager

Proprietary or Trade Name: TrachVox

Common/Usual Name: Tracheal HME with speech valve and suction port

Classification Name: Laryngeal (Taub) Prosthesis – Accessory

Predicate Devices:
In Health – Blom-Singer Tracheostoma with HumidiFilter Cap – K821568
Passy Muir Speaking Valves – K944451
Gibeck, Inc. – Trach-Vent – K952845
Vital Signs – Breathe Easy – K914336
Intersurgical – Hydro-Trach T - exempt
B&B Technologies – Bodai Suction Safe – K811241

Device Description:

The TrachVox connects to a 15 mm tracheostomy or endotracheal tube connector of a spontaneously breathing patient. It incorporates four (4) key features:

- HME media for humidifying inhaled air
- Suction port
- Method for closing off exhalation to outside and divert the exhaled breathe around the tracheostomy tube and through the vocal cords for speech
- Connector for delivery of supplemental oxygen

Intended Use:

Indicated Use --

For patients breathing spontaneously via a tracheostomy tube, the TrachVox provides heat and humidity for entrained air and incorporates a cough relief and suction port valve. The unit may be closed by the patient's finger, which directs the air through the vocal cords to facilitate speech.

For patients breathing spontaneously via an endotracheal tube the TrachVox provides heat and moisture for the inhaled air. For single patient use.

Environment of Use -- Home, Hospital, ICU, Sub-acute Institutions

Comparison to Predicate Devices:

Attribute	Proposed TrachVox device
For spontaneously breathing tracheostomy patients	Yes
Incorporated speech valve	Yes
Provides heat and humidity	Yes
Can provide supplemental oxygen	Yes
Intended to connect to tracheostomy tube of spontaneously breathing patient	Yes
Can connect to an ET tube of spontaneously breathing patient	Yes
Intended for single patient up to 24 hours	Yes
Prescription	Yes
Intended population	Any patient
Intended Environment of Use	Home, Hospital, sub-acute, ICU
Placement in various locations in circuit	Yes
Supplemental oxygen connection	Yes
Standard 15/22 mm connectors	Yes
Dead Space (ml)	9.5 ml
Resistance to flow	0.23 cm H_2O @ 30 Lpm or 0.9 cm H_2O @ 60 Lpm
Weight	2.9 gm
Normally closed suction slit valve	Yes
Speech valve normally open for inhalation	Yes
Allows exhalation to atmosphere freely	Yes
Method for diverting exhaled air through vocal cord for facilitating speech (Speech valve)	Cover suction valve with fingers, depress housing, compressing foam and closes off exhalation to atmosphere vents
Method for revert to normal exhalation after speaking	Remove finger, foam spring-action raises housing, opening exhalation to atmosphere vents
Moisture output (mg H_2O/l) ISO 9360	20.1 mg H_2O /l @ 500 ml TV
Moisture output (mg H_2O/l) ISO 9360 with supplemental oxygen	14.9 mg H_2O /l @ 10 Lpm
Housing components - polypropylene	Yes
HME media	Foam
Valve	Silicone
None under Section 514	Yes
ISO 5356-1 Conical 15/22	Yes
ISO 9360 – HME moisture output	Yes

Differences between Other Legally Marketed Predicate Devices

The data within the submission demonstrates that the proposed devices when compared to the predicate devices are safe and effective and are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2002

Engineered Medical Systems
C/O Mr. Paul Dryden
Promedic, Incorporated
6329 W. Waterview Court
McCordsville, Indiana 46055-9501

Re: K013728
Trade/Device Name: Trach Vox
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: April 30, 2002
Received: May 1, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2.3 Indications for Use

510(k) Number: K013728 (To be assigned)

Device Name: TrachVox

Intended Use: For patients breathing spontaneously via a tracheostomy tube, the TrachVox provides heat and humidity for entrained air and incorporates a cough relief and suction port valve. The unit may be closed by the patient's finger, which directs the air through the vocal cords to facilitate speech.

For patients breathing spontaneously via an endotracheal tube (ET tube) the TrachVox provides heat and moisture for the inhaled air.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013728

Prescription Use ✓ **or** **Over-the-counter use** __
(Per CFR 801.109)