DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2005

Tracoe Medical GmbH
C/O Mr. Michael A. Warren
Boston Medical Products, Incorporated
117 Flanders Road
Westborough, Massachusetts 01581

Re: K043160
Trade/Device Name: Tracoe Phon Assist I
Regulation Number: 868.5800
Regulation Name: Tracheostomy Tube and Tube Cuff
Regulatory Class: II
Product Code: JOH
Dated: January 24, 2005
Received: January 25, 2005

Dear Mr. Warren:

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,

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

SECTION 4- Statement of Indications for Use

INDICATIONS FOR USE

510(k) Number: Not Issued

Device Name: Tracoe Phon Assist I

Indications for Use:

The Tracoe Phon Assist I (Ref Models 650-S/SO and 650-T/TO) are one way valves with and without a supplementary oxygen port designed to allow tracheostomy patients with an intact larynx to vocalize without the need for finger occlusion. The single patient use valves are attached to the outer aspect of a tracheostomy tube with a 15mm standard connector (Phon Assist I- Model 650-T/TO) or a Tracoe Stoma Button (Phon Assist I- Model 650-S/SO). Both valves consist of an identical cylindrical housing with a silicone membrane which allows air to enter in a unidirectional fashion upon inspiration and close upon expiration whereby the airflow is redirected up to the larynx and through the mouth. The Phon Assist I (Ref Model 650-T/TO) Speaking Valves are indicated for uncuffed tracheostomy patients , cuffed tubes that have been fennestrated or deflated and Tracoe Stoma Buttons(Ref Model 650-S/SO) in the cases of:

- Mild Tracheal Stenosis
- Laryngeal Tumors
- Bilateral Vocal Cord Paralysis
- Trachealmalacia
- Head Trauma
- Broncheopulmonary Dysplasia
- Amyotrophic Lateral Sclerosis
- Chronic Obstructive Pulmonary Disease

Prescription Use: X AND/OR Over-The-Counter-Use: ________
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH, Office of Device Evaluation

510(K) NOTIFICATION- TRACOE PHON ASSIST I TRACHEOSTOMY SPEAKING VALVES

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K043160