5.4 510(k) Summary of Safety and Effectiveness

Date Thursday, June 27, 2002

510(k) Number K022125 (To be assigned)

Submitter's Name

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Contact Person

Eddy Åberg
Director of Quality & Regulatory Affairs

Trade or Proprietary Name Provox® FreeHands HME™

Common or Usual Name Heat and Moisture Exchanger with a Speech Valve

Device Classification Name Tracheostomy Tube and Tube Cuff

Product Code 73 JOH

Predicate Devices

Provox® HME Cassette
510(k) Number : K014102
Atos Medical AB, Sweden

Blom-Singer Adjustable Tracheostoma Valve with HumidiFilter Cap
510(k) Number: K821568
Inhealth Technologies, USA

Bivona™ Tracheostoma Valve II
510(k) Number: K852272
Bivona Medical Technologies, USA

Intended Use The Provox® FreeHands system is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and

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moist from exhaled air in the device. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

Description of the Device

The Provox® FreeHands system consists of two functional units that work together:

- A Provox® FreeHands speech valve unit in a reusable housing, containing two independent valves: an internal, exchangeable valve membrane (speaking valve) and a hinged valve on the top (cough-relief valve)
- A disposable Provox® FreeHands HME™ Cassette, which has to be connected to the lower part of the valve housing before it is ready to use.

After proper adjustment and attachment of speech valve unit and HME cassette, the completed Provox® FreeHands HME™ is inserted into either Provox® Adhesive base plate or Provox® LaryTube™ with ring.

The speech valve unit allows hands-free tracheostoma occlusion for voice prosthesis users.

The speech valve closes, as exhalation pressure is in-creased briefly, just as it increases when one starts to talk loudly in normal laryngeal speech. If the exhalation pressure does not increase rapidly, the valve stays open and allows normal breathing. Once the valve is closed, a small magnet holds it in the closed position. There is no need to maintain high air pressure in the trachea/windpipe in order to keep the valve closed. When the pressure in the trachea/windpipe drops to a very low level, or during inhalation, the valve opens and allows free breathing again.

There are two valve positions, which can be adjusted by simple rotation of the valve housing. The "speaking position" (On) allows the automatic change between stoma closure and normal breathing as described above. The "breathing position" (Off) allows a higher airflow without closing the valve. This is also achieved by the use of two magnets, which keep the valve open despite the increased airflow during physical activity.

Clinical Test

Performed by the Netherlands Cancer Institute, Amsterdam. The Protocol Review Board of the Netherlands Cancer Institute

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approved the study. A comparison was made between Provox® FreeHands HME™, Provox® HME Cassette and Blom-Singer Adjustable Tracheostoma Valve with HumidiFilter Cap.

Test results support the conclusion that the actual device performance satisfies the design intent.

Technological Characteristics

The proposed device is substantially equivalent to the legally marketed predicate devices in design, intended use and materials of manufacturer.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 3 0 2002

Atos Medical, Inc.
c/o Paul Dryden
ProMedic, Inc.
6329 W. Waterview Ct.
McCordsville, IN 46055

Re: K022125
Trade/Device Name: Provox FreeHands HME, Model 7710
Regulation Number: 21 CFR 874.3730
Regulation Name: Laryngeal Prosthesis (Taub Design)
Regulatory Class: Class II
Product Code: EWL
Dated: June 27, 2002
Received: July 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) 594-4613. 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

5.3 Indications for Use

Applicant: Atos Medical AB, Sweden

510(k) Number: K022125 (To be assigned)

Device Name: Provox® FreeHands HME™

Intended Use:

The Provox® FreeHands system is a heat and moisture exchanger (HME) that heats and humidifies inhaled air by retaining heat and moist from exhaled air in the device. For patients with a voice prosthesis or surgical speech fistula it may also facilitate voicing.

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

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ **or** **Over-the-counter**_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nos and Throat Devises

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