Summary of Safety and Effectiveness

Company Name:	DYMEDIX, Inc. 3989 Central Ave. NE Suite 116 Minneapolis, MN 55421
Contact:	Bill Ham, President, COO
Phone:	(763) 789-8280
Fax:	(763) 781-4120
Summary Date:	February 9, 2004
Trade Name:	DYMEDIX Reusable Airflow/Snore Sensor
Common Name:	Airflow Sensor
Classification Name:	Predicate airflow/snore sensors have been found substantially equivalent to 21 CFR 868.2375, Breathing Frequency Monitor, Class II, BZQ.

Predicate Devices:

510(k) Number:	K990321
Manufacture:	DYMEDIX Incorporated
Trade Name:	Gemini Sensor (Disposable)

510(k) Number:	K913396
Manufacture:	Pro-Tech Services Inc.
Trade Name:	Cannula-Style Thermocouple Airflow Sensor

1.0 Description of the Reusable Airflow/Snore Sensor

During evaluation of sleep disorders and other clinical applications for airflow recording, an airflow sensor is applied to the patient, typically under the nasal passages, to support recording of airflow signals. During the evaluation of sleep disorders and other clinical applications for breath sounds (snore) recording, a snore sensor is applied to the patient to support recording of snore signals. These recorded signals are analyzed by a qualified physician, clinician or licensed medical practitioner in support of diagnosis of sleep and airflow disorders.

The Reusable Airflow/Snore Sensor is a pyroelectricity (pyro) and piezoelectric (piezo) sensor. The temperature difference between patient exhaled air and ambient air generates

a small voltage signal, which can be recorded as airflow by diagnostic recording equipment. The vibration from breath sounds (snoring) produce a small voltage signal, which can be recorded as snoring by diagnostic recording equipment. The user's recording device displays the resulting signal for interpretation by a trained physician or clinician.

Polarized Polyvinylidene Fluoride Film (PVDF) is the temperature sensing material. The polarized PVDF material has pyro (temperature) signal generation capability. Polarized PVDF material self generates a small electrical charge in the presence of temperature. The predicate Disposable Airflow/Snore Sensor (K990321) applied the same PVDF Film airflow and breath sound (snore) sensing technology.

The DYMEDIX Airflow/Snore Sensor consists of a temperature sensitive material (PVDF) molded into a reusable housing. The molding material is PVC. This same PVC material is used in the lead wires from the sensor. This same PVC material is used with the predicate DYMEDIX Disposable Airflow/Snore Sensor lead wires, reference K990321.

2.0 Intended Use of the Reusable Airflow/Snore Sensor

The DYMEDIX Incorporated Reusable Airflow/Snore Sensor is used with existing recording devices in support of diagnostic recording of nasal, oral airflow and breath sounds (snore). The sensors are used with patients who require a sleep study.

3.0 Technological Characteristics

Polarized Polyvinylidene Fluoride Film (PVDF) is the temperature sensing material. The polarized PVDF material has pyro (temperature) signal generation capability. Polarized PVDF material self generates a small electrical charge in the presence of temperature.

4.0 Data Summary

Representative laboratory data are presented to demonstrate equivalent performance of the Reusable Airflow/Snore Sensor to the predicate Gemini Sensor.

5.0 Conclusions

The laboratory data and standards certifications support the conclusion of the safety and effectiveness the Reusable Airflow/Snore Sensor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Dymedix, Incorporated
C/O Mr. Robert Mosenkis
CITECH
5200 Butler Pike
Plymouth Meeting, Pennsylvania 19462-1298

Re: K040069
Trade/Device Name: Dymedix Reusable Airflow/Snore Sensor
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: April 27, 2004
Received: April 28, 2004

Dear Mr. Mosenkis:

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.

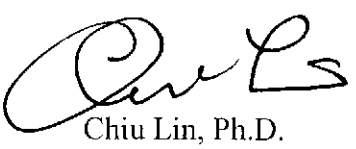
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-5613. 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/dsma/dsmamain.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

Indications for Use

510(k) Number (if known): K040069

Device Name: Reusable Airflow/Snore Sensor

Indications for Use:

The DYMEDIX Incorporated Reusable Airflow/Snore Sensor is used with existing recording devices in support of diagnostic recording of nasal, oral airflow and breathing sounds (snore). The sensors are used with patients who require a sleep study.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K040069

(Posted November 13, 2003)