K990321

JUN 1

AlphaMed, Inc.
3989 Central Av. N.E. Suite 560 Minneapolis, MN., 55421

Summary of Safety and Effectiveness

Company Name:	AlphaMed, Inc. 3989 Central Ave. NE Suite 560 Minneapolis, MN 55421
Contact:	Peter Stasz, President CEO
Phone:	(612) 789-8280
Fax:	(612) 781-4120
Summary Date:	January 28, 1999
Trade Name:	AlphaMed Breathing/Snoring Sensors, Snoring Sensors
Common Name:	Breathing Sensors, Snoring Sensor
Classification Name:	Predicate breathing sensors have been found to be substantially equivalent to 21 CFR 868.2375, Breathing Frequency Monitor. Class II, BZQ Predicate snoring sensors have been found substantially equivalent to 21 CFR 868.2375, Ventilatory Effort Recorder, Class II, MNR
Predicate Device(s):	510(k) Number: K913749 Manufacture: EdenTec inc. Trade Name: EdenTrace Airflow Cable Model 3171and Sleep Lab Airflow Cable Model 3170 Sensor 510(k) Number: K940015 Manufacture: Pro-Tech Inc. Trade Name: Snoring Microphone

1.0 Description of Sensors

The Breathing/Snoring Sensors and Snoring Sensors are disposable, single patient use devices. The Breathing/Snoring Sensors combine breathing and snoring sound sensing capabilities in one sensor.

The sensors use a self-generating signal technology. The sensors contain no electronics or software and require no special interface electronics.

The sensors attach to the patient with medical grade tape. The Breathing/Snoring Sensors are applied under the nostrils and above the lip. The Breath Sounds sensors are applied to the throat of the patient.

The sensors connect to existing recording equipment by means of an AlphaMed Adapter Cable. The existing recording equipment amplifies the signal the sensors generate in response to a temperature change and/or a vibration due to breath sounds. The existing recording device provides patient electrical isolation for the applied sensors.

2.0 Intended Use of Sensors

The disposable sensors are applied to the patient during a sleep study evaluation. The sensors provide a signal which is recorded as airflow and/or breath sounds. Trained professionals (physicians, clinicians) interpret the recorded signals in support of sleep study diagnosis. The sensors are contraindicated for use as apnea monitoring sensors.

3.0 Technological Characteristics

The sensors consist of a temperature and vibration sensitive material covered with conductive ink to collect the electrical charge generated by the temperature and vibration sensitive material. The conductive ink surface has electrodes lead wires attached. The lead wires comply with 21 CFR Part 898 Performance Standards for Electrode Lead Wires and Patient Cables.

The lead wires interface to existing sleep recording devices by a supplied Adapter Cable. Different Adapter Cables are available to support interface to various sleep recording instruments.

4.0 Data Summary

Laboratory data are presented to establish the performance of the Breathing/Snoring Sensors and Breath Sounds Sensors. Material biocompatibility data in compliance with ISO 10993 are provided or prior use of materials with other medical devices establishes the biocompatibility of the sensor materials. A Certification of Conformance to the Medical Device Safety Standard IEC 601-1, Subclause 56.3, Paragraph c is provided.

5.0 Conclusions

The laboratory data, biocompatibility information and certification presented support the conclusion of the safety and effectiveness of the Breathing/Snoring Sensors and Breath Sounds sensors.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1999

Mr. Peter Stasz
AlphaMed, Inc.
3989 Central Avenue, N.E., Suite 560
Minneapolis, MN 55421

Re: K990321
AlphaMed Breathing/Snoring/Sensors, Snoring Sensors
Regulatory Class: II (two)
Product Code: 73 MNR
Dated: April 29, 1999
Received: April 30, 1999

Dear Mr. Stasz:

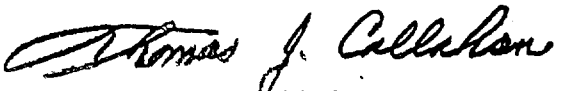
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Phone: (612) 789-8280

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Summary Date: January 28, 1999

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Common Name: Breathing Sensors, Snoring Sensor

Classification Name: Predicate breathing sensors have been found to be substantially equivalent to 21 CFR 868.2375, Breathing Frequency Monitor. Class II, BZQ

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Manufacture: EdenTec inc.
Trade Name: EdenTrace Airflow Cable Model 3171and Sleep Lab Airflow Cable Model 3170 Sensor

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Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K990321

Device Name: AlphaMed Airflow/Snoring Sensors, Snoring-Sensor

Indications For Use:

The disposable AlphaMed Inc. Breathing/Snoring Sensors and Snoring Sensor are used with existing recording devices in support of diagnostic recording of nasal and oral airflow and recording of breath sounds. The sensors are used with patients who require a sleep study recording.

The sensors are contraindicated for support of apnea monitoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Arthur A. Ciarlante

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990321

(Optional Format 3-10-98)

prescriptions use 801.109 ✓

OTC ____