MAY 11 2000

K001030

Summary of Safety and Effectiveness

Company Name:	DYmedix, Inc. 3989 Central Ave. NE Suite 560 Minneapolis, MN 55421
Contact:	Peter Stasz, CEO
Phone:	(612) 789-8280
Fax:	(612) 781-4120
Summary Date:	March 23, 2000
Trade Name:	DYmedix Respiratory Belt Sensor, Model 6000S DYmedix Limb Movement Sensor, Model 3000S
Common Name:	Respiration Effort Sensor, Limb Movement Sensor
Classification Name:	Predicate respiration effort sensors have been found substantially equivalent to 21 CFR 868.2375, Breathing Frequency Monitor, Class II, BZQ. Predicate limb movement sensors have been found substantially equivalent to 21 CFR 868.2375, Breathing Frequency Monitor, Class II, BZQ.

Predicate Device(s):

510(k) Number:	K923402
Manufacture:	Pro-Tech Inc.
Trade Name:	Crystal Trace Piezo Respiratory Effort Sensor
Product Code:	73 BZQ, 21 CFR 868.2375, Breathing Frequency Monitor.

510(k) Number:	K935518
Manufacture:	EPM Information Systems Inc.
Trade Name:	Moving Images Motion Detector Sensor (Periodic Limb Movement)
Product Code:	73 BZQ, 21 CFR 868.2375, Breathing Frequency Monitor.

Predicate Device(s) Continued:

510(k) Number: K990321

Manufacture: DYmedix Inc. (Formerly AlphaMed Inc.)

Trade Name: Snoring Sensor

Product Code: 73 BZQ, 21 CFR 868.2375, Breathing Frequency Monitor

1.0 Description of Sensors

The Respiratory Belt Sensor and Limb Movement Sensor are disposable, single patient use devices. The sensors use a self-generating, piezo material technology. The piezo material generates a small voltage in response to motion. The sensors contain no active electronics or software.

The Respiratory Belt Sensor attaches to the patient with cloth and elastic strap. The Limb Movement Sensor is applied to the patient with medical grade tape.

The Respiratory Belt Sensor is applied to the upper chest and/or abdomen. Respiration effort results in motion of the chest and/or abdomen which the sensor transfers to a small voltage signal which can be recorded.

The Limb Movement sensors are applied to the arm, hand, leg or foot of the patient. The sensor translates limb movement into a small voltage signal which can be recorded.

The sensors connect to the user's sleep study recording equipment. The sleep study recording equipment amplifies and conditions the sensor signal to the user's preferences. The sleep study recording device provides electrical isolation for the applied sensors.

2.0 Intended Use of Sensors

The disposable sensors are applied to the patient prior to a sleep study evaluation. The Respiratory Belt Sensor provides a signal that is recorded as respiration effort, chest/abdomen movement. The Limb Movement Sensor provides a signal that is recorded as arm, hand, leg, foot movement. 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 piezo material, polarized Polyvinylidene Fluoride Film (PVDF) sensor assembly. The sensor assembly has lead wires attached. The lead wires comply with 21 CFR Part 898 Performance Standards for Sensor Lead Wires and Patient Cables. The sensor lead wires interfaces to the user's existing sleep recording device.

4.0 Data Summary

Laboratory data are presented to establish the performance of the Respiratory Belt Sensor and Limb Movement Sensor in comparison to predicate sensors. Patient contact biocompatibility is supported by sensor material equivalence to prior DYmedix 510(k) submission data, 510(k) K990321 and material common to the clothing industry.

A Certification of Conformance to the FDA Performance Standard for Lead Wires and Patient Cables, 21 CFR Part 898 is provided.

5.0 Conclusions

The laboratory data, skin contact material information and certification presented support the conclusion of the safety and effectiveness the Respiratory Belt Sensor and Limb Movement Sensor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Mr. Peter Stasz
CEO
Dymedix, Inc.
3989 Central Ave. NE, Suite 560
Minneapolis, MN 55421

Re: K001030
Respiratory Belt Sensor and Limb Movement Sensor
Regulatory Class: II (Two)
Product Code: 73 BZQ
Dated: March 28, 2000
Received: March 30, 2000

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" (21CFR 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,

Mark N Melkerson

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001030

Device Name: DYmedix Inc. Respiratory Belt Sensor and Limb Movement Sensor

Indications For Use:

The DYmedix Inc. Respiratory Belt Sensor and Limb Movement Sensor are used with the user's sleep study recording devices in support of diagnostic recording of respiratory effort and limb movement. The sensors are used with patients who require a sleep study recording. The sensors are single patient use, disposable devices.

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)

(Optional Format 3-10-98)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001030