K040605

Summary of Safety and Effectiveness

APR 2 6 2004

Company Name: DYMEDIX, Inc.
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Minneapolis, MN 55421

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Summary Date: April 12, 2004

Trade Name: Reusable Respiratory Effort Belt Sensor
Reusable Limb Movement Sensor

Common Name: Respiration Effort Sensor, Limb Movement Sensor

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

Predicate Device(s):

510(k) Number: K001030
Manufacture: DYMEDIX Inc.
Trade Name: Respiratory Effort Belt Sensor, Periodic Limb Movement Sensor

510(k) Number: K923402
Manufacture: Pro-Tech, Inc.
Trade Name: Crystal Trace Piezo Respiratory Effort Sensor

510(k) Number: K940014
Manufacture: Pro-Tech, Inc.
Trade Name: PLM Sensor, Model PLM1 (Periodic Limb Movement)

1.0 Description of Sensors

The Respiratory Effort Belt Sensor and Limb Movement Sensor are reusable devices. The sensors use a self-generating, piezo material technology. The piezo material generates a small voltage in response to stretch, compression and vibration due to motion. The sensors contain no active electronics or software.

The Respiratory Effort Belt Sensor attaches to the patient with a Velcro belt and a cloth strap. The Limb Movement Sensor is applied to the patient with a Velcro belt.

The Respiratory Effort Belt Sensor is applied to the upper chest and/or abdomen. Respiration effort results in stretch of the sensor with chest and/or abdomen circumference change indicative of respiration effort. The sensor transfers this change to a small voltage signal which can be recorded.

The Limb Movement Sensor is 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 sensors are applied to the patient prior to a sleep study evaluation. The Respiratory Effort 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.

The sensors indication for use is:

> The DYMEDIX, Inc. Reusable Respiratory Effort Belt Sensor and Reusable Limb Movement Sensor are used with existing 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.

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 interface to the user's existing sleep recording device.

4.0 Data Summary

Laboratory data are presented to establish the performance of the Reusable Respiratory Effort Belt Sensor and Reusable Limb Movement Sensor in comparison to predicate sensors. Patient contact material biocompatibility is provided.

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 Effort Belt Sensor and Limb Movement Sensor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2004

Dymedix, Inc.
C/O Mr. Gary Syring
Quality and Regulatory Associates, LLC
800 Levanger LN.
Stoughton, WI 53589

Re: K040605
Trade/Device Name: Dymedix Reusable Respiratory Effort Belt Sensor, Model 601
Regulation Number: 868.2375
Regulation Name: Respiratory Belt Sensor and Limb Movement Sensor
Regulatory Class: II
Product Code: BZQ
Dated: March 02, 2004
Received: March 08, 2004

Dear Mr. Syring:

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): K040605

Device Name: Reusable Respiratory Effort Belt Sensor and a Reusable Limb Movement Sensor

Indications for Use:

The DYMEDIX, Inc. Reusable Respiratory Effort Belt Sensor and Reusable Limb Movement Sensor are used with existing 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.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number: K040605