K070855

MAR 20 2008

Section 5: 510(k) Summary

DynaDx Corporation
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Contact: Yanhui Liu

Summary Prepared: March 20, 2007

Trade Name: *Sleep Quality*

Common Name: Apnea Examination System

Classification Name: Ventilatory Effort Recorder

Predicate Devices Identification:

CFR21: 868.2375
Product Code: MNR
Device Class: II
Legally Marketed Device: Lifescreen Apnea
Manufacturer: Del Mar Reynolds Medical, Inc.
K#: K042745

Description:

Sleep Quality is a software system, which can probe the dynamical interactions between heart rate and respiratory variability during sleep by using a single lead Electrocardiogram (ECG) recording. It is designed to support FDA approved Holter Monitor devices on the market. *Sleep Quality* system takes text format ECG recording as input. It requires that supported Holter devices are able to export their recording into ASCII data format. Most of the commercially available Holter Monitors devices have this capability. ECG recording data is first collected by a standard Holter device during subject's sleep, is converted into ASCII data format, and is then analyzed by the *Sleep Quality* system. By recognizing episodes of Sleep Disordered Breathing (SDB), the software indicates that apneic events have occurred and estimated the Apnea-Hypopnea Index (AHI). To detect SDB, the algorithm derives both RR Interval and ECG-Derived Respiratory (EDR) information from the ECG recording.

Intended Use:

DynaDx *Sleep Quality* is intended for use on adult patients only as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score. The ECG recording may be obtained at any location specified by a physician including home, hospital or clinic. Subjects screened for sleep apnea should have periods of sleep of at least 4 hours duration during which the ECG is predominantly sinus rhythm in nature.

Predicate Product Comparison Chart:

Product Parameter	**Sleep Quality (Submission Device) DynaDx Corporation K070855**	**Lifescreen Apnea (Predicate Device) Del Mar Reynolds Inc. K042745**
Device Class	Class II	Class II
Product Code	MNR	MNR
Device Type	Ventilator Effort Recorder	Ventilator Effort Recorder
Common Name	Apnea Examination Software	Apnea Examination Software
Regulation Number	868.2375	886.2375
Intended Use	*Sleep Quality* is intended for use on adult patients only as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score. The ECG recording may be obtained at any location specified by a physician including home, hospital or clinic. Subjects screened for sleep apnea should have periods of sleep of at least 4 hours duration during which the ECG is predominantly sinus rhythm in nature.	*Lifescreen Apnea* is intended for use on adult patients only as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score. The ECG recording may be obtained at any location specified by a physician including home, hospital or clinic. Subjects screened for sleep apnea should have periods of sleep of at least 4 hours duration during which the ECG is predominantly sinus rhythm in nature.
Target Population	Adults	Adults
Apnea-Hypopnea Index (AHI) determination	Apnea-Hypopnea Index (AHI) derived from ECG signal through proprietary algorithm	Apnea-Hypopnea Index (AHI) derived from ECG signal through proprietary algorithm
Detection of Sleep Disordered Breathing (SDB)	To detect SDB, the algorithm derives both RR Interval and ECG-Derived Respiratory (EDR) information from the ECG recording.	To detect SDB, the algorithm derives both RR Interval and ECG-Derived Respiratory (EDR) information from the ECG recording.
Device for collecting signal	FDA approved Holter Monitor with text format ECG signal output	Del Mar Reynolds Lifescreen digital Holter recorder
Data Collection	Home, hospital, clinic	Home, hospital, clinic

Location		
Environment of Use	Hospital and clinic	Hospital and clinic
Software Validation	Yes	Yes
Clinical Study	Yes	Yes
Clinical Trial	No	Yes
Per-subject Sensitivity	95.0%	85.0%
Per-subject Specificity	90.0%	83.3%
Per Subject Accuracy	92.9%	84.3%
Per Subject Positive Predictivity	92.7%	87.1%
Sleep Length for Test (minutes)	26100	26100
Per-minute sensitivity	84.5%	80.9%
Per-minute specificity	83.0%	78.1%
Per-minute Accuracy	83.8%	79.5%
Per-minute Positive Predictivity	83.3%	78.7%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 20 2008

DynaDx Corporation
C/O Mr. EJ Smith
Regulatory Consultant
Smith Associates
1676 Village Green, Suite A
Crofton, Maryland 21114

Re: K070855
Trade/Device Name: Sleep Quality
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: February 19, 2008
Received: March 10, 2008

Dear Mr. Smith:

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.

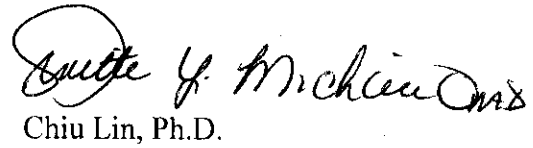
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.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): _____

Device Name: *Sleep Quality*

Indications for Use:

DynaDx *Sleep Quality* is intended for use on adult patients only as a screening device to determine the need for clinical diagnosis and evaluation by polysomnography based on the patient's score. The ECG recording may be obtained at any location specified by a physician including home, hospital or clinic. Subjects screened for sleep apnea should have periods of sleep of at least 4 hours duration during which the ECG is predominantly sinus rhythm in nature.

Prescription Use ___√___ (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: K070855

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