DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 19 2005

Del Mar Reynolds Medical, Incorporated
C/O Dr. George Myers
Official Correspondent
Medsys, Incorporated
377 Route 17S
Hasbrouck Heights, New Jersey 07604

Re: K042745
Trade/Device Name: Lifescreen Apnea
Regulation Number: 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: December 13, 2004
Received: December 16, 2004

Dear Dr. Myers:

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.

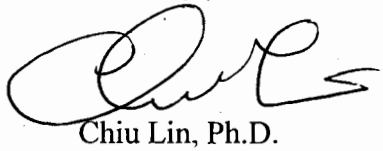
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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): K042745

Device Name: Lifescreen Apnea

Indications for Use:

The device 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 ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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: K042745

Del Mar Reynolds Inc.
510(k) Submission
Lifescreen Apnea
September 7, 2004

510(k) Summary

1. Submitter Information

Name: Del Mar Reynolds Medical Inc.

Address:

Del Mar Reynolds Inc.
13 Whatney
Irvine, CA 92618

Telephone Number: 949-699-3300
Fax Number: 949-699-3380

Contact Person:
Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: September 7, 2004

2. Name of Device

Trade Name:	Lifescreen Apnea
Common Name:	Apnea Examination System
Classification name:	Ventilatory Effort Recorder

3. Equivalent legally-marketed devices.

Silent Night V, K000253, manufactured by Sleep Solutions

4. Description

Lifescreen Apnea is a software option for the LifeScreen ECG Holter scanning software. The *Lifescreen Apnea* option is a software addition only – no hardware changes are involved.

operation, electrocardiogram (ECG) data is collected by a standard Del Mar Reynolds Holter system and is then analyzed by its Holter scanning system with the *Lifescreen Apnea* option added. By recognizing episodes of Sleep Disordered Breathing (SDB), the program indicates the probability that apneic events have occurred and estimates the Apnea-Hypopnea (AHI) Index. To detect SDB, the algorithm derives both RR Interval and ECG-Derived Respiratory (EDR) information from the ECG.

5. Intended Use

"Lifescreen Apnea is indicated for screening adults for the probability that they suffer from obstructive sleep apnea, mixed apnea or hypopnea, in order to evaluate the necessity for a polysomonographic examination. 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."

6. Performance Data

(a) Non-clinical tests

4. Tests with input data from data bases
5. Validation tests
6. Tests to check the operation of the algorithms

(b) Clinical tests

Lifescreen Apnea has been extensively tested in a clinical trial. The diagnostic criteria have also been established with a separate training group. Diagnostic criteria were established using a separate training group.

The results of the tests were:

Per-minute statistics

		Expert	
		N	P
Algorithm	n	9449	845
	p	1012	5669

	mean	95% C.I.
Accuracy	89.1	88.58-89.52
Sensitivity	87.0	86.19-87.82
Specificity	90.3	89.74-90.88
Positive predictivity	84.9	

Where:

N or n = negative (non-SDB) *upper case: expert classification*

P or p = positive (SDB detected) *lower case: algorithm classification*

Accuracy	[(Nn + Pp) / Total] * 100 %
Sensitivity	[Pp / (Pn + Pp)] * 100 %
Specificity	[Nn / (Nn + Np)] * 100 %
Positive Predictivity	[Pp / (Pp + Np)] * 100 %

(c) Conclusions

Lifescreen Apnea is equivalent in safety and efficacy to the legally marketed predicate devices.