K083620

MAR 6 2009

510 (k) SUMMARY

The Siesta Group Somnolyzer® 24X7

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Applicant: The Siesta Group North America, Inc.
5475 Airport Terminal Road
Salisbury, MD 21804
Telephone: (443) 944-8189
Facsimile: (443) 944-8191

Contact Person: Zvi Ladin, PhD.
Principal
Boston MedTech Advisors, Inc.
990 Washington Street
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Dedham, MA 02026
Telephone: (781) 407 0900 x104
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Email: zladin@bmtadvisors.com

Date Prepared: December 4, 2008

Name of Device and Name/Address of Sponsor

Trade/Proprietary Name: Somnolyzer® 24X7
Common Name: Sleep Analysis System

Classification Name: Ventilatory Effort Recorder

Classification Panel: Anesthesiology and Respiratory Devices Branch

C.F.R. Section 21 C.F.R. § 868.2375

Manufacturing Facility: The Siesta Group, GmbH
Schlosshoferstrasse 11/3
Vienna 1210
Austria

Predicate Devices

Morpheus™ 1, Automated Sleep Study Scoring and Data System by Widemed, Ltd. cleared under 510(k) #K022506.

Intended Use / Indications for Use
Somnolyzer 24X7 is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory disorders.
Somnolyzer 24X7 is intended to be used for analysis (automatic scoring and manual re-scoring), display, redisplay (retrieve), summarize, reports generation and networking of data received from monitoring devices typically used to evaluate sleep and respiratory related sleep disorders.
This device is to be used under the supervision of a physician.

Technological Characteristics
Somnolyzer 24X7 is a software system for automatic analysis of sleep, respiratory and movement information recorded during sleep studies. It processes information recorded during sleep by electrodes and sensors attached to the body. It generates reports that include quantitative sleep, breathing and motion parameters, used to evaluate sleep and respiratory-related disorders.

Performance Data
Clinical performance testing was conducted.

Substantial Equivalence
Somnolyzer 24X7 has the same intended use and indications for use, principles of operation and performance characteristics as the predicate device and is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 6 2009

The Siesta Group North America Incorporated
C/o Zvi Ladin, Ph.D
Principal
Boston MedTech Advisors, Incorporated
990 Washington Street, Suite 204
Dedham, Massachusetts 02026

Re: K083620
Trade/Device Name: Somnolyzer® 24X7
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: December 5, 2009
Received: December 8, 2009

Dear Dr. Ladin:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting 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: Somnolyzer® 24X7

Indications For Use: Somnolyzer 24X7 is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory disorders.

Somnolyzer 24X7 is intended to be used for analysis (automatic scoring and manual re-scoring), display, redisplay (retrieve), summarize, reports generation and networking of data received from monitoring devices typically used to evaluate sleep and respiratory related sleep disorders.

This device is to be used under the supervision of a physician.

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)

Susan Runner

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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