

510(k) SUMMARY

AUG 3 1 2011

510(k) Number K 111314

- 5.1 **Applicant's Name:** WideMed LTD
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- 5.2 **Contact Person:** John Smith, M.D., J.D.
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www.hoganlovells.com
- 5.3 **Date Prepared:** May 4, 2011
- 5.4 **Trade Name:** Morpheus Ox Automated Sleep Study
Scoring and Data Management System
- 5.5 **Classification Name:** Ventilatory Effort Recorder / Breathing
Frequency Monitor
- 5.6 **Medical Specialty:** Anesthesiology
- 5.7 **Product Code:** Ventilatory Effort Recorder, MNR
- 5.8 **Device Class:** Class II
- 5.9 **Regulation Number:** 21 C.F.R. §868.2375
- 5.10 **Panel:** Anesthesiology
- 5.11 **Predicate Devices:**
1. The Noga Automated Sleep Study Scoring and Data Management System (WideMed, Ltd.), cleared under K070326
 2. Apnealink (Resmed, Germany) cleared under K070263
 3. ARES (Advanced Brain Monitoring, Inc, USA) cleared under K071230
 4. Somnomedics SOMNOscreen (Somnomedics GMBH & Company KG.); cleared under K060708

5.12 Performance Standards:

1. IEC 60601-1-4 + A1, Medical electrical equipment Part 1: General requirements for safety 4. Collateral Standard: Programmable electrical medical systems, Edition 1.1, 2000-4
2. ISO 14971-1, Application of risk management to medical devices, 2007.

5.13 Intended Use / Indication for Use:

The Morpheus Ox Automated Sleep Study Scoring and Data Management System is a computer program (software) intended for use as an aid in the detection of Cheyne-Stokes Respiration (CSR), and to estimate Apnea Hypopnea Index (AHI), in a Cardiac patient population that is suspected of having Sleep Disordered Breathing (SDB). The Morpheus Ox System is intended to be used for analysis, display, redisplay (retrieve), reports generation and networking of physiological data received from an oximeter device. It does not perform automatic classification of respiratory events as central or obstructive. This system is to be used under the supervision of a physician.

Morpheus Ox displays heart rate, saturation and photoplethysmograph signals, acquired from an oximeter device. Morpheus Ox may also display signals including: EtCO₂, Respiratory impedance, Plethysmograph Derived Respiratory (PDR) calculated signal, Activity, ECG, EEG, P flow, T flow, C flow, EMG, EOG, Snore, Leg movement, Abdomen, Thorax, EPAP, IPAP.

5.14 Device Description:

The Morpheus Ox Automated Sleep Study Scoring and Data Management System is a computer program (software) intended for use as an aid in the detection of Cheyne-Stokes Respiration (CSR), and to estimate Apnea Hypopnea Index (AHI), in a Cardiac patient population that is suspected of having Sleep Disordered Breathing (SDB).

The Morpheus Ox System is designed to process the raw signal data acquired by an oximeter device in standard medical download format, analyze them, obtain the study's analysis results, generate summary reports, and display the signals' data and reports on a personal computer, using a standard Internet Explorer Browser.

Signals from the oximeter device include the following:

- Saturation
- Photoplethysmograph signal

Scoring analysis and display includes:

- Cheyne-Stokes Respiration (CSR)
- Apnea/Hypopnea Index (AHI)
- Display of acquired signals such as EtCO₂, Respiratory impedance, Photoplethysmograph Derived Respiratory (PDR) calculated signal,

ECG, EEG, P flow, T flow, C flow, EMG, EOG, Snore, Leg movement, Abdomen, Thorax, EPAP, IPAP, and Heart rate.

5.15 Substantial Equivalence:

Intended Use

Like the cleared predicate devices, the Morpheus Ox System is intended for use as an aid in diagnosing sleep related breathing disorders. Accordingly, the device meets its first requirement of substantial equivalence.

Additionally, the Morpheus Ox System is further indicated to aid in the detection of Cheyne-Stokes Respiration (CSR), and to estimate Apnea Hypopnea Index (AHI). Likewise, the ApneaLink and SOMNOscreen devices provide CSR information, and the SOMNOscreen, Noga System and ARES device calculate the AHI. This information may be used to assist physicians in the diagnosis of sleep related breathing disorders. The Morpheus Ox System is further indicated to display other information obtained from the connected photoplethysmograph system, consistent with information provided by the cleared predicates.

The use of Morpheus Ox System in cardiac patients exclusively to provide information to assist in diagnosis of sleep related breathing disorders, and especially in the detection of CSR and estimation of AHI, does not alter the intended diagnostic effect of the device, namely the provision of information that can be used to assist in diagnosis of such disorders.

Technological Characteristics

Like the cleared Noga System, the Morpheus Ox System is a software-only program that is used in conjunction with a cleared pulse oximeter device. Both devices process the raw signal data acquired by a pulse oximeter system in standard medical format, analyze the signals, obtain the study's analysis results, generate summary reports, and display the signals' data and reports on a personal computer, using a standard Internet Explorer Browser. The Morpheus Ox software program is based on the Noga software program with the changes required to support its intended use and indications for use from the analysis of a different set of signals. The core software components and architecture are substantially equivalent.

Performance Testing

Software verification and validation testing was conducted to evaluate the performance of the Morpheus Ox System and to verify that it performs according to its specifications described in the Software Requirements Specifications (SRS). In addition, a clinical study was conducted to validate the accuracy of the Morpheus Ox System against both a gold-standard PSG and predicate device.

Summary

Based on the performance testing results, including software verification and validation process and the analysis of the similarities and differences, the Morpheus Ox System is substantially equivalent to its predicates.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Deganit Barak-Shinar
C/O Dr. John Smith
Hogan Lovells US LLP
555 Thirteenth Street, NW
Washington, DC 20004

AUG 31 2011

Re: K111314
Trade/Device Name: Morpheus Ox Automated Sleep Study Scoring and Data Management System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: August 17, 2011
Received: August 17, 2011

Dear Dr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Page 2 – Dr. Smith

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "AW for".

Anthony D. Watson, B.S., M.S., M.B.A.
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: Morpheus Ox Automated Sleep Study Scoring and Data Management System

Indications for Use:

The Morpheus Ox Automated Sleep Study Scoring and Data Management System is a computer program (software) intended for use as an aid in the detection of Cheyne-Stokes Respiration (CSR), and to estimate Apnea Hypopnea Index (AHI), in a Cardiac patient population that is suspected of having Sleep Disordered Breathing (SDB). The Morpheus Ox System is intended to be used for analysis, display, redisplay (retrieve), reports generation and networking of physiological data received from an oximeter device. It does not perform automatic classification of respiratory events as central or obstructive. This system is to be used under the supervision of a physician.

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Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)



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(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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