510(K) SUMMARY

510(K) Number K K070326 MAY 25 2007

5.1 Applicant's Name: WideMed LTD
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5.2 Contact Person: Dorit Winitz, Ph.D.
Biomedical Strategy (2004) Ltd.
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5.3 Date Prepared: January 2007

5.4 Trade Name: Noga 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: 868.2375

5.10 Panel: Anesthesiology

5.11 Predicate Device:

1. The Morpheus™ 1 (WideMed, Ltd.), cleared under K022506.
2. The Silent Night V (Sleep Solutions, Inc.), cleared under K000253.
3. Gold standard PSG manual scoring (e.g., manual scoring of ALICE-5 PSG, cleared under K040595)

5.15 Substantial Equivalence:

Intended Use

With regard to its intended use, the Noga System is substantially equivalent to the combination of its predicate devices, all enable an automatic analysis of physiological acquired signals and are intended for providing information on sleep disordered breathing (SDB) for use as an aid for the diagnosis of respiratory related sleep disorders.

Technological Characteristics and Mode of Operation

Similarly to Morpheus, the Noga System is a computer program analyzing third party's physiological input signals. Both devices convert these raw data signals from their respective recorder device [PSG (Morpheus) or physiological activity monitoring device (Noga)] into WideMed standard format prior to analysis.

The Noga software program is based on the Morpheus software program with the changes required to support the analysis of limited set of signals. The core software components and architecture are substantially equivalent, while minor differences include changes in modularity and layering that do not have a functional consequence, but were implemented to enhance software maintenance and reliability.

Performance Testing

Software verification and validation testing was conducted to evaluate the performance of the Noga System and to verify that it performs according to its specifications described in the Software Requirements Specifications (SRS).

A clinical study was conducted to validate the accuracy of the Noga System to detect respiratory related sleep disorders against both a gold-standard PSG and the Morpheus predicate device. The number of respiratory events and the total sleep time as measured by the Noga System with regard to the gold-standard result in an accurate representation of AHI. Statistical analysis of the test results indicated high correlation of AHI across devices. Further analysis indicated that the sensitivity of Noga for a cutoff of AHI $\geq$15 is 100% and specificity is 92.7% when compared to gold-standard, and 92.8% sensitivity and 94.8% specificity when compared to the Morpheus predicate.

Summary

Based on the performance testing results, including software verification and validation process and the analysis of the similarities and differences, WideMed Ltd believes that the Noga System is substantially equivalent to its predicates without raising new issues of safety or effectiveness.

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, 2000.

5.13 Intended Use / Indication for Use:

The Noga Automated Sleep Study Scoring and Data Management System is a computer program (software) intended for use as an aid for the diagnosis of respiratory related sleep disorders.
The Noga System is intended to be used for analysis, display, redisplay (retrieve), summarize, reports generation and networking of physiological data received from a physiological activity monitoring device.
Physiological data includes: ECG, SpO_2, $EtCO_2$ and Impedance respiration

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

5.14 Device Description:

The Noga Automated Study Scoring and Data Management System (Noga System) is a Web-based computer program (software), intended for use as an aid to the diagnosis of respiratory-related sleep disorders.

The Noga System is designed to process the raw signal data acquired by a third party physiological activity monitoring 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 physiological activity monitoring device include the following:

- ECG
- Impedance respiration
- $EtCO_2$
- SpO_2

Scoring Analysis includes:

- Apnea/Hypopnea Index (AHI)
- Sleep Staging (Sleep - Wake stages, and Total Sleep Time)
- Respiratory Events Detection (Apnea and Hypopnea)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

WideMed Limited
C/O Dorit Winitz, Ph. D.
Regulatory Affairs Consultant
BioMedical Strategy (2004) Limited
7 Jabotinsky Street
Ramat-Gan 52520
ISRAEL

MAY 25 2007

Re: K070326
Trade/Device Name: Noga 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: April 30, 2007
Received: May 3, 2007

Dear Dr. Winitz:

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.

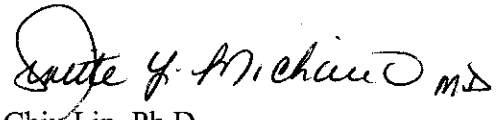
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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): K070326

Device Name: Noga Automated Sleep Study Scoring and Data Management System

Indications for Use:

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The Noga System is intended to be used for analysis, display, redisplay (retrieve), summarize, reports generation and networking of physiological data received from a physiological activity monitoring device.

Physiological data includes: ECG, SpO_2, $EtCO_2$ and Impedance respiration.

Prescription Use __√____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

K070326

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Concurrence of CDRH, Office of Device Evaluation (ODE)

5/22/07

(Division Sign-Off) Acting Chief

Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: _____