K022506

WideMed
Enabling Remote Care

MAY 15 2003

510(k) Summary:

Morpheus™ 1, Automated Sleep Study Scoring and Data Management System

510(k) Number:

Company Name:

WideMed Ltd.

Contact Person: David Solomon, Ph.D.,
R&D Director

Telephone: +972-8-690-9488.
Fax: +972-8-690-9489

Trade Name:

Morpheus™ 1, Automated Sleep Study Scoring and Data Management System.

Classification name: Breathing Frequency Monitor

Classification: MNR

Predicate Device:

Compumedics Sleep Monitoring System, Compumedics Sleep Pty. Ltd, Australia cleared under 510(k) no. K955841.

Indications for Use:

The Morpheus™ 1 Automated Sleep Study Scoring and Data Management System is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory disorders.
The Morpheus™ 1, Automated Sleep Study Scoring and Data Management System 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.

Substantial Equivalence:

The Morpheus™ 1, Automated Sleep Study Scoring and Data Management System has the same intended use and the same principle of operation as the Compumedics Sleep Monitoring System, cleared under 510(k) no. K955841 and is therefore substantially equivalent to that device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 15 2003

Mr. David Solomon
WideMed Limited
Omer Industrial Park, Building 8c
POB 3002
Omer 84965
ISRAEL

Re: K022506
Trade/Device Name: Morpheus™ 1 Automated Sleep Study Scoring and Data Management System
Regulation Number: 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: II
Product Code: MNR
Dated: March 9, 2003
Received: March 14, 2003

Dear Mr. Solomon:

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.

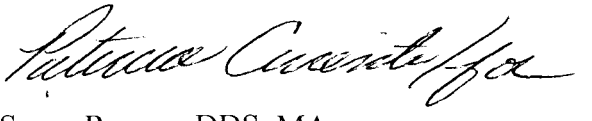
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4646. 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/dsma/dsmamain.html

Sincerely yours,



Susan Runner, DDS, MA
Interim 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): K022506

Device Name: Morpheus™ 1, Automated Sleep Study Scoring and Data Management System

Indications for Use: The Morpheus™ 1 Automated Sleep Study Scoring and Data Management System is a computer program (software) intended for use as an aid for the diagnosis of sleep and respiratory disorders.

The Morpheus™ 1, Automated Sleep Study Scoring and Data Management System 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.

(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: K022506

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)