K071556

Section 6: 510(k) Summary

510(k) Summary

JUL 18 2007

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Manufacturing/ Distribution Address: SOMNOmedics GmbH
Am Sonnenstuhl 63
Randersacker, Germany D-97236

Establishment Registration Number: Active, awaiting assignment of registration number

Date submitted: June 6, 2007

Proprietary Name: Somnomedics SOMNOscreen EEG10-20

Common Name: Ventilatory Effort Recorder

Classification Status: Class II per regulations §868.2375 Breathing frequency monitor

Product Codes: MNR

Predicate Device: Somnomedics SOMNOscreen (K060708) cleared January 24, 2007

Device Description: The SOMNOscreen EEG10-20 is a portable physiological signal recording system intended to be used to record, display, monitor, print and store biophysical events to

aid in the diagnosis of neurologic and sleep disorders. The device is intended to be prescribed for use by a physician in the office, sleep laboratory or patient's home.

This device is NOT designed to be used in a Life Support situation.
This device is not designed for use on patients with cardiac pacemakers.

Indication for Use: The SOMNOscreen $_{EEG10-20}$ is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having sleep-related breathing disorders.

Summary of Technological Characteristics: The system provides up to 40 channels for data acquisition; 22 AC Channels, 20 Referential and 2 Differential, 11 Respiratory and AUX Channels, 7 Internal Channels (SPO2, Pulse Rate, Plethysmogram, Body Position, Light, Patient Marker, Thorax/Abdominal Respiratory Effort).

The SOMNOscreen $_{EEG10-20}$ includes a Compact Flash Card and Reader, Li ION Batteries, (2350mAh) with 1 x Battery Charger, a Carry Bag for housing the SOMNOscreen $_{EEG10-20}$ and Sensors, Instruction Manuals and the DOMINO software for Initialization, Data Transfer and Analysis.

Summary of Nonclinical Testing: The SOMNOscreen $_{EEG10-20}$ was subject to the same preclinical requirements as the previously cleared predicate device the Somnomedics SOMNOscreen (K060708).

Performance testing was conducted to confirm compliance to device specifications; all functions were verified to operate as designed. Measured parameters met required ranges and accuracies. Testing to the international standards for electrical safety and electromagnetic compatibility were performed. SOMNOscreen $_{EEG10-200}$ was found to be compliant with the requirements of these standards.

Substantial Equivalence Discussion:
The SOMNOscreen (K060708) and the SOMNOscreen $_{EEG10-20}$ differ only in the number of AC-Channels. The predicate device provides up to 28 channels for data acquisition; 10 AC Channels, 8 Referential and 2 Differential, 11 Respiratory and AUX Channels, 7 Internal

Channels (SPO2, Pulse Rate, Plethysmogram, Body Position, Light, Patient Marker, Thorax/Abdominal Respiratory Effort) as compared to the SOMNOscreen $_{EEG10-20}$ providing an additional 12 data acquisition Channels, 12 AC Channels, and 12 Referential Channels (40 channels for data acquisition; 22 AC Channels, 20 Referential and 2 Differential, 11 Respiratory and AUX Channels, 7 Internal Channels).

Conclusion:

SOMNOMEDICS Somnoscreen $_{EEG10-20}$ is substantially equivalent to Somnomedics SOMNOscreen (K060708) already on the market and presents no new concerns about safety and effectiveness. Additionally, the device has identical indications to the predicate device and the labeling of the device is consistent both with FDA's guidance as well as current medical practice. SOMNOMEDICS Somnoscreen $_{EEG10-20}$ has the same principles of operation and technological characteristics as the previously 510k cleared predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 18 2007

SOMNOmedics GmbH
C/O Ms. Cherita James
Regulatory Consultant
M. Squared Associates, Incorporated
719 A Street North East
Washington, DC 20002

Re: K071556
Trade/Device Name: SOMNOscreen EEG10-20
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: July 9, 2007
Received: July 10, 2007

Dear Ms. James:

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): K071556

Device Name: SOMNOscreen EEG10-20

Indications For Use: The SOMNOscreen EEG10-20 is a non-life-supporting portable physiological signal recording device intended to be used for testing adult patients suspected of having sleep-related breathing disorders.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 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

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