K965079

510(k) Summary

JUL 10 1997

NEURIM SOMNITOR 32K ACTIVITY MONITOR DEVICE

Common/Classification Name: Unclassified

Sponsor: Neurim Pharmaceuticals, Ltd.
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Contact: Ran Frenkel

Prepared: December 10, 1996

A. LEGALLY MARKETED PREDICATE DEVICES

The **Somnitor 32K Sleep Activity Monitor** is similar in design, intended use, and performance to the Mini-Motion Logger Actigraph by Ambulatory Monitoring which was cleared by FDA as K854030. This 510(k) Summary will summarize the basis for a decision that the Somnitor 32K is substantially equivalent to the predicate device.

B. DEVICE DESCRIPTION

The **Somnitor 32K Activity Monitor** is a wrist worn device consisting of an activity (movement) detector and a data logger with internal data storage. The device is used with a personal computer running software which can download data from the data logger and analyze it according to a validated algorithm to determine periods of sleep and wakefulness. Four algorithms for assessing sleep activity data may be used for analysis, including the Bounded Trigger algorithm, the Cole algorithm, the Sadeh algorithm, and a new Neurim algorithm.

C. INTENDED USE

The **Somnitor 32K Activity Monitor** is intended to monitor physical activity with an ambulatory monitoring and data logging device and after downloading the data to a personal computer, determine the periods when the patient was awake or sleeping using a validated algorithm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

T. Whit Athey, Ph.D.
Neurim Pharmaceuticals, Ltd.
c/o C.L. McIntosh Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

JUL 10 1997

Re: K965079
Somnitor 32K Sleep Activity Monitor
Regulatory Class: Unclassified
Product Code: 84 LEL
Dated: April 11, 1997
Received: April 11, 1997

Dear Dr. Athey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K965079

Device Name: Somnitor 32K Activity Monitor

Indications For Use:

The **Somnitor 32K Activity Monitor** is intended to monitor physical activity with an ambulatory device and after downloading the data to a personal computer, determine the periods when the patient was awake or sleeping using a validated algorithm.

(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 Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K965079

Prescription Use ✓
(Per 21 CFR 801.109)

OR ~~Over-The-Counter Use~~