AUG -7 1998

K981844

RMP, Inc.
Sleep Management System
510(k) Summary

Submitter's Name, Address, and Telephone Number

Murray Jarman, President
RMP, Inc.
716 Sunset Road
Boynton Beach, FL 33435
Telephone: (561) 735-4874
Facsimile: (561) 734-6078

Contact Person

Terry G. Mahn
Fish & Richardson PC
Suite 500
601 Thirteenth St., NW
Washington, DC 20005
Telephone: (202) 783-5070
Facsimile: (202) 783-2331

as Regulatory Counsel to RMP, Inc.

Date Prepared

May 21, 1998

Name of Device

Sleep Management System

Classification Name

Biofeedback Device

Common Name

Sleep Assessment or Sleep Timer Device

Predicate Devices

Thought Technology, Ltd.'s GSR2 Relaxation/Biofeedback Monitor
Ambulatory Monitoring, Inc.'s Actigraph

Intended Use

RMP, Inc.'s Sleep Management System is intended to provide sleep assessment.

Substantial Equivalence

The Sleep Management System consists of a slender plastic case with front and back faces and a plastic strap. The user wears the strap around his wrist so that the device will not drop to the floor when the user falls asleep. On the front face, the device has a display, three function buttons, and two electrodes. On the back face, the device has a thumb-activated switch. The display shows either minutes and hours awake or asleep. Two of the three function buttons cause either time awake or time asleep to be displayed and the third function button is the stop/reset button.

The two electrodes are located in a recessed section of the front face. The two electrodes form two ends of a circuit. The circuit is completed by placing fingers across the electrodes. The current in the circuit flows through the user's fingers to pass from one electrode to the other electrode. The switch on the back face of the case and the circuit formed between the two electrodes operate the timing function of the device.

The circuitry of the device includes a 1.5 volt watch battery, power supply, clock, alarm, light, memory, delay and a control and routing circuit. The power supply powers the device using the battery's stored energy. The clock times the user's time awake and time asleep. By pressing the various function buttons, the device will display the time awake or asleep. The memory stores the user's time awake and time asleep. The timing functions have a three second delay for switching between functions so that the user can briefly adjust finger positioning without changing modes.

Thought Technology Ltd.'s GSR2 Biofeedback Monitor is intended to diagnose sleeping disorders and provide biofeedback related to relaxation. The device consists of a plastic case with two recessed sections on the front panel, a retention snap, an earphone or meter jack, an electrode or thermistor jack, and a volume control dial on the side. A stainless steel sensing plate resides within each recessed section. The sensing plates are at ends of a circuit.

Ambulatory Monitoring, Inc.'s cleared Actigraph is a wrist watch-like device intended to provide information regarding length and time of sleep and the number of disruptions and their possible source (i.e., sleep disorders). The device has a velcro or plastic wrist strap. It also has a display panel that displays time and indicators as to whether the device is collecting data, is idle, or has a full memory. The device contains an accelerometer to detect motion and memory to store the data generated. The information stored in the device is downloaded so that it can be analyzed by software provided by the company. The software provides statistics for estimated sleep and wake totals, sleep latency, and nap frequency and duration. It also provides information on sleep quality. The statistics are estimated using sleep estimation algorithms.

The RMP SMS is substantially equivalent to the GSR2 and Actigraph because they have the same intended use and very similar technological characteristics and principles of operation. For instance, the devices are intended to provide sleep assessment, and they provide information regarding time awake and time asleep.

The RMP SMS and the predicate devices consist of a case worn or pressed against the user's wrist or fingers to measure an indicator of sleep. For instance, the RMP SMS and GSR2 use galvanic skin resistance as an indicator of sleep by measuring the current flowing through the user's finger or fingers between the two electrode. The difference between using one or two fingers does not raise new issues of safety or effectiveness because in either instance the current level is very low and will not harm the patient. Moreover, the estimates of time asleep and time awake are based not on the quantity of the current but on the presence or absence of a current flowing between the two electrodes.

The current flowing through the user of the RMP SMS is 45 microamps or 70 microamps maximum. The GSR2 has a 45 microamp current flowing through the user. These currents are very similar in magnitude. The difference in magnitude does not raise new issues of safety or effectiveness because the difference is very small and the total magnitude is also very small. Any other minor technological differences do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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RMP, Inc.
c/o Fish & Richardson, P.C.
Mr. Terry G. Mahn
Regulatory Counsel
601 Thirteenth Street, N.W., Suite 500
Washington, D.C. 20005

Re: K981844
Trade Name: Sleep Management System
Regulatory Class: II
Product Code: HCC
Dated: May 22, 1998
Received: May 26, 1998

Dear Mr. Mahn:

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 (for the indications for use stated in the enclosure) 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.

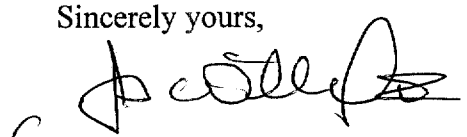
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K981844

Device Name: Sleep Management System

Indications For Use:

To provide sleep assessment. For instance, the device can assess current sleep habits by measuring sleep latency and total sleep time.

(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 General Restorative Devices
510(k) Number K981844

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)