510(k) SUMMARY: OCT 15 2001 K010997

"This summary of 510(k) safety and effectivness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

Submitter's Name and Address:

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Contact person: David T. Krausman, Ph.D.

Date summary was prepared: April 2, 2001

Name of Device:

Trade Name: PAM-RL

Common Name: Activity Recording Device

Classification Name: Electroencephalograph

Identification of predicate device:

Number K992410 - "ACTITRAC" - Individual Monitoring Systems, INC.

Product Code - GWQ

Statement of intended use:

The PAM-RL is a small, limb-worn activity monitor designed for documenting physical movements associated with applications in physiological monitoring. The device is intended to be used to analyze limb activity associated with movement during sleep. The unit can also be used to assess activity in any instance where quantifiable analysis of physical motion is desirable.

Device Description

Functions of the device:

The PAM-RL is a compact, limb-worn, battery-operated activity monitor. The monitor consists of the activity monitor itself and a velcro band.

The PAM-RL is intended for the measurement, storage, and analysis of limb activity. The PAM-RL can be attached to the subject's limb and through the use of an accelerometer, motion of that limb is measured, the activity is stored within the activity monitor.

A computer program is used to set up the PAM-RL to collect data. This program runs on an IBM-compatible personal computer (PC). The major functions of the application software are to program the device to collect data, retrieve the data from the activity monitor, display the data, and to store the data for future reference and comparison.

The PAM-RL uses a smart download cable to provide a communiations link between the PAM-RL and the PC. To download data from the PAM-RL to the PC, one end of the PAM-RL's smart cable is inserted into the PAM-RL's port via a miniature 2.5 mm phone plug and the other end connected to the serial communications port of the PC via a standard 9-pin RS-232 COM port.

Basic scientific concepts:

The PAM-RL utilizes a motion sensor known as an accelerometer to monitor the occurrence and degree of motion. This type of sensor provides an analog signal where the amplitude and speed of motion produces a signal whose magnitude and duration depend on the amount of motion. The activity signals are amplified and digitized by the on-board circuit. This information is stored in memory on board the device as activity counts. Activity can alternatively be stored in units of milli-g.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 5 2001

Individual Monitoring Systems, Inc.
David T. Krausman
1055 Taylor Avenue Suite 300
Baltimore, MD 21286

Re: K010997
Trade/Device Name: PAM-RL
Regulation Number: 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: GWQ
Dated: August 20, 2001
Received: August 20, 2001

Dear Mr. Krausman:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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 Walker for

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

Enclosure

510(k) NUMBER (IF KNOWN): K010997

DEVICE NAME: PAM-RL

INDICATIONS FOR USE:

The PAM-RL is a small, limb-worn activity monitor, typically placed on the leg or wrist, designed for documenting physical movements associated with applications in physiological monitoring. The device is intended to monitor limb activity associated with movement during sleep. The unit can also be used to assess activity in any instance where quantifiable analysis of physical motion is desirable.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010997