510(k) SUMMARY: OCT 15 1999 K992410

"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: July 19, 1999

Name of Device:

Trade Name: ActiTrac

Common Name: Activity Recording Device

Classification Name: Electroencephalograph

Identification of predicate device:

Number K983533 - "ACTIWATCH" - MINI-MITTER CO., INC.

Product Code - GWQ

Statement of intended use:

The ActiTrac is a small wrist-worn activity monitor designed for documenting physical movements associated with applications in physiological monitoring. The device is intended to be used to analyze circadian rhythms, automatically collect and score data for sleep parameters. These parameters, representing the number and intensity of limb movements, are directly correlated to sleep efficiency. 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 ActiTrac is a compact, wrist-worn, battery-operated activity monitor whose physical characteristics are similar to a small wristwatch. The monitor consists of the activity monitor itself and a wrist band.

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

A computer program is used to set up the ActiTrac 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 ActiTrac uses a smart download cable to provide a communiations link between the ActiTrac and the PC. To download data from the ActiTrac to the PC, one end of the ActiTrac's smart cable is inserted into the ActiTrac'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 ActiTrac 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.

Physical characteristics "ActiTrac" vs. "Actiwatch (Predicate)"

Parameter:	ActiTrac:	Actiwatch (Predicate):
Size	37 x 55 x 12 mm	37 x 29 x 9 mm
Weight	23 grams	17 grams
Battery type	Lithium Keeper #LTC-7PN	CR 2025 coin cell
Battery life	4 years, typical	6 months, typical
Accelerometer	piezoelectric	piezoelectric
Accelerometer sensitivity	<.012 g-force	<.01 g-force
Controller	Microprocessor	Microprocessor
Electronic components	Surface mount	Surface mount
Frame cover	ABS plastic	Polycarbonate plastic
Back cover	ABS plastic	Metal
Wrist band	Vinyl with buckle	Plastic with buckle
Moisture susceptibility	Water resistant	Water resistant
Storage Temperature	-10C to 50C	-10C to 50C
Operating Temperature	0C to 40C	0C to 40C

Functional characteristics "ActiTrac" vs. "Actiwatch (Predicate)"

Parameter:	**ActiTrac:**	**Actiwatch (Predicate):**
Recording days @ 1 minute	31 days/48KB	11 days/16KB, 44days/64KB
Sampling method	Analog to digital conversion	Analog to digital conversion
Recording method	Digital integration	Digital integration
Sampling rate	40 per second	32 per second
Data size per epoch	8 bit byte	8 bit byte
Recording epochs	2 seconds to 2 minutes*	2 seconds to 15 minutes
Memory size	48 KB	16 KB or 64 KB
Data units	activity counts or milli-g	activity counts only
Input/output format	Serial data	Serial data
Download method	Smart cable	Reader device
External display device	Personal computer	Personal computer
Displayed data	Dual bar graph	Dual bar graph
Application display software	PC Windows 95 & 98	PC Windows 95 & 98
Sleep scoring software	ActiScore	Actiware-Sleep

* Application software is used to convert 1 or 2 minute recording epochs to 15 minute display epochs.

Technological characteristics of ActiTrac and predicate device:

Both the ActiTrac and the predicate device, ActiWatch, use an accelerometer to detect accelerated motion in the range 0.01 g and upwards. Both devices detect motion and measure the amount and duration of motion. Both devices use analog to digital conversion methods and digital integration to convert motion to activity counts. Both devices record data on a computer board and the data can later be downloaded to a PC for analysis and storage. Both devices are typically wrist-worn and battery operated.

Assessment of ActiTrac Performance Data:

Counts vs. Motion:

The most important performance characteristic of the ActiTrac is its sensitivity to motion. This characteristic is measured by programming the device to collect data in fixed intervals. For precise calibration, the device is subjected to a uniform, harmonic motion produced by a moving platform set for a constant frequency of 3.968 Hz and an amplitude of 0.2 g. The output of the device is compared to a gold standard accelerometer also placed on the moving platform. From these results, the acceleration is calculated. Activity counts are then computed from the acceleration. Motion as low as 0.01 g can be measured. Data formats from both devices are similar as shown in EXHIBIT #2.

Variation between devices:

Due to small variations between characteristics and also due to variations in experimental control, there will be small differences between the activity counts measured with separate devices. Each ActiTrac is calibrated and checked to meet output specifications at or better than ±1% as compared to our established laboratory standard. Movement acceleration in the range of 0.1g to 1.0g are typical for human subjects; this is the region where the ActiTrac has its smallest variation between devices.

Comparison of Physical Attributes for "ActiTrac" and "Actiwatch"

Promotional literature for both devices showing similar physical characteristics is illustrated in EXHIBIT #1.

Comparison of Output Data for "ActiTrac" and "Actiwatch"

Output data for both devices showing similar data formats and graphic display characteristics is illustrated in EXHIBIT #2.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 1999

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

Re: K992410
Trade Name: ACTITRAC
Regulatory Class: II
Product Code: GWQ
Dated: July 19, 1999
Received: July 20, 1999

Dear Dr. Krausman:

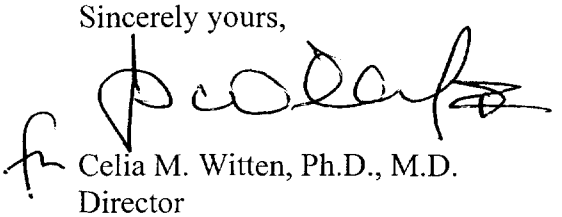
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K992410

DEVICE NAME: ACTITRAC

INDICATIONS FOR USE:

Intended Use:

The ActiTrac is a small wrist-worn activity monitor designed for documenting physical movements associated with applications in physiological monitoring. The device is intended to be used to analyze circadian rhythms, automatically collect and score data for sleep parameters. These parameters, representing the number and intensity of limb movements, are directly correlated to sleep efficiency. 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 X OR Over-The-Counter-Use_
(Per 21 CFR 801.109) (Optional Format 1-

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992410