

K991033

Mini-Mitter Co, Inc.

510(k) Premarket Notification

Actiwatch-Score®

March 26, 1999

JUN 23 1999

**10.0 510(K) SUMMARY**

**10.1 Summary Information**

**10.1.1 Submitter's Name and Address**

Jack E. McKenzie, Ph.D.  
Mini-Mitter Co., Inc.  
P.O. Box 3386  
Sunriver, Oregon 97707

Date summary was prepared: March 26, 1999

**10.1.2 Name of Device**

Trade Name:	Actiwatch-Score®
Common Name:	Activity Recording Device
Classification Name:	System, Telemetry, Physiological Signal Conditioner

**10.1.3 Identification of predicate device**

Number K983533 – Wrist Actigraph – Mini Mitter Co., Inc. - Product Code GYE

#### **10.1.4 Device Description**

##### **10.1.4.1 Functions of the device**

The *Actiwatch-Score®* 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 disposable wrist band.

The *Actiwatch-Score®* is intended for the measurement, storage, and analysis of body activity. The *Actiwatch-Score®* 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 *Actiwatch-Score®* to collect data. This program is called *Actiware-Sleep* and runs on an IBM-compatible personal computer (PC). The major functions of *Actiware-Sleep* are to create a patient score schedule, 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 *Actiwatch®* Reader is a compact interface device that provides a communications link between the *Actiwatch-Score®* and the PC. The *Actiwatch®* Reader is connected to the serial communications port of the PC via a standard 9-conductor RS-232 cable.

##### **10.1.4.2 Basic scientific concepts**

The *Actiwatch-Score®* utilizes a motion sensor known as an "accelerometer" to monitor the occurrence and degree of motion. This type of sensor integrates the amplitude and speed of motion and produces a small 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. In addition, the patient self-score data are stored as integer values within memory.

**10.1.4.3 Pertinent physical characteristics of the Actiwatch-Score®:**

<b>Parameter</b>	<b>Value</b>
Size	37x35x10 mm
Weight	25 grams
Battery type	CR 2025 coin cell
Battery life	6 months, typical
Accelerometer sensitivity	<.01 g-force
Frame and battery cover	Titanium
Frame cover	Polycarbonate plastic
Wrist band	Nylon with buckle
Moisture susceptibility	Water resistant
Sampling intervals	15 seconds to 15 minutes
Recording time	5 to 340 days, depending upon epoch
Storage Temperature	-10 C to 50 C at 0-95% relative humidity
Operating Temperature	0 C to 40 C

**10.2 Statement of intended use**

The *Actiwatch-Score®* is a compact, lightweight, wrist-worn activity monitor that can be used to analyze circadian rhythms, automatically collect and analyze data for sleep parameters, and assess activity in any instance where quantifiable analysis of physical motion is desirable. In addition, the *Actiwatch-Score®* has a built-in score pad that allows the subject to subjectively assign and enter a score from 0 to 9. The score pad can be used as a substitute or in addition to the traditional patient diary used in conjunction with activity monitoring.

### **10.3 Technological characteristics of this device and predicate device**

Both the *Actiwatch-Score®* and the predicate device, *Actiwatch®*, use an accelerometer to detect accelerated motion in the range 0.01 g and upwards. The *Actiwatch-Score®* detects motion and measures amount and duration of motion. The *Actiwatch®* also detects motion and the duration of motion. Each device records data and the data can later be downloaded to a PC for analysis and storage. Both devices are battery operated.

### **10.4 Assessment of Performance Data**

The *Actiwatch-Score®* audibly signals the patient to enter a self-score in accordance with a pre-arranged score schedule. The signal is a beep provided by an on-board digital buzzer. The device must consistently send the audible signal to the patient to enter his/her score on time. To test this timing capability, a device was programmed with a score schedule that alerted the subject to enter a score every 15 minutes. A chronograph was used as a timing standard in a side-by-side test to determine the device timing capability. The results of this test are shown in Attachment 1. The horizontal axis is the timing schedule while the vertical axis is the response result. The *Actiwatch-Score®* audible alarm was in 100% timing agreement with the chronograph standard.

In addition to the score timing test, the device was also tested to determine the accuracy with which it records patient scores. An *Actiwatch-score* was programmed to beep an alarm once per hour beginning at 12:00 noon and ending at 21:00. For each hour's beep, a score was entered. The data were downloaded at the end of the session and the recorded scores compared to the entered scores. Results of this test are shown in Attachment No. 2. No errors nor disagreement were noted between the entered scores and the recorded scores.

### **10.5 Patient Scoring Schedule**

A standard default scoring schedule appears during setup and this schedule can be programmed into the device. Alternatively, during device setup, a patient scoring schedule can be

created or loaded from PC storage and programmed into the device. A typical scoring schedule is shown in Attachment 3.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 23 1999

Jack E. McKenzie, Ph.D.  
Vice President of Market Development  
Mini-Mitter Company, Inc.  
P.O. Box 3386  
56885 Enterprise Drive  
Sunriver, Oregon 97707

Re: K991033  
Trade Name: Actiwatch-Score®  
Regulatory Class: II  
Product Code: GWQ  
Dated: March 26, 1999  
Received: March 29, 1999

Dear Dr. McKenzie:

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.

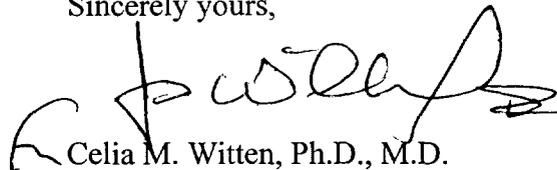
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Jack E. McKenzie, Ph.D.

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,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

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

2.0 INDICATIONS FOR USE

510(k) Number (if known):

K991033

Device Name:

Actiwatch-Score®

Indications for Use:

The *Actiwatch-Score®* is a compact, lightweight, wrist-worn activity monitor that can be used to analyze circadian rhythms, automatically collect and analyze data for sleep parameters, and assess activity in any instance where quantifiable analysis of physical motion is desirable. In addition, the *Actiwatch-Score®* has a built-in score pad that allows the subject to subjectively assign and enter a score from 0 to 9. The score pad can be used as a substitute or in addition to the traditional patient diary used in conjunction with activity monitoring.

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

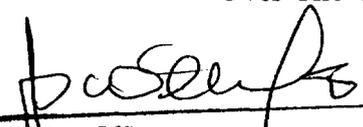
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K991033