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: January 8, 1999

10.1.2 Name of Device

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

10.1.3 Identification of predicate device

Number K854030 – Wrist Actigraph – Ambulatory Monitoring, Inc. - Product Code GWQ

10.1.4 Device Description

10.1.4.1 Functions of the device

The Actiwatch® 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® is intended for the measurement, storage, and analysis of body activity. The Actiwatch® 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® to collect data. This program is called *Sleepwatch* and runs on an IBM-compatible personal computer (PC). The major functions of Sleepwatch 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 Actiwatch® Reader is a compact interface device that provides a communications link between the Actiwatch® 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® 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.

10.1.4.3 Pertinent physical characteristics of the Actiwatch®:

Parameter	**Value**
Size	37x29x9 mm
Weight	17 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	2 seconds to 15 minutes
Recording time	1.4 to 365 days, depending upon epoch
Memory	16 KB in AW-16 64 KB in AW-64
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® is designed for documenting physical movements associated with applications in physiological monitoring. The Actiwatch® is intended for the measurement, storage, and analysis of body activity. The Actiwatch® can be attached to the subjects limb or trunk and through the use of an accelerometer, motion is measured, the activity is stored within the device. The Actiwatch® comes with its own software for data processing and display.

10.2.1 Technological characteristics of this device and predicate device

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

10.3 Assessment of Performance Data

10.3.1 Counts vs. motion

The most important performance characteristic of the Actiwatch® is its sensitivity to motion. This characteristic was measured by programming the device to collect data on one-minute intervals. The device was then subjected to a uniform, simple harmonic motion produced by a DC motor moving a lever at a constant speed. From the rotational speed of the motor and the length of the lever arm, the maximum acceleration can be calculated. Activity counts were compared to the maximum acceleration. Attachment No. 1 shows the results of this test. Motion as low as 0.01 g and as large as 10 g can be measured.

10.3.2 Variation between devices

Due to small variations between device characteristics and also due to variations in experimental control, there will be small differences between the activity counts measured with separate devices. These differences have been measured for a sample of five devices. The results are shown in Attachment No. 2. Movement acceleration in the range of 1G is typical for human subjects; this is the region where the Actiwatch® has its smallest variation between devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1999

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

Re: K983533
Trade Name: Actiwatch®
Regulatory Class: II
Product Code: GWQ
Dated: January 8, 1999
Received: January 12, 1999

Dear Dr. McKenzie:

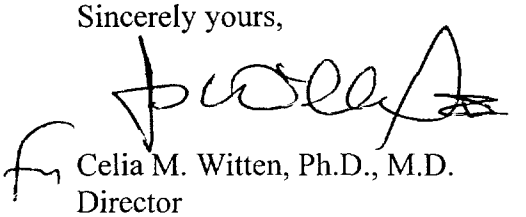
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

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

2.0 INDICATIONS FOR USE

510(k) Number (if known): K983533

Device Name: Actiwatch®

Indications for Use:

The Actiwatch® is an ultra-compact, lightweight, wrist-worn activity and ambient light monitor that can be used to analyze circadian rhythms, automatically collect and score data for sleep parameters, and 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 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983533