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JUL 16 2004

K040554

8 510(k) Summary

8.1 Submitter's Name and Address

John G. Schneider
Manufacturing Technology, Inc.
70 Ready Ave., NW
Fort Walton Beach, FL 32548
Ph: 850-244-7211 ext. 348 Fax: 850-664-5349
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8.2 Date Summary Prepared

June 17, 2004.

8.3 Name of Device

Trade Name: ActiGraph

Common Name: Activity Recording Device

Classification Name: Electroencephalograph (as per 21 CFR 882.1400)

8.4 Identification of Predicate Devices

Number K983533 – "Actiwatch" – Mini-Mitter

Number K992410 – "Actitrac" – Individual Monitoring, Inc.

Product Code – GWQ

8.5 Statement of Intended Use

The ActiGraph is a small limb worn activity monitor designed for documenting physical movements associated with applications in physiological monitoring. The device's intended use is 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.

8.6 Device Description

8.6.1 Functions of the Device

The ActiGraph is a compact wrist, waist, or ankle worn, battery-operated activity monitor whose physical characteristics are similar to a wristwatch. The monitor consists of the activity monitor itself and a disposable wrist strap, belt clip, or nylon pouch.

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

A computer program is used to set up the ActiGraph to collect data. This program is called Actisoft and runs on an IBM-compatible personal computer (PC) having a WINDOWS OS. The major functions of Actisoft are to program the device to collect data, retrieve the data from the activity monitor, display the data, and rename and store the data for storage for future reference and comparison.

The ActiGraph's Reader Interface Unit is a compact interface device that provides a communications link between the ActiGraph and the PC. The ActiGraph Reader is connected to the serial communications port of the PC via a standard 9-conductor RS-232 cable or an USB adapter.

8.6.2 Basic Scientific Concepts

The ActiGraph 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, filtered, and digitized by the on-board electronics. This information is stored in memory on board the device as activity counts.

8.7 Information of Device Specification

8.7.1 Counts vs. Motion

The most important performance characteristic of the ActiGraph is its sensitivity to motion. This characteristic is a measurement of its response amplitude, at 0.75 Hertz the peak sensitivity of the device. The device is then subjected to critical frequencies and the amplitude response measured. This output is then compared to the response standard and all ActiGraphs must be within 2% of this standard.

8.7.2 Variation Between Devices

Due to small variations between devices characteristics can be attributed to variations in electronic components. This will account for small differences between the activity counts measured with separate devices. These differences have been measured for a sample of ten devices. The results are shown in Attachment J. Movement acceleration in the range of 1G at 0.75 Hertz is typical for human subjects and this is the region where the ActiGraph has its smallest variation between devices.

8.8 Labeling

The labeling for the ActiGraph is covered in its operator's manual, which is in Attachment A and our marketing material, Attachment B.

8.9 A Comparison with a Predicate Device

8.9.1 Technological Characteristics

Technological characteristics of this device and predicate devices use an accelerometer to detect accelerated motion in the range 0.016 g and upward. The data stored in the ActiGraph is the integration of motion with time (amplitude and duration). The Actiwatch, by Mini-Mitter, detects motion and measures the amount and duration of motion. Each device records data on an electronic circuit board and the data can later be downloaded to a PC for analysis and storage. All the devices are battery operated.

8.9.2 *Physical Characteristics*

The following Table 1 illustrates pertinent physical characteristics of the ActiGraph comparing it to the Actiwatch.

Parameter	**ActiGraph**	**Actiwatch®**
Size	2" x 2" x 0.5"	1.5" x 1.1" x 0.4"
Weight	1.5 oz, with battery 2.5 oz	0.6 oz, with battery 1.0 oz
Battery Type	CR2430	CR2025
Battery Life	6 months	6 months
Battery Type	Lithium/Manganese Dioxide (Li/MnO_2)	Lithium/Manganese Dioxide (Li/MnO_2)
Accelerometer sensitivity	16 milliGs	10 milliGs
Enclosure	Polycarbonate	Polycarbonate
Wrist Band/Belt Clip/Pouch	Nylon w/ Velcro©/Polycarbonate/Nylon w/ Velcro©	Wrist band: Nylon with buckle
Moisture susceptibility	Water resistant	Water Resistant
Sampling intervals	1 second and up	2 seconds to 15 minutes
Recording time	2 hours to 180 days (end of battery life)	1.4 to 365 days, depending on epoch
Memory	64kB in AM7164; 256kB in AM71256	16kB in AW-16; 64kB in AW-64
Storage Temperature	-10°C to 50°C	-10°C to 50°C
Operating Temperature	0°C to 45°C	0°C to 40°C

Table 1 – Comparing ActiGraph and Actiwatch

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

Mr. John G. Schneider
Strategic Accounts Manager
Manufacturing Technology Incorporated
70 Ready Avenue, NW
Fort Walton Beach, Florida 32548

Re: K040554
Trade/Device Name: ActiGraph
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: June 15, 2004
Received: June 22, 2004

Dear Mr. Schneider:

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.

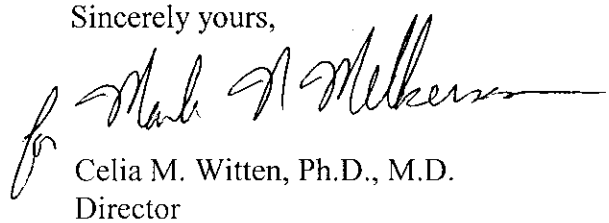
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,



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

Indications for Use

510(k) Number (if known): K040554

Device Name: ActiGraph

Indications For Use:

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

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N. Melkerson

for K040554

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

510(k) Number K040554