K080545

VII 510(k) Summary

JUL 24 2008

Applicant:
ActiGraph, LLC
15 W. Main St.
Pensacola, FL 32502
Phone: (850) 332-7900
Fax: (859) 332-7904

Point of Contact: John G. Schneider, VP of R&D

Trade Name: ActiTrainer

Common Names: Activity Recording Device

Classification Name: ISD

Equivalent Legally Marketed device: The ActiTrainer is similar in function to the ActiGraph LLC's legally marketed activity monitor, the Actigraph, K040554.

Description of Device: The ActiTrainer is housed in a polycarbonate plastic housing. It is 8.5 cm long by 3.4 cm wide by 1.6 cm thick and it weights 51 grams. It also has an optional Polar® heart strap. Data is downloaded into a PC via a USB plug and the data is displayed with ActiGraph LLC's ActiLife software.

Intended Use. The ActiTrainer is a small worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring. The device is intended to monitor the activity associated with movement during sleep. The ActiTrainer can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.

Technological Characteristics: The ActiTrainer is substantially equivalent to the Actigraph, they both record and same movement with accelerometer and save the data internally on RAM. They both use an on board microprocessor for controlling the data which can be displayed with ActiGraph LLC's ActiLife data. ActiTrainer has an optional heart rate channel and expanded memory capability to handle the extra data.

Comparison Table		
Parameter	**Actigraph (Predicate)**	**ActiTrainer**
Size	5.1 x 5.1 x 1.1	8.5 x 3.4 x 1.6
Weight	42.5 grams	51 grams
Battery Type	Lithium/Manganese Dioxide	Lithium Ion
Accelerometer Sensivity	16 milliGs	4 milliGs
Enclosure	Polycarbonate	Polycarbonate
Sampling Intervals	1 second and 4 minutes	1 second to 4 minutes
Recording Time @ 1min. Epoch	11 days	14 days
Memory	256kB	1024kB
Storage Temperature	-10°C to 50°C	-10°C to 50°C
Operating Temperature	0°C to 40°C	0°C to 40°C
Heart Rate	n.a.	BPM

Table 1. Comparing the ActiTrainer to the Actigraph.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Actigraph, LLC.
% Mr. John Schneider
Vice President of R & D
15 West Main Street
Pensacola, Florida 32502

JUL 24 2008

Re: K080545
Trade Name: ActiTrainer
Regulation Number: 21 CFR 890.5360
Regulation Name: Measuring Exercise Equipment
Regulatory Class: Class II
Product Code: ISD
Dated: June 6, 2008
Received: June 11, 2008

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.
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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K080545

Device Name: ActiTrainer

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number k080545

15 West Main Street Pensacola, FL USA Ph: 850-332-7900 Fax: 850-332-7904
Website: www.TheActiGraph.com