K132764

JAN 21 2014

5.0 510(K) SUMMARY

5.1 Summary information

5.1.1 Submitter's name and address

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Date summary was prepared: 16th January 2014

5.1.2 Name of device

Trade Names:	*MotionWatch* and *PRO-Diary*
Common Name:	Activity Recording Device
Classification Name:	Unclassified
Product Regulation:	Unclassified
Product Code:	LEL

5.1.3 Identification of predicate devices

Actiwatch® (Mini-Mitter Co. Inc.), 510(k) Number : **K983533**

Actiwatch-Score® (Mini-Mitter Co. Inc.), 510(k) Number : **K991033**

5.2 Device description

5.2.1.1 Functions of the device

MotionWatch and *PRO-Diary* are compact, ambulatory, battery-operated activity recorders with physical characteristics similar to a small wristwatch.

The *MotionWatch* and *PRO-Diary* are intended for the acquisition and analysis of the physical activity of the body during daily living and sleep. The *MotionWatch* and *PRO-Diary* use state of the art miniature accelerometer technology to measure movements of the limb or torso and store these data within the device. The devices differ in that the *MotionWatch* incorporates an ambient light sensor whereby the *PRO-Diary* incorporates a display and score-pad to allow subjective inputs.

The *MotionWatch* and *PRO-Diary* require operational software to allow configuration, data download, storage and off-line analysis of activity data by a health care provider. The software can be run on an IBM-Compatible PC and the device is connected directly by means of a standard Universal Serial Bus connection for configuration and download.

5.2.1.2 Basic scientific concepts

The *MotionWatch* and *PRO-Diary* utilize a motion sensor known as an "accelerometer" to measure the occurrence and degree of motion. The sensor is a solid state device with a digital output directly proportional to physical acceleration in 1, 2 or 3 axes of orientation. The acceleration data are processed into "counts" before being stored in the non-volatile memory of the device.

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5.2.1.3 Physical characteristics of Device

Pertinent physical characteristics of the *MotionWatch* are shown in Table 5.1.

TABLE 5.1: PHYSICAL CHARACTERISTICS OF *MOTIONWATCH* AND *PRO-DIARY*

Parameter	MotionWatch	PRO-Diary	Condition/Note
Size	36mm x 28.2mm x 9.4mm	51.5mm x 34.6mm x 9.4mm	Outer dimensions (excluding strap)
Weight	9.1 grams	16 grams	excluding strap
Battery Type	CR2032, User replacable	Fixed, rechargeable	
Battery Life	6 Months	3 Weeks	Typical
Acceleration Range	0.01g to 8g	0.01g to 8g	
Casing material	Polycarbonate/ABS	Polycarbonate/ABS	
Wrist band	Nylon with stainless steel buckle	Nylon with stainless steel buckle	
Moisture resistance	IPX7[1]	IP42[2]	1) Water resistant to 1m for 1 hour. 2) Drip resistant
Sampling Intervals (epochs)	1 Second to 1 Minute	1 Second to 1 Minute	User selectable
Recording time	6 to 182 days	6 to 21 days	Depending upon epoch
Memory	512KB	4MB	Non-Volatile
Indicators	Single LED Status	OLED Display for subjective scoring	
Storage Temperature	-25°C to 70°C	-25°C to 70°C	0-93% RH
Operating Temperature	5°C to 40°C	5°C to 40°C	0-93% RH

5.3 Statement of the intended use

The MotionWatch and PRO-Diary are compact, lightweight, body-worn activity monitoring devices that may be used to document physical movement associated with applications in physiological monitoring. The devices are intended to monitor limb or body movements during daily living and sleep. The MotionWatch and PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired.

Additionally, the PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can

be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring.

5.4 Comparison of the MotionWatch with the predicate device

The *MotionWatch* is substantially equivalent to the predicate [*Actiwatch*® FDA 510(k) Number: K983533]. The *MotionWatch* and the *Actiwatch*® are both physical activity recording systems based upon the concept of an ambulatory, unattended recorder that logs data to the device. Each of these devices is a solid-state recorder with accelerometer sensor, data collection means, and with the ability to store data until it is transferred to a personal computer. The *MotionWatch* and the *Actiwatch*® are of similar mechanical materials, construction, size, and human interface characteristics. The *MotionWatch* and the *Actiwatch*® are of similar electronic design and their operational characteristics and indications for use are equivalent. Table 5.2 compares the features of the *MotionWatch* with those of the *Actiwatch*®.

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TABLE 5.2. COMPARISON OF MOTIONWATCH TO ACTIWATCH

COMPARISON PARAMETER	*MotionWatch* *(Current Device)*	*Actiwatch* (Predicate Device)

Indications for use	The MotionWatch and PRO-Diary are compact, lightweight, body-worn activity monitoring devices that may be used to document physical movement associated with applications in physiological monitoring. The devices are intended to monitor limb or body movements during daily living and sleep. The MotionWatch and PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired. Additionally, the PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring.	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 store data for sleep parameters, and assess activity in any instance where quantifiable analysis of physical motion is desirable.
Device general description	Compact, wearable, battery-operated physical activity *data recorder*	Compact, wearable, battery-operated physical activity *data recorder*
Activity channels	1, 2, or 3	1
Visual appearance and physical description of Recorder	Plastic molded wristwatch style casing with detachable band. Size 36 x 28.2 x 9.4 (excluding band)	Plastic molded wristwatch style casing with detachable band. Size 37 x 29 x 9 (excluding band)
Weight	9.1 grams	17 grams
Materials	ABS blend	ABS Blend
Sampling Intervals (epoch)	1, 2, 5, 10, 15, 30, 60 seconds	15, 30, 60, 120, 300, 600 seconds
Recording time	182 Days @ 60s epoch	45 Days @ 60s epoch
Memory	512kBytes	64kBytes
Raw Sampling rate	50 Hz	32 Hz
A/D conversion	12 bits	8 bits
Frequency response	3 to 11 Hz	3 to 11 Hz

Moisture Susceptibility	IPX7	IPX7
Sterility	None required	None required
Biocompatibility (skin contact type)	Standard nylon wrist band in contact with intact skin surface.	Standard nylon wrist band in contact with intact skin surface.
Human factors	Worn in wrist like a wristwatch; no user interaction is required.	Worn in wrist like a wristwatch; no user interaction is required.
Electrical safety (Recorder)	Battery operated	Battery operated
Power used (Recorder)	3.0 volt coin cell type CR2032 (1 each, user-replaceable)	3.0 volt coin cell type CR2025 (1 each, user-replaceable)
Battery Life (typical)	6 months	6 months

5.5 Comparison of the PRO-Diary with the predicate device

The *PRO-Diary* is substantially equivalent to the predicate [*Actiwatch-Score*® FDA 510(k) Number: K991033]. The *PRO-Diary* and the *Actiwatch-Score*® are both physical activity recording systems based upon the concept of an ambulatory, unattended recorder that logs data to the device. Each of these devices is a solid-state recorder with accelerometer sensor, data collection means, and with the ability to store data until it is transferred to a personal computer. The *PRO-Diary* and the *Actiwatch-Score*® both incorporate a score-pad for the prompting and input of subjective patient data. The *PRO-Diary* and the *Actiwatch-Score*® are of similar mechanical materials, construction, size, and human interface characteristics. The *PRO-Diary* and the *Actiwatch-Score*® are of similar electronic design and their operational characteristics and indications for use are equivalent.

Table 5.3 compares the features of the PRO-Diary with those of the Actiwatch-Score®.

TABLE 5.3. COMPARISON OF PRO-DIARY TO ACTIWATCH-SCORE

COMPARISON PARAMETER	*PRO-Diary (Current Device)*	*Actiwatch-Score* (Predicate Device)

Indications For Use	The MotionWatch and PRO-Diary are compact, lightweight, body-worn activity monitoring devices that may be used to document physical movement associated with applications in physiological monitoring. The devices are intended to monitor limb or body movements during daily living and sleep. The MotionWatch and PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired. Additionally, the PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring.	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.
Device general description	Compact, wearable, battery-operated physical activity *data recorder* with integrated score pad.	Compact, wearable, battery-operated physical activity *data recorder* with integrated score pad.
Activity channels	1, 2, or 3	1
Visual appearance and physical description of Recorder	Plastic molded wristwatch style casing with detachable band. Size 51.5 x 34.6 x 9.4mm (excluding band)	Plastic molded wristwatch style casing with detachable band. Size 37 x 35 x 12mm (excluding band)
Weight	16 grams	25 grams
Materials	ABS blend	ABS Blend
Sampling Intervals (epoch)	1, 2, 5, 10, 15, 30, 60 seconds	15, 30, 60, 120, 300, 600 seconds
Recording time	21 Days @ 60s epoch	45 Days @ 60s epoch
Memory	4MBytes	64kBytes
Raw Sampling rate	50 Hz	32 Hz
A/D conversion	12 bits	8 bits
Frequency response	3 to 11 Hz	3 to 11 Hz

Moisture Susceptibility	IP32	IP52
Sterility	None required	None required
Biocompatibility (skin contact type)	Standard nylon wrist band in contact with intact skin surface.	Standard nylon wrist band in contact with intact skin surface.
Human factors	Worn on wrist like a wristwatch; display and score-pad for subjective input.	Worn on wrist like a wristwatch; display and score-pad for subjective input.
Electrical safety (Recorder)	Battery operated	Battery operated
Power used (Recorder)	3.7 volt rechargeable (1 each, not user-replaceable)	3.0 volt coin cell type CR2025 (1 each; user-replaceable)
Battery Life (typical)	21 days between charging	6 months between replacement

5.6 Assessment of non-clinical performance data

There are no special controls or consensus standards applicable to the measurement of body movement. To verify the performance of the *MotionWatch* and *PRO-Diary* a sample of devices were subjected to a suite of bespoke tests to verify each performance parameter. Table 5.4 provides a summary of the MotionWatch non-clinical performance testing.

TABLE 5.4: SUMMARY OF MOTIONWATCH NON-CLINICAL PERFORMANCE TESTING

Requirement summary	Test/verification Method	Pass/fail criteria	Test result
The device shall measure linear acceleration with an accuracy of +/-5% over the full range	Apply a range of simulated reference acceleration and record the results.	The recorded acceleration over the test range shall meet the requirement.	**PASS**
The device accuracy shall be <= +/-5% at the calibration point (i.e. 1g).	Collate random sample of calibration records and examine inter-device variation.	The variation in calibration values shall meet or exceed the requirement.	**PASS**
The device shall have a frequency response of 3 to 11 Hz	Apply a fixed acceleration over a range of frequencies and record the results	The frequency response shall meet the requirement to within +/-10%	**PASS**
The device shall output zero counts when no physical stimulus is applied	Set-up a sample device and record for a period with no physical stimulus.	The device shall record zero for the period of no physical stimulus.	**PASS**.
The light sensor shall have an accuracy of +/-7.5% over the stated range.	Record a range of light from darkness to sunlight with a sample device simultaneously with a calibrated light meter. Compare the results	The device shall meet the requirement, however it is acceptable that the accuracy worsens as light level increases. The accuracy over particular ranges shall be specified in the IFU.	**PASS**.
The device shall output zero lux when the sensor is in total darkness	Record data with the light sensor covered with fully opaque tape.	The device shall record zero lux for the test period.	**PASS**
The device shall recover from unexpected reset events and/or total loss of power with no effect on the stored data.	A sample device shall be subjected to multiple power on reset events and the stored data shall be subsequently downloaded and examined.	No loss of function/data shall occur following the multiple reset events.	**PASS**

Table 5.5 provides a summary of the PRO-Diary non-clinical performance testing.

TABLE 5.5: SUMMARY OF PRO-DIARY NON-CLINICAL PERFORMANCE TESTING

Requirement summary	Test/verification Method	Pass/fail criteria	Test result
The device shall measure linear acceleration with an accuracy of +/-5% over the full range	Apply a range of simulated reference acceleration and record the results.	The recorded acceleration over the test range shall meet the requirement.	**PASS**
The device accuracy shall be <= +/-5% at the calibration point (i.e. 1g).	Collate random sample of calibration records and examine inter-device variation.	The variation in calibration values shall meet or exceed the requirement.	**PASS**
The device shall have a frequency response of 3 to 11 Hz	Apply a fixed acceleration over a range of frequencies and record the results	The frequency response shall meet the requirement to within +/-10%	**PASS**
The device shall output zero counts when no physical stimulus is applied	Set-up a sample device and record for a period with no physical stimulus.	The device shall record zero for the period of no physical stimulus.	**PASS**
The display shall be legible in low-light conditions (<100 lux) with normal corrected vision.	A sample device is observed under the stated light conditions	The display shall be legible in accordance with the requirements	**PASS**
The display shall be legible in bright-light conditions (<20000 lux) with normal corrected vision.	A sample device is observed under the stated light conditions	The display shall be legible in accordance with the requirements	**PASS**
The responses to questions shall be accurately recorded and displayed in the results viewer.	A sample device is used to record entries pre-defined in a written log. The downloaded and displayed data are compared to the written log.	There shall be no differences between the electronically reported data and the written log	**PASS**

In addition to performance testing, the devices have been evaluated and tested for safety and electromagnetic interference according to the following internationally recognized standards:

IEC60601-1: 2005 *Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance.*

IEC60601-1-11:2010 *Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance. Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*

IEC60601-1-2: 2007, *Medical Electrical Equipment - PART 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.*

The testing according to these standards has raised no issues as to the safety and effectiveness of the present devices or the present devices compared to the predicate devices.

5.7 Conclusion

The results of the performance testing and safety and environmental testing show that the *MotionWatch* and *PRO-Diary* are as safe, as effective, and perform as well as the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 21, 2014

CamNtech Ltd.
c/o Mr. Howard Smith
Engineering Director
Upper Pendrill Court
Ermine Street North
Papworth Everard,
Cambridge, United Kingdom CB233UY

Re: K132764
Trade/Device Name: MotionWatch and PRO-Diary
Regulation Number: Unclassified
Common Name: Sleep Assessment Device (Activity Recorder)
Regulatory Class: Class II
Product Code: LEL
Dated: December 16, 2013
Received: December 17, 2013

Dear Mr. Smith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K132764

Device Name: MotionWatch and PRO-Diary

Indications for Use:

The MotionWatch and PRO-Diary are compact, lightweight, body-worn activity monitoring devices that may be used to document physical movement associated with applications in physiological monitoring. The devices are intended to monitor limb or body movements during daily living and sleep. The MotionWatch and PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired.

Additionally, the PRO-Diary has a built-in score pad that allows the wearer to subjectively assign and enter responses to pre-programmed questions. The score pad can be used as a substitute or in addition to the traditional written patient diary in conjunction with activity monitoring.

Prescription Use_X____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of Center of Devices and Radiological Health (CDRH)

Carlos L. Pena -S