DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 25, 2016

Condor Instruments Ltda. - EPP
Rodrigo Trevisan Okamoto,
Managing Director
Rua Brigadeiro Luis Antonio, 551, Cj 124
Sao Paulo, SP Brazil 01318-000

Re: K151784
Trade/Device Name: ActTrust
Regulation Number: 21 CFR
Regulation Name: Unclassified
Regulatory Class: Unclassified
Product Code: LEL
Dated: April 18, 2016
Received: April 22, 2016

Dear Rodrigo Okamoto:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

William J. Heetderks -A

Digitally signed by William J. Heetderks -A
DN: c=US, o=U.S. Government, ou=HHS, ou=NIH, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -A
Date: 2016.05.25 15:41:54 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151784

Device Name

ActTrust

Indications for Use *(Describe)*
The ActTrust is an ultra-compact, lightweight, wrist-worn activity, temperature 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. The device is intended to monitor limb or body movements during daily living and sleep. ActTrust is indicated for adults of 22 years of age and over.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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06/02/2015

5 510(K) SUMMARY

5.1 Summary information

5.1.1 Submitter's name and address

Rodrigo Trevisan Okamoto, Managing Director

Condor Instruments LTDA - EPP

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São Paulo , SP, Brazil

01318-000

Tel: +55 11 2129-6662

Date summary was prepared: 2th June 2015

5.1.2 Name of device

Trade Names: ActTrust

Common Name: Activity Recording Device, Actimeter

Classification Name: Unclassified

Product Regulation: Unclassified

Product Code: LEL

Device non-sterile when used

5.1.3 Identification of predicate devices

Number K983533 - "Actiwatch" - Mini-Mitter
Number K132764 - "MotionWatch and PRO-Diary" – CamNtech
Number K111514 - "SBV2 System" – SLEEP PERFORMANCE D.B.A. FATIGUE SCIENCE

5.2 Device description

5.2.1 Functions of the device

ActTrust is a compact, ambulatory, battery-operated data recorder with physical characteristics similar to a small wristwatch.

The ActTrust is intended for the acquisition and analysis of the physical activity of the body, peripheral temperature and light exposure during daily living and sleep. The ActTrust uses state of the art miniature electronic technology to measure the data and store these data within the device.

The ActTrust require operational software to allow configuration, data download, storage and off-line analysis of activity data by a health care provider. The device is connected directly by means of a standard Universal Serial Bus connection for configuration and download.

5.2.2 Basic scientific concepts

The ActTrust 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 before being stored in the non-volatile memory of the device.

The temperature sensor is a thermistor. These sensors electrical resistance changes according to the temperature. These chances are read by a micro-controller and the values are then stored in the non-volatile memory of the device.

The light sensor measures the total light and its components in RGB-IR spectrum and then these data are stored in the non-volatile memory of the device.

5.2.3 Physical characteristics of Device

Pertinent physical characteristics of the ActTrust are shown in Table 5. 1.

Table 1 - PHYSICAL CHARACTERISTICS OF ActTrust

Parameter	ActTrust	Condition/Note
Size	47mm x 31mm x 12 mm	Outer dimensions (excluding strap)
Weight	19 grams	excluding strap
Battery Type	Fixed, rechargeable	
Battery Life	3 Months	Typical
Acceleration Range	0.01g to 4g	
Casing material	Polycarbonate	
Wrist band	silicone with stainless steel buckle	
Moisture Resistance	IP67	Water resistant to 1m for 1 hour.
Sampling Intervals (epochs)	1s to 86400s	User selectable
Recording time	typical 90 days	Depending upon epoch
Memory	4 MB	Non-Volatile
Storage Temperature	-20 °C a 60 °C	

Operating Temperature	0 °C a 60 °C	

5.3 Statement of the intended use

The ActTrust is an ultra-compact, lightweight, wrist-worn activity, temperature 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. The device is intended to monitor limb or body movements during daily living and sleep. ActTrust is indicated for adults of 22 years of age and over.

5.4 Comparison of the ActTrust with the predicate device

The ActTrust is Substantially equivalent to the predicates [Actiwatch® FDA 510(k) Number: K983533, SBV2 System FDA 510(k) Number: K111514, and Motion Watch FDA 510(k) Number: K132764] . The ActTrust and the Predicate Devices are all 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 capability to store data until it is transferred to a personal Computer. The ActTrust and the Predicate Devices are of similar mechanical designs, construction, size, and human interface characteristics. The ActTrust and the Predicate Devices are of similar electronic design and their operational characteristics and indications for use are equivalent. Table 5.2 compares the features of the ActTrust with those of the Predicate Devices.

Table 2 - COMPARISON OF ACTTRUST TO PREDICATE DEVICES

COMPARISON PARAMETER	ActTrust (Current Device)	Actiwatch (Predicate device)	SBV2 System (Predicate Device)	Motion Watch (Predicate device)
Indications for use	The ActTrust is an ultra-compact, lightweight, wrist-worn activity, temperature and ambient light monitor that can be used to analyze circadian rhythms, automatically collect and store data for sleep parameters, and	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,	The SBV2 System is an activity monitor designed and intended for documenting physical movements associated with applications in physiological monitoring. The device's intended use is to analyze limb activity associated with movement during	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

	limb or body movements during daily living and sleep. ActTrust is indicated for adults of 22 years of age and over.	and assess activity in any instance where quantifiable analysis of physical motion is desirable.	sleep and to extract information about certain sleep parameters from these movements. SBV2 can also be used to assess activity in any instance where quantifiable analysis of physical motion is desirable. The use of the SBV2 is restricted to adults 22 years of age and over.	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.
Device general description	Compact, wearable, battery-operated physical activity data recorder	Compact, wearable, battery-operated physical activity data recorder	Compact, wearable, battery-operated physical activity data recorder	Compact, wearable, battery-operated physical activity data recorder
Activity channels	1, 2, or 3	1	1	1, 2, or 3
Visual appearance and physical description	Plastic molded wristwatch style casing with detachable band. Size 47 x 31 x 12 (excluding band)	Plastic molded wristwatch style casing with detachable band. Size 37 x 29 x 9	Plastic molded wristwatch style casing with detachable band. Size 38.1 x 38.1 x	Plastic molded wristwatch style casing with detachable band. Size 36 x 28.2 x 9.4 (excluding band)
Weight	19 grams	17 grams	28.3 grams	9.1 grams
Frame Cover	Polycarbonate	Polycarbonate	Polycarbonate	ABS blend
Sampling Intervals	Any between 1 and 86400 seconds	15, 30, 60, 120, 300, 600 seconds	60 seconds	1, 2, 5, 10, 30, 60 seconds
Recording time	90 Days @ 60s epoch	45Days @ 60s epoch	30 Days @ 60s epoch	182 Days @ 60s epoch

Memory	4 MB	64 kB	64 kB	512 kB
Raw Sampling rate	25 Hz	32Hz	16Hz	50 Hz
A/D conversion	12 bits	8 bits	8 bits	12 bits
Frequency response	0.5 to 12.5 Hz	3 to 11Hz	3 to 11Hz	3 to 11 Hz
Moisture Susceptibility	IPX7	IPX7	IP X6	IPX7
Sterility	None required	None required	None required	None required
Biocompatibility (skin contact type)	Standard silicon wrist band in contact with intact skin surface.	Standard nylon wrist band in contact with intact	Santoprene 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.	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	Battery operated	Battery operated
Power used (Recorder)	3.7 volt coin cell type LIR2032H (1 each, rechargeable)	3.0 volt coin cell type CR2025 (1 each, user-replaceable)	Rechargeable 3.7V Lithium Coin Cell	3.0 volt coin cell type CR2032 (1 each, user-replaceable)
Battery Life (typical)	3 months	6 months	30 days	6 months

5.5 Differences between ActTrust and Predicate Devices

5.5.1 Differences between ActTrust and SBV2 system (Predicate Device)

All the differences between the ActTrust and the SBV2 system have no effect on the safety of the device and implies in minor functionalities changes.

5.5.2 Differences between ActTrust and Actiwatch (Predicate Device)

The meaningful difference between differences between ActTrust and Actiwatch predicate device is the means of commercial distribution. The ActTrust is intended for Over-The-Counter commercial distribution. Actiwatch is indicated for Prescription Use.

5.5.3 Differences between ActTrust and Motion Watch (Predicate Device)

All the differences between the ActTrust and the SBV2 system have no effect on the safety of the device and implies in minor functionalities changes.

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 ActTrust 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 ActTrust non-clinical performance testing.

TABLE 5.4: SUMMARY OF ACTTRUST 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 0.5 to 12.5 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.	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**
The Thermistor shall have an accuracy of +/- 0.5°C over the stated range.	Put the devices in a climatic chamber and a ramp curve on the temperature and examine inter-device variation.	The temperature must be between the specified range	**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.

UL1642:2012, Lithium Battery – Standard for safety.

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.

Furthermore, an analysis and rationale about the devices biocompatibility and sterile process was made and the summaries are shown in Tables 5.5 and 5.6.

TABLE 5.5: SUMMARY OF ACTTRUST BIOCOMPATIBILITY ANALYSIS

Item	Material	Contact Classification	Rationale

Frame cover	Polycarbonate	Surface-contacting, up to 3 months	Same material as the one used in other devices previously approved
Wristband	Hypoallergenic silicone	Surface-contacting, up to 3 months	Made of hypoallergenic silicone and designed and used in commercial watches.
Cover Plate	Stainless steel AISI 430	Surface-contacting, up to 3 months	The AISI 430 is graded as surgical and has historically been used in many biocompatible devices.

TABLE 5.6: SUMMARY OF ACTTRUST STERILIZATION ANALYSIS

Item	Material	STERILIZATION
Frame cover	Polycarbonate	non-sterile when used
Wristband	Hypoallergenic silicone	non-sterile when used
Cover Plate	Stainless steel AISI 430	non-sterile when used

5.7 Conclusion

The results of the performance testing and safety and environmental testing show that the ActTrust is as safe, as effective, and perform as well as the predicate device.