July 3, 2020

True Wearables, Inc.
℅ Amy Fowler
Regulatory Counsel
Gardner Law, PLLC
423 Main Street
Stillwater, Minnesota 55082

Re: K200537
Trade/Device Name: Oxxiom Pulse Oximetry System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: June 2, 2020
Received: June 4, 2020

Dear Amy Fowler:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd Courtney
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200537

Device Name
Oxxiom Pulse Oximetry System

Indications for Use *(Describe)*

The Oxxiom Pulse Oximetry System is a wireless, fully disposable, single-use device indicated for measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). It may be used for spot checking, intermittent monitoring, and/or data collection of patients 12 years and older in low acuity settings in facilities such as hospitals, clinics and doctor's offices. It can also be used in home healthcare settings under prescription use. It is not intended for continuous monitoring.

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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510(k) Summary

According to 21 CFR 807.92

Date Prepared: June 2, 2020

Submitter Information

Submitter:	True Wearables, Incorporated 29826 Avenida de Las Banderas, Suite 300 Rancho Santa Margarita, CA 92688
Manufacturer:	True Wearables, Incorporated 29826 Avenida de Las Banderas, Suite 300 Rancho Santa Margarita, CA 92688

Establishment Registration Number: 3012234356

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Alternate Contact:	Marcelo Lamego CEO, True Wearables, Inc
Phone:	949-709-0850
Fax:	NA
E-mail:	mmlamego@truewearables.com

Name of Device and Classification

Trade Name:	Oxxiom® Pulse Oximetry System
Common Name:	Pulse Oximetry System
Device Classification:	Oximeter, CFR §870.2700, Class II
Product Code(s):	DQA

Predicate Device

Predicate:	Guardian Angel GA1000 Digital Vital Sign Monitoring System; K162580

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Intended Use/Indications for Use

The Oxxiom Pulse Oximetry System is a wireless, fully disposable, single-use device indicated for measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). It may be used for spot checking, intermittent monitoring, and/or data collection of patients 12 years and older in low acuity settings in facilities such as hospitals, clinics, and doctor's offices. It can also be used in home healthcare settings under prescription use. It is not intended for continuous monitoring.

Device Description

Oxxiom Pulse Oximetry System is a wireless, fully disposable, single-use device for measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). It also measures Pulse Amplitude (PA). It is a prescription device for spot checking, intermittent monitoring, and data collection.

Oxxiom has two main components, the Oxxiom device (hardware device) and the Oxxiom Rx App. Oxxiom also provides tape to apply the device to the finger. Oxxiom also requires the use of an iOS display device, such as an iPhone, iPad, or iPod, that has iOS version 10.1 or later. The iOS device is not provided with the Oxxiom Pulse Oximetry System.

Oxxiom is small, lightweight, and has a 24-hour battery life. The device simultaneously, and wirelessly transfers all collected data through a Bluetooth connection to the Oxxiom App on the iOS device, which analyzes data, displays information, provides warnings as necessary, and stores the information.

Oxxiom has been tested on a subject population with devices placed on the finger. Monitoring at other sites of the body is not recommended. The principle of operation is based upon the noninvasive reflectance of red and infrared light.

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Summary of Comparison of Intended Use and Technological Characteristic

Oxxiom Pulse Oximetry System is compared below to the legally marketed predicate device, Guardian Angel GA1000 Digital Vital Sign Monitoring System K162580

Characteristic	Subject Device	Predicate Device
Product Name	Oxxiom Pulse Oximetry System	Guardian Angel GA1000 Digital Vital Sign Monitoring System
Manufacturer	True Wearables, Inc	Taiwan Aulisa Medical Devices Technologies, Inc
Regulation	Oximeter CFR §870.2700 Pulse Oximeter	Oximeter CFR §870.2700 Pulse Oximeter
Product Code(s)	DQA	DQA
Device Class	Class II	Class II
Indications for Use	The Oxxiom® Pulse Oximetry System is a wireless, fully disposable, single-use device indicated for measuring, displaying, and storing functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). It may be used for spot checking, intermittent monitoring, and/or data collection of patients 12 years and older in low acuity settings in facilities such as hospitals, clinics, and doctor's offices. It can also be used in home healthcare settings under prescription use. It is not intended for continuous monitoring.	The Guardian Angel GA1000 Digital Vital Sign Monitoring System is indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate of adult and pediatric patients. It is indicated for spot-checking and / or continuous monitoring of patients during non-motion and under well-perfused conditions. The intended environment of use is hospital. This system is a reusable device.
Type of Use	Spot checking Intermittent monitoring Data collection	Spot checking Continuous use
Motion	Non-motion	Non-motion
Patient Population	Patients 12 years and older	Adult Pediatric
Perfusion	Well	Well
Environment of Use	Hospitals, clinics, doctor's offices. Home (under prescription use)	Hospitals

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Characteristic	Subject Device		Predicate Device	
Disposable	Yes		No	
Application Site	Finger		Finger	
Technology	Red and Infrared reflectance technology		Red and Infrared transmittance technology	
System Components	Wireless, disposable oximeter device and software App. User to supply iOS device		Sensor Module and Display Unit	
Wireless Technology / Data Transmission	Bluetooth V4.0		Bluetooth V4.0	
Display	Non-dedicated iOS Device Display		Dedicated Display	
Software Level of Concern	Moderate		Moderate	
SpO2 Specifications (No Motion)	Displayed Range:	1-100%	Displayed Range:	1-100%
	Declared Range:	70-100%	Declared Range:	70-100%
	Accuracy	Patients 12 years and older ± 3.5%	Accuracy (Adults and Pediatrics)	Adults/Pediatrics ± 3%
Pulse Rate Specifications (No Motion) Controls	Displayed Range:	25-250 bpm	Displayed Range:	30-290 bpm
	Accuracy	Patients 12 years and older ± 3 bpm	Accuracy (Adults and Pediatrics)	Adults/Pediatrics ± 3 bpm
Measurement Wavelengths and Output Power	Red 655 nm Infrared 940 nm		Red 660 nm @ 1.8 mw nominal Infrared 905 nm @ 2 mw nominal	

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Characteristic	Subject Device	Predicate Device
Battery	Wireless Disposable Oximeter: Non rechargeable Lithium Manganese Dioxide (LiMnO2), 150 mAh, 3 V	Sensor Module: 3.7 V Lithium Battery Display Unit: Lithium Battery, AC Adaptor
Alarm	Audible and visual pulse rate, oxygen saturation, low battery, out of range, and off patient alarms	Audible and visual pulse rate and oxygen saturation alarms. Low battery and critical battery, disconnection alarms

Comparative analysis of the indication statements between the subject and predicate devices show both similarities and differences. The core indications of measuring and displaying SpO2 and PR is the same for both devices. The patient population for both devices is for adult and pediatric patient populations, but Oxxiom provides age 12 as a specific age limit. Both devices are for prescription use and for use in hospitals, but Oxxiom is indicated for additional environments, including clinics, doctor's offices and home use. While the predicate device is for continuous monitoring and spot checking, the subject device is indicated for low acuity setting spot checking/intermittent use. These differences in indications for use are all within the same intended use and support substantial equivalence. These differences do not affect the safety or efficacy of the subject device when used according to its labeling. The labeling addresses these differences and provide appropriate instructions for use.

There are some differences in technological characteristics, including the feature of disposable versus reusable and iOS nondedicated display versus dedicated display that do not present different questions of safety and efficacy. Comparison of the similarities and differences between the proposed device and the predicate do not raise new or different questions of safety and effectiveness, when compared to the predicated devices and therefore support the proposed device as substantially equivalent to the predicate devices.

Summary of Performance Testing

Oxxiom Pulse Oximetry System is supported by electrical safety, electromagnetic compatibility, software validation, biocompatibility, clinical testing and other device performance tests to ensure appropriate functionality and demonstrate substantial equivalence to the predicate device. FDA Guidance – Pulse Ox*imeters – Premarket Notification Submissions [510(k)s]* was consulted in determining necessary testing. Software verification and validation testing was done according to FDA Guidance – *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.*

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Nonclinical and Clinical Functional and Safety Testing

The following functional and safety testing has been conducted for the OXXIOM device, performed according to the OXXIOM device product requirement specification and quality system to illustrate substantial equivalence.

Test	Reference	Result
Electrical Safety	IEC 60601-1 IEC 60601-1-2	Pass
Clinical Performance Testing	ISO 80601-2-61:2011	Pass
Biocompatibility Testing	ISO 10993-10:2010 ISO 10993-2 ISO 10993-5 ISO 10993-10 ISO 10993-12	Pass Pass Pass Pass Pass
EMC Testing	IEC 60601-1-2	Pass
Alarm Testing	IEC 60601-1-8	Pass
FCC Testing and Certifications	FCC Part 15 Subpart B Class B FCC Part 15 Subpart C	Pass
Wireless Coexistence Testing	FDA Guidance Radio Frequency Wireless Technology in Medical Device (2013)	Pass
Software Verification and Validation	IEC 62304: FDA Guidance—Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	Pass

Additional tests performed on the Oxxiom Pulse Oximetry System include the following:

Non-standard testing:

1. **Battery capacity/life**: Test results for energy capacity and voltage limits verification of the Oxxiom's Li-MnO2 Battery.
2. **Drop testing**: Performance/functionality of the Oxxiom pulse oximeter, after being dropped from various heights.

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3. **Shipping conditions**: Demonstrate the ability of the Oxxiom pulse oximeter packaging to protect shipped items from foreseeable stresses encountered during shipping.
4. **Shelf Life**: Validate the ability of Oxxiom pulse oximeter to withstand storage conditions for 12 months by using an accelerated shelf life study method.
5. **Environmental**: Environmental temperature and humidity testing performed on the Oxxiom pulse oximeter, in order to verify and validate the ability of Oxxiom to withstand operational conditions from 5°C - 40°C and 5% - 95% RH.
6. **Water Resistance**: Demonstrate the ability of the Oxxiom pulse oximeter to withstand water immersion.
7. **Skin Surface Temperature**: Demonstrate the Oxxiom pulse oximeter meets skin surface temperature requirements.
8. **Ambient Light Testing**: Demonstrate Oxxiom's performance under different ambient light conditions (incandescent and fluorescent lights, and sunlight light).
9. **Silence, Airplane, Guided Access Modes**: Demonstrate Oxxiom operates as intended under the various iOS modes.
10. **Dimensions**: Verify Oxxiom's dimensions, weight, outer edges (no sharp edges), and sterility (No visible particles).
11. **Display Range and Waveforms**: Oxxiom Pulse Oximetry meets specifications in terms if display ranges (i.e., SpO2: 1-100%, PR: 25-250 BPM, PA: 0.03-20%, Waveforms: graph with auto-adjustable scale).

Clinical Evaluation

A comparative, single-center, non-randomized study was conducted to evaluate SpO2 accuracy and performance of the sensor placed on fingers during non-motion conditions over the range of 70-100% SaO2 arterial blood samples assessed by CO-Oximetry. Arterial blood sampling was used as the basis for comparison.

The demographics of subjects in this study included five males and five females. They range by age (21-37 years), weight (134-230 lbs.), height (62-74"), and BMI (20.7 – 35). For race and ethnicity, the subject pool included two Black/African-American, one Asian, and seven White subjects. One of the ten subjects was of Hispanic/Latino ethnicity and the other nine were not.

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The skin pigmentation tones ranged from light to dark, meeting the protocol requirements of having at least 2 (15%) of subjects be of dark pigmented skin.

The Accuracy root mean square (Arms) between measured SpO2 and reference SaO2 met the 3.5% specification for the sensor. Arms is based on statistically distributed measurements, therefore, a sensor/oximeter with n Arms specification of 3.5 is expected to have approximately 68% of the data points fall within that range. The SpO2 performance accuracy evaluated over the SaO2 range of 70-100% under non-motion conditions was shown to have an Arms value of 3.4. This study provides supporting evidence that the SpO2 accuracy performance meets an acceptable specification for the sensor passing an Arms specification of 3.5 under steady state/non-motion conditions over the range of 70-100%.

Conclusion

In this 510(k), the low-risk intended use/indications for use statement and technological characteristics of the Oxxiom Pulse Oximetry System are demonstrated to be substantially equivalent to the Guardian Angel GA1000 Digital Vital Sign Monitoring System. Substantial equivalence is based upon the comparison of labeling, clinical data, and nonclinical/bench testing data. The difference in technological features of the subject device compared to the predicate does not raise different questions of safety and effectiveness. No animal testing was conducted.