November 8, 2022

Shenzhen Viatom Technology Co., Ltd.
Weifeng Tao
Regulatory Manager
4E, Building 3, Tingwei Industrial Park, No.6 Liufang Road
Block 67, Xin'an Street, Baoan District, 5
Shenzhen, Guangdong 518101
China

Re: K203812
Trade/Device Name: Oxyfit Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: November 7, 2022
Received: November 7, 2022

Dear Weifeng Tao:

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,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203812

Device Name
Pulse Oximeter

Indications for Use *(Describe)*
The Pulse Oximeter is a non-invasive device intended for spot checking and/or continuous data collection of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in home environments and clinical institutions except acute clinical environment.

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
K203812

This summary of 510(k) information is submitted as required by requirements of SMDA and21 CFR §807.92.

1. Submission sponsor

Submission Date	Dec.18.2020
Submitter's Name	Shenzhen Viatom Technology Co., Ltd.
Address	4E, Building 3, Tingwei Industrial Park, No.6 Liufang Road, Block 67, Xin'an Street, Baoan District, Shenzhen, 518101, Guangdong, China
Contact person	Zhou Saixin
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2. Submission correspondent

Name	Shenzhen Viatom Technology Co., Ltd.
Address	4E, Building 3, Tingwei Industrial Park, No.6 Liufang Road, Block 67, Xin'an Street, Baoan District, Shenzhen, 518101, Guangdong, China
Contact person	Mr.Weifeng Tao
E-mail	taoweifeng@viatomtech.com

3. Subject Device Information

Trade/Device Name	Oxyfit Pulse Oximeter
Model	PO6,PO6A
Common name	Pulse Oximeter
Regulatory Class	Class II
Classification	21CFR 870.2700/Oximeter/DQA
Submission type	Traditional 510(K)

4. Predicate Device Information

4.1Primary Predicate Device

510(k) Number: K200414

Trade/ Device Name: Pulse Oximeter

Regulation Number: 21 CFR 870.2700

Regulation Name: Oximeter

Regulatory Class: II

Product Code: DQA

Manufacturer: Shenzhen Aeon Technology Co., Ltd.

4.2Reference Predicate Device

510(k) Number: K150869

Trade/ Device Name: Checkme Pro Health Monitor

Regulation Number: 21 CFR 870.2300

Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)

Regulatory Class: II

Product Code: MWI

Manufacturer: Shenzhen Viatom Technology Co., Ltd.

5. Device Descriptions

The Pulse Oximeter is a non-invasive device intended for spot checking and/or continuous data collection of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in home environments and clinical institutions except acute clinical environment.

The Pulse Oximeter has two models.Model PO6 and Model PO6A are almost the same (include principle, structure, material, production process, performance) except appearance, details see below:

Model	Appearance color
PO6	Blue
PO6A	Gray

The device consists of main unit, SpO_2 sensor and charging cable. The main unitis mainly composed of MCU, power management circuit,SpO_2 measurement circuit,display control circuit, etc.

The device is powered by internal battery. The device is not for life supporting or life-sustaining, not for implant. The device or sensor is not sterile, the sensor does not needsterilization, and the sensor is reusable but does not need re-sterilization since it is notsterile. The device is for prescription. The device does not contain drug or biological products.

6. Intended Use/ Indications for Use

The Pulse Oximeter is a non-invasive device intended for spot checking and/or continuous data collection of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in home environments and clinical institutions except acute clinical environment.

7. Substantial equivalence Comparisons to the 510(k) Cleared Devices(Predicate Devices)

Characteristics	Subject Device	Primary Predicate Device	Reference Predicate Device	Remark
Name of the device	Oxyfit Pulse Oximeter PO6,PO6A	Pulse Oximeter A310B	Checkme Pro Health Monitor	---
Manufacturer	Shenzhen Viatom Technology Co., Ltd	Shenzhen Aeon Technology Co., Ltd.	Shenzhen Viatom Technology Co., Ltd	---
510(K) Number	N/A	K200414	K150869	---
Product code	21 CFR 870.2700, DQA	21 CFR 870.2700, DQA	21 CFR 870.2300, MWI Secondary product codes: 21 CFR 870.2700, DQA 21 CFR 870.2340, DPS 21 CFR 880.2910, FLL 21 CFR 870.2300, DRT	Substantial equivalent
Classification	II	II	II	Substantial equivalent

Indication for Use	The Pulse Oximeter is a non-invasive device intended for spot checking and/or continuous data collection of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR). This portable device is indicated for use in adult patients in home environments and clinical institutions except acute clinical environment.	The Pulse Oximeter is a non-invasive device intended for spot checking of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (PR). This portable device is indicated for use in adult patients in clinical institution and home environments.	The Checkme Pro Health Monitor is intended to be used for measuring, displaying, reviewing and storing of ECG (adults only), oxygen saturation and pulse rate (adults only for continuous data collection and recording, adults and pediatrics for spot-checking) and temperature in the home or in healthcare facilities. This device is not intended to substitute for a hospital diagnostic ECG device and not to be used on patients with implanted cardiac devices, such as pacemakers and/or implanted cardio-defibrillators (ICDs).	Different 1)
Rx or OTC	Rx	Rx	Rx	Substantial equivalent
Patient type	Adults	Adults	Adult and pediatric	Different 2)
Intended application site	Finger	Finger	Finger	Substantial equivalent
Principle	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by measuring the absorption of red and infrared (IR) light passing	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused	The device displays numerical values for functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate by measuring the absorption of red and infrared (IR) light passing through perfused	Substantial equivalent

	through perfused tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	tissue. Changes in the absorption caused by the pulsation of blood in the vascular bed are used to determine oxygen saturation and pulse rate.	
LED wavelength	Red=660 nm; Infrared=940 nm;	Red=660 nm; Infrared=905 nm;	Red=660 nm; Infrared=940 nm;	Different 3)
SpO_2 display range	0%-100%	0%-100%	0%-100%	Substantial equivalent
SpO_2 measurement accuracy	70%-100%: ±2% (Arms:1.57) 70%-80%: ±3% 80%-90%: ±2% 90%-100%: ±2% 0%-69%: not defined	70~100%, ±3%; 0-69%, unspecified;	70%-100%: ±2% (Arms:1.88) 70%-80%: ±3% 80%-90%: ±2% 90%-100%: ±2% 0%-69%: not defined	Substantial equivalent
SpO_2 resolution	1%	1%	1%	Substantial equivalent
Pulse rate measurement range	30 bpm~250 bpm	30 bpm~250 bpm	30 bpm~250 bpm	Substantial equivalent
Pulse rate accuracy	±2bpm or ±2% (whichever is greater)	±2bpm	±2bpm or ±2% (whichever is greater)	Substantial equivalent
Pulse rate resolution	1bpm	±2bpm	1bpm	Substantial equivalent
Power supply	Lithium rechargeable battery	2 AAA alkaline batteries	Lithium rechargeable battery	Different 4)
Wireless	Bluetooth	Bluetooth	Bluetooth	Substantial equivalent

Contacting duration	Prolonged (24h to 30 day)	Less than 24h	Less than 24h	Substantial equivalent
Contacting type	Skin surface-contacting	Skin surface-contacting	Skin surface-contacting	Substantial equivalent
Biocompatibility of patient contact parts	Comply with ISO 10993-1	Comply with ISO 10993-1	Comply with ISO 10993-1	Substantial equivalent
Standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-61 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-61 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 ISO 80601-2-61 ISO 10993-5 ISO 10993-10	Substantial equivalent

Justification of difference:

Different 1):

Compared with Primary Predicate Device:

The subject device is used for spot-check and/or continuous data collection whereas the primary predicate device is used in adults for spot-checking.

The difference is the function "and/or continuous data collection".But the reference predicate device is also used in adults for spot-check and continuous data collection. And the subject device is based on the reference predicate device. So the difference does not affect the safety and effectiveness of the subject device.And the subject device together meets the requirements of the IEC 60601-1,IEC 60601-1-11,ISO 80601-2-61 and IEC 60601-1-2.

Compared with Reference Predicate Device:

The subject device is used for spot-check and/or continuous data collection in adults, whereas the reference predicate device is used in adults only for continuous data collection and recording, as well as adults and pediatrics for spot-checking.The subject device is based on the reference predicate device, So they are substantially equivalent, just different expression.

Both the subject device and the reference predicate device have similar function including measuring, displaying, storing and transmitting of pulse oxygen saturation(SpO_2) and Pulse Rate.The reference predicate device is a Cardiac Monitor and has more function (such as ECG and Temperature).The function of the subject device is obviously within the range of the Reference Predicate Device. So the differences will not raise new questions of safety and effectiveness. The subject devices passed the test of bench test and ISO 80601-2-61.

Different 2):

Compared with Primary Predicate Device:

Both the subject device and the primary predicate device are same.

Compared with Reference Predicate Device:

The subject device is used for adult patients whereas the reference predicate device is used in a wider range of patient types like adults and pediatric patients. The Patient type of the subject device is obviously within the range of the Reference Predicate Device.The differences does not affect the safety and effectiveness of the subject device.

Different 3):

Compared with Primary Predicate Device:

Infrared LED Wavelength of the subject device is 940nm, and primary predicate's wavelength is 905nm. These two wavelengths are both adopted widely in measurement of SpO_2. What's more, the reference predicate's wavelength is 940nm. And the subject device together meets the requirements of the IEC 60601-1, IEC 60601-1-11, ISO 80601-2-61 and IEC 60601-1-2.The differences does not affect the safety and effectiveness of the subject device.

Compared with Reference Predicate Device:

Both the subject device and the reference predicate device are same.

Different 4):

Compared with Primary Predicate Device:

The power supply of the subject device is Lithium rechargeable battery, and the power supply of the primary predicate device is 2 AAA alkaline batteries. And the subject device together meets the requirements of the IEC 60601-1,IEC 60601-1-11,ISO 80601-2-61 and IEC 60601-1-2.What's more,the power supply of the reference predicate device is Lithium rechargeable battery.So the differences does not affect the safety and effectiveness of the subject device.

Compared with Reference Predicate Device:

Both the subject device and the reference predicate device are same.

8. Brief discussions of the non-clinical tests

The subject device conforms to the following guidances and standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- ISO 80601-2-61: Medical electrical equipment – Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.
- IEC 60601-1-11: Medical electrical equipment -- Part 1-11: 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
- ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)]
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization
- ISO 14971 Risk Management
- 47 CFR FCC PART 15. Subpart C Unintentional Radiators/ Miscellaneous Wireless Communtations Service
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.
- FDA Guidance for Pulse Oximeters - Premarket Notification Submissions [510(k)s]
- FDA Guidance for Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It is concluded that the subject Pulse Oximeter device is in compliance with the requirements of the aforementioned tests.

9. Brief discussions of clinical tests

The pulse oximeter(PO6、PO6A) was subjected to clinical testing. The functional oxygen saturation (SpO2) measurement has been validated in accordance with ISO 80601-2-61.

Clinical testing (controlled desaturation study) was conducted, during induced hypoxia studies ona total of 12 healthy adult (healthy, non-smoking, light-to-dark-skinned) in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the subject device was compared with arterial hemoglobin oxygen (SaO2) value, determined from blood samples with a CO-oximeter (control device). The accuracy of the subject device is in comparison with the control device over the SpO2 range of 70~100%.

The SpO2 accuracy results include:

• 1.57% which meets the accuracy requirement of less than or equal to 2% under no motion condition. The accuracy specification is reported as accuracy root mean square (Arms).

The result met the criteria specified in the ISO 80601-2-61; In addition, there were no reported adverse effects during these investigations.

10. Brief discussions of Biocompatibility tests

The patient-contacting components and materials are listed together with the corresponding test items in the following table. The contact duration is limited to be within 24 hours to 30 days, and the type of contact belongs to surface medical device-intact skin with prolonged duration

Patient-contacting Components	**Contact Materials**	**Leverage biocompatibility test items**
Enclosure	PC	Cytotoxicity Skin Sensitization Test Skin Irritation Test
Finger sleeve	Silicone	

The PC, Silicone of the test article is identical to the medical device in its final finished form in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, additives, cleaning agents, mold release agents).

Based on International Standard ISO 10993 and FDA Biological evaluation guidance,the material are tested for vitro cytotoxicity, irritation and Skin Sensitization.

The biocompatibility test results demonstrated that there's no cytotoxic potential, no evidence of significant irritation nor evidence of sensitization. Thus, the device meets the requirement of Biocompatibility.

11. Brief discussions of Bluetooth tests

The device Bluetooth will be enabled automatically after it's turned on.

To establish a Bluetooth connection:

- Keep the device Bluetooth enabled.
- Make sure the phone Bluetooth is enabled.

And the testing included the Wireless Coexistence tests via Bluetooth, results of which demonstrate the Bluetooth performance of the subject device.

12. Software information

The software level of concern for the subject device is MODERATE. According to FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Guidance for Industry and FDA Staff", the software validation documentation summarizes the required information for a MODERATE Level of Concern device. And a testing included the Cybersecurity tests, results of which demonstrate the Cybersecurity of the subject device.

13. Other information (such as required by FDA guidance):

No other information.

14. Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Shenzhen Viatom Technology Co., Ltd. concludes that the subject device has the same intended use as the predicate device, and the technological differences do not raise different questions of safety and effectiveness.