Vyvo Technology Corp.(VT)
Aileen Fu
Official Correspondent
Shenzhen Global Medical Technology Services Co., Ltd
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Shenzhen, Guangdong 8100
China

March 4, 2024

Re: K231288
Trade/Device Name: Vyvo
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: December 15, 2023
Received: February 2, 2024

Dear Aileen Fu:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231288

Device Name
VYVO Life Watch

Indications for Use *(Describe)*

The VYVO Life Watch is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. It is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This summary of 510(k) information is submitted as specified in SMDA and 21 CFR §807.92.

1 Administrative Information

Submission Date	December 15, 2023
Manufacturer information	Submitter's Name: Vyvo Technology Corp.(VT) Address: 123 NW 23 RD Street City Miami, FL Contact person: Alfonso Cioffi TEL: +1 2016470536 E-Mail: a.cioffi@helohealth.com
Submission Correspondent	Contact person: Fu Ailing Tel: +86-13538216349 Email: Aileenfu@coctd.com Company: Shenzhen Global Medical Technology Services Co., Ltd Address: Room 1702, Shenxintaifeng Building, No. 86, Qianjin 1st Road, Bao'an District, Shenzhen, 518101, Guangdong, China
Establishment registration number	NA

2 Proposed Device Information

Common name of the device	WL Watch Oximeter
Trade name of the device	VYVO Life Watch
Type/Model of the device	WL
Classification information	Regulation Medical Specialty: Cardiovascular 510(k) Review Panel: Anesthesiology Classification name: Oximeter Regulation Number: 21 CFR 870.2700 Device Class: II Product Code: DQA
Type of 510(k) submission	Traditional

3 Predicate and Reference Devices

Predicate Device:

Sponsor:	Bio-Beat Technologies Ltd.
Device:	BB-613 Watch Oximeter
510(K) Number:	K181006

Reference Device:

Sponsor:	Beijing Choice Electronic Technology Company, Limited
Device:	Wrist Pulse Oximeter
510(K) Number:	K122046

4 Device Description

The Life Watch, Model WL is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse rate (PR). The expected measuring location of the device is the finger, which actively presses onto the sensor on the side of the watch for measurement. The Life Watch is a watch-like device with a reflectance pulse oximetry sensor located at the side of the watch case. The reflectance pulse oximetry sensor includes two light emitting diodes (LEDs) of red wavelength (660 nm) and infrared wavelength (940 nm), and one photodiode light detector placed next to each other. Light beams are emitted from LEDs through the skin to the arteriolar bed of the tissue. Changes in light absorption during the pulsing cycle are measured by the photodiode light detector as scattered lights are reflected back from the pulsating arteriolar bed. The functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse rate are measured by the well-established non-invasive pulse oximetry technology where the red and infrared light is absorbed in different amounts depending on the oxygenation of the blood during the arterial pulsing. The maximum optical output power is less than 2 mW. The Life Watch is a single-patient use, non-sterile pulse oximeter. It is available in one configuration as a standalone device with a wrist pulse oximeter and a detachable watchband for wearing the pulse oximeter on the wrist.

The Life Watch is a compact and light weight device which consists of a reflectance pulse oximetry sensor, a color graphic OLED display, a lithium ion polymer rechargeable battery, an analog and digital unit, a microprocessor and an operating software. The functions of the life watch include the following: (1) Measurement and display of the functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse rate; (2) Spot-checking of specific physiological parameters of adult patients; (3) Easy to read OLED graphic display; (4) Peripheral micro-USB connector used as the battery charging base; (5) Built-in rechargeable lithium ion polymer battery (3.8V, 250mAh) (6) Low battery power indicator in OLED graphic display.

The device consists of the watch case, band, charging case, USB cable.

The proposed device is not used for life-supporting or life-sustaining, and not for implant. The device does not contain drug or biological products.

5 Intended Use/ Indications for Use

The VYVO Life Watch is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. It is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.

6 Comparison

Table 1 Substantial Equivalence Comparison

Item	Subject Device (K231288)	Primary Predicate Device (K181006)	Reference Device (K122046)	Explanation of Differences Between Predicate and Subject Devices
Device Name	VYVO Life Watch	BB-613 Watch Oximeter	Wrist Pulse Oximeter	N/A
Device Model	WL	BB-613	MD300W4	N/A
Manufacturer	Vyvo Technology Co., Ltd.	Bio-Beat Technologies Ltd.	Beijing Choice Electronic Technology Company, Limited	N/A
Product Code	DQA	DQA	DQA	Same
Regulation Number	21 CFR870.2700	21 CFR870.2700	21 CFR870.2700	Same
Indication for Use	The VYVO Life Watch is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. It is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.	The BB-613 Watch Oximeter is a small, wrist-worn device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. It is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.	The MD300W4 wrist pulse oximeter is a portable non-invasive device intended for spot checking, data collection and recording of arterial oxygen saturation (SpO2) and pulse rate of adult and pediatric patient at home and hospital (including clinical use In internist/surgery, Anesthesia, intensive care and etc).	Same
Intended Population	Adult	Adult	Adult, pediatric	Same
Composition	A main unit	A main unit	A main unit, SpO2 sensor	Same
Principle of Operation	Pulse reflectance technology, Two LED (red + IR) and photo diode absorbs reflected light	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light	Pulse reflectance technology, Two (red + IR) and photo diode absorbs reflected light	Same as the reference device K122046.
Intended Application Site	Finger	Wrist	Finger	Same as the reference device K122046.

Measurement type	Spot	Spot	Spot	Same
Emitted light peak wavelength	940nm (IR), 660nm (Red)	880nm (IR), 650nm (Red)	940nm (IR), 660nm (Red)	Same as the reference device K122046.
Display Parameter	SpO2, pulse rate	SpO2, pulse rate	SpO2, pulse rate	Same
Sensor	MAX30101	Unspecified	M-50G	Due to different design scheme, the difference does not raise any new issue of substantial equivalence according to performance test reports.
SpO2 module	Integrated into main unit	Integrated into main unit	M-50G, Insertion into main unit as an accessory	Same
SpO2 Display Range	70%-100%	70%-100%	0%-100%	Same
SpO2 Measuring Range	70% to 100%	70% to 100%	70% to 100%	Same
SpO2 Measuring Accuracy	±3% for 70% ~ 80%; ±3% for 80% ~ 90%; ±3% for 90% ~ 100%;	70%-80%±3% 80%-90%±3% 90%-100%±3%	70%-100%±3% 90%-100%±2% 80%-90%±3% 70%-80%±3% >70% unspecified	Same
SpO2 Resolution	1%	70%-100%, ±3% or ±3 digits Display: 2 characters	1%	Same as the reference device K122046.
Pulse Rate Measuring Range	40 to 200 bpm	40 to 240 bpm	30 to 235 bpm	Difference but is within the PR measuring range of the predicate device or the reference device.
Pulse Rate Measuring Accuracy	±2bpm or ±2% (whichever is greater)	±3bpm	±2bpm or 2% (the greater)	Same as the reference device K122046.
PR Resolution	1bpm	±3% or ±3 digits	1bpm	Same as the

			Display: 3 characters		reference device K122046.
Patient-Contacting Components/ Materials		Case/Polycarbonate; Photodiode window; Watchband/silicone	Case/Polycarbonate; Photodiode window; Watchband/Silicone	Belt/Medical silica gel and Nylon	Same
Contact Duration		Prolonged contact duration >24h to 30d	Prolonged contact duration >24h to 30d	Prolonged contact duration >24h to 30d	Same
Application Method		User wears the device as a watch and powers it on	User wears the device as a watch and powers it on	User wears the device on finger	Same
Sterility		Supplied and used non-sterile	Supplied and used non-sterile	Supplied and used non-sterile	Same
Display		OLED	LCD on device	OLED	Same as the reference device K122046.
Data storage		No	No	72-Hour	Same
Transmission mode		No	Bluetooth	USB or GPRS	N/A
Working Time		About 5-7 days of continuous use	5 days of continuous use	Work for 10h continuously	Same or better
Power supply		3.8V Lithium-ion rechargeable battery	5V Lithium-ion rechargeable battery	4.2V Lithium-ion rechargeable battery	Due to different design scheme, the difference does not raise any new issue of substantial equivalence according to test reports on battery and device.
Type of protection against Electrical shock		Type BF	Type BF	Type BF	Same
Operating Environment	**Temperature**	0°C ~35°C	4°C to 39°C (39°F to 103°F)	5℃~ 40℃	The slightly different operating temperature does not raise any new issue of substantial equivalence according

					to IEC 60601-1 test report.
	Relative Humidity	10%~95%, non-condensing	Up to 95%, non-condensing	≤80%, non-condensing	Difference but is within the range of the predicate device.
	Atmospheric pressure	70kPa~106kPa	700 to 1060hPa (70kPa~106kPa)	86kPa~106kPa	Same
Storage and Transportation Environment	**Temperature**	5°C ~28°C	-20°C to 70°C (-4°F to 158° F)	-20℃～55℃	Difference but is within the range of the predicate device or the reference device.
	Relative Humidity	20%~75%, non-condensing	Up to 95%, non-condensing	≤93%, non-condensation	Difference but is within the range of the predicate device or the reference device.
	Atmospheric pressure	70kPa~106kPa	465 hpa to 1060hPa (46.5kPa~106kPa)	50kPa～106kPa	Difference but is within the range of the predicate device or the reference device.
Enclosure		49x37x137mm	48X38X16mm	133mmx63mmx33mm	Difference but does not raise any new issue of substantial equivalence
SpO2 Sensor		Built in main unit	Built in main unit	Accessory of main unit	Same
EMC and Electrical Safety	**Electrical Safety**	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Compliance with IEC 60601-1	Same
		Compliance with IEC 60601-1-11	Compliance with IEC 60601-1-11	Compliance with IEC 60601-1-11	Same
	Electromagnetic Compatibility	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same
Performance Testing	**Laboratory Testing**	Compliance with ISO 80601-2-61	Compliance with ISO 80601-2-61	Compliance with ISO 9919	Same
	Clinical Testing	Compliance with ISO 80601-2-61	Compliance with ISO 80601-2-61	Compliance with ISO 9919	Same
Biocompatibility	**Biocompatibility**	Compliance with ISO	Compliance with ISO	Compliance with ISO	Same

	Statement	10993	10993	10993	
	Biocompatibility Tests conducted	Cytotoxicity, Delayed Contact Sensitization, Skin Irritation	Cytotoxicity, Delayed Contact Sensitization, Skin Irritation	Cytotoxicity, Delayed Contact Sensitization, Skin Irritation	Same
	Summary of the biocompatibility tests	No toxicity to cells, No delayed contact sensitization, No irritation to skin	No toxicity to cells, No delayed contact sensitization, No irritation to skin	No toxicity to cells, No delayed contact sensitization, No irritation to skin	Same
Software	**Software Level of concern**	Moderate	Moderate	Moderate	Same
	Brief description of software testing	Software Validation in compliance with the FDA's Guidance "Content of Premarket Submissions for Device Software Functions".	Software validation per FDA guidance including cybersecurity	The Software Validation is in compliance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.	Same
	Cybersecurity testing	Not applicable	Validated	Validated	N/A

According to above table, VYVO Life Watch and BB-613 Watch Oximeter have the same intended use. Although the subject device and the predicate device have sightly different technological characteristics, but the differences do not raise any new questions of safety and effectiveness and affect substantial equivalence.

7 Non-clinical Tests

The subject device was tested to demonstrate substantial equivalence in accordance with the following standards and guidances.

- ✧ IEC 60601-1:2005+A1:2012+A2+2020 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance;
- ✧ IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests;
- ✧ IEC 60601-1-11: 2015 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 80601-2-61:2017 Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment
- ✧ ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity;
- ✧ ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization;
- ✧ ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation;
- ✧ Software Validation in compliance with the FDA's Guidance "Content of Premarket Submissions for Device Software Functions".

8 Clinical test

The clinical test of the subject device has been conducted in accordance with the FDA's guidance "Pulse Oximeters - Premarket Notification Submission [510(k)s]" and the standard ISO 80601-2-61:2017.

The functional oxygen saturation (SpO2) measurement has been validated on a total of 12 subjects with Fitzpatrick skin types. In addition, the 12 subjects include 6 healthy adult males and 6 healthy adult females, and their age range is from 19 to 42 years old. Testing shows equivalence to simultaneous measurements from the predicate device. No adverse event is found and the safety and effectiveness of the subject device is identical with that of the predicate device.

9 Conclusion

Totally, the subject device VYVO Life Watch has the same intended use, indications for use, and technological characteristics as the predicate device BB-613 Watch Oximeter. Additionally, non-clinical and clinical test results have demonstrated that the VYVO Life Watch is the same as safe and effective as the BB-613 Watch Oximeter, and the slight technological differences do not raise any issue of safety and effectiveness. As a result, the VYVO Life Watch is substantially equivalent to the BB-613 Watch Oximeter.