May 20, 2024

AViTA Corporation
Maggie Chao
9F, No.78, Sec.1, Kwang-Fu Rd.
New Taipei City, San-Chung District 24158
Taiwan

Re: K223399
Trade/Device Name: AViTA Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: February 1, 2024
Received: February 1, 2024

Dear Maggie Chao:

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.

Submission Number *(if known)*

K223399

Device Name

AViTA Pulse Oximeter (SP61)

Indications for Use *(Describe)*

The AViTA Pulse Oximeter is intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adults as non-invasive spot checking in professional caring environment. It is designed for fingers between 0.8cm and 2.5cm (0.3 inches to 1 inches) and for patients during no-motion condition. The device is prescription only.

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

This summary of 510(k) information is being submitted in accordance with the requirement of 21 CFR 807.92.

1 **Submitter's Name:** AViTA Corporation

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Telephone number: +886-2-8512-1568 ext.2010

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Applicant Contact: Meggie Chao

The Date of the Summary: May 2, 2024

2 **Trade/Proprietary Name:** AViTA Pulse Oximeter

Common Name: Pulse Oximeter

Model numbers: SP61

Review Panel: Anesthesiology

Classification Product Code: DQA

Classification name: Oximeter

Regulation Number: 870.2700

Device Class: II

3 PREDICATE DEVICE

510(k) Number:	K193350
Trade Name:	Leadtek Fingertip Pulse Oximeter
Manufacturer:	Leadtek Research Incorporation

4 DEVICE DESCRIPTION

The AViTA Pulse Oximeter SPO2 is non-invasive spot checking, not provided sterile, multi-use device, which can measure and display user's oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) through finger during no-motion condition. The subject device is not for life-supporting or life-sustaining, not for implant and does not contain drug or biological products. The device is for prescription use only.

The subject device consists of sensor, electronic circuits, display and plastic enclosures. It is a battery powered

device and is adopted with two color OLED screen to display SpO2 and PR. It is software-driven and does not include alarms. Table 1 shows the specifications for the subject device.

AViTA pulse oximeters work by the principles of spectrophotometry, emitting two different wavelengths of light, typically red and infrared, through a pulsating capillary bed, such as a fingertip. The sensor on the other side of the tissue detects the light that emerges from the tissues. The device then measures the intensity of red and infrared light that is transmitted through the capillary bed.

Based on the differences in absorption between oxygenated and deoxygenated blood at specific wavelengths, the device can calculate the ratio of oxygenated hemoglobin (HbO) to total hemoglobin in the blood, which is known as oxygen saturation (SpO2).

It's important to keep the finger or the measurement site stationary during the reading to avoid introducing motion artifacts that could affect the accuracy of the measurement. Additionally, it is recommended to use the pulse oximeter before or after engaging in sports activities rather than during physical exercise. Do not use for continuous monitoring. **Table 1** shows the specifications for the subject device.

Table 1 Technical Specification

Property	**Specification**
Dimension	L68mm (2.68") x W37.8mm (1.49") x H28mm (1.1")
Weight (without battery)	26g (0,92 ounces)
Display	Two color OLED
Auto on/off	Whenever user inserts a finger, the device will turn on automatically. Vice versa, the device will turn off automatically when the finger is removed from it.
Input key	◎ key for screen rotate
Measurement Method	wavelength
SpO_2 Range & Resolution	Range: 0% to 100% resolution: 1%
SpO_2 Accuracy	Range 70% to 100% range ± 2%, less than 70% are unspecified
Pulse Rate Range & Resolution	Range: 30 to 250 bpm; resolution: 1 bpm
Pulse Rate Accuracy	±2 bpm or ±2%, whichever is greater
Water-resistance	Against water splash (IP22 Approved)
Battery Type	1 AAA-size Alkaline battery
Usage Life	> 18 hrs typical operation under default setting
Shelf Life	3 years

Ambient Temperature	Operation: 5 °C - 40 °C (41 °F - 104 °F); Storage: -30°C ~ 70 °C (-22 °F ~ 158 °F)
Atmospheric Pressure	Operation & storage are both 700 hPa - 1060 hPa
Humidity	Operation & storage are both 10% - 90%, non-condensing

5 INDICATIONS FOR USE

The AViTA Pulse Oximeter is intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adults as non-invasive spot checking in professional caring environment. It is designed for fingers between 0.8cm and 2.5cm (0.3 inches to 1 inches) and for patients during no-motion condition. The device is prescription only.

The Indications for Use statement for the AViTA Pulse Oximeter is not identical to the predicate device; however, the differences do not alter the intended diagnostic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adults as non-invasive spot checking in professional caring environment.

6 DEVICE COMPARISON TABLE

Item	Subject Device	Predicate Device
Product Name	**AViTA Pulse Oximeter**	**Leadtek Fingertip Pulse Oximeter**
Model No.	**SP61**	**8D01B and 8D01C**
510(k) Information		
Regulation Number	870.2700	870.2700
Classification	Class II	Class II
Product Code	DQA	DQA
Indication for Use		
Statement	The AViTA Pulse Oximeter is intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adults as non-invasive spot checking in professional caring environment. It is designed for fingers between 0.8cm and 2.5cm (0.3 inches to 1 inches) and for patients during no-motion condition. The device is prescription only.	The **8D01B** and **8D01C** are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for both adults and adolescent as non-invasive spot checking in home and professional caring environment. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches to 0.9 inches) and for patients during no-motion condition.
Population	adults	adults and adolescent
Application site	Finger	Finger
Performance	normal condition	normal condition

Stand-alone or module	stand-alone	stand-alone
Single use or not	multiple use	multiple use
Use environment	professional caring environment	home and professional caring environment
Test Principle		
Principle	The LED contains a red light and an infrared light that are differentially absorbed by oxygenated and oxygenated hemoglobin. Based on the relative absorption of the two wavelengths that is determined by the sensor, the POX determines the relative amount of oxygenated and deoxygenated hemoglobin, which is calculated as SpO2. In order to make the SpO2 calculation independent of skin color, finger size, etc., the pulse oximeter sensor uses only the time varying light absorption component generated by the patient's pulse.	Determine the functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate by measuring the absorption of red and infrared light passing through perfused tissue. Changes in absorption caused by the pulsation of blood in the vascular bed are used to determine SpO2 reading and pulse rate.
Wavelength	Dual wavelength LED (660 nanometers @ 3.2mW and 905 nanometers @2.4mW; both as max average	Dual wavelength LED (660 nanometers @ 0.8mW and 940 nanometers @ 1.2mW; both as max average
Energy		
Type	Battery	Battery
Battery	AAA Alkaline battery x 1	AAA Alkaline battery x 1
Operation Features		
On/Off	Automatic turn on and off	Automatic turn on and off
Display	Two color OLED	Full color OLED
Input Key	A 4-directional key	A 5-directional key (**8D01B)** or a single push-down (**8D01C)** key
Warning /Indicator	Visual indicator	**8D01B:** Audio and visual warning **8D01C:** Visual indicator
Warning / Indicator Function	Reading starts to flash as an indicator to user when SpO2 and Pulse rate drop out of the setting range.	**8D01B**: Appear red color with beep sounds when SpO2 and pulse rate out of the setting range. Low SpO2 warning: default 87%; setting range: 50% to 95% High SpO2 warning: default off; setting range: 80% to 100% Low HR warning: default off; setting range: 30 to 110 bpm High HR warning:default off; setting range: 75 to 250 bpm
Display Rotation	Yes	Yes
General Specification		
Usage Life	> 24 hrs typical operation under default setting	> 24 hrs typical operation under default setting

Operating Temperature	5 ℃ to 40 ℃ (41 ℉ to 104 ℉)	5 ℃ to 40 ℃ (41 ℉ to 104 ℉)
Storage Temperature	-30~70℃ (-22~158 ℉)	-30℃ to 70 ℃ (-22 ℉ to 158 ℉)
Humidity	10% - 90% (non-condensing)	10% to 90%, non-condensing for both operating and storage
Atmospheric Pressure	700 hPa – 1060 hPa for both operating and storage	700 hPa – 1013 hPa for both operating and storage
Water Resistance	IP22	IP22
Classification		
Applied Part	Type BF	Type BF
Safety	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2
Harmonized Standard	ISO 80601-2-61	ISO 80601-2-61
Mode of Operation	Spot checking	Spot checking
Appearance		
Weight	weight without battery: 26g (0,92 ounces)	weight without battery: 26g (0,92 ounces)
Size	L68mm (2.68") x W37.8mm (1.49") x H28mm (1.1")	L67.5 mm (2.63”) x W38 mm (1.48”) x H25 mm (0.98”)
Pulse Oximetry		
Range	70%-100%	0% to 100%
Resolution	Resolution	Resolution
Accuracy	70% to 100% range ± 2%, less than 70% are unspecified	70% to 100% range ± 2%, less than 70% are unspecified
Biocompatibility Testing		
Cytotoxicity	In accordance with ISO 10993-1	In accordance with ISO 10993-1
Skin sensitization	In accordance with ISO 10993-1	In accordance with ISO 10993-1
Skin irritation	In accordance with ISO 10993-1	In accordance with ISO 10993-1
Heart Rate Specification		
Range	30 to 250 bpm	30 to 250 bpm
Resolution	1 bpm	1 bpm
Accuracy	±2 bpm or ±2%, whichever is greater	±1 bpm or ±1%, whichever is greater

7 PERFORMANCE SUMMARY

The following tests were conducted to evaluate the safety and effectiveness of the subject device, and the test results indicated that the subject device is safe and effective.

7.1 Performance Data【807.92(b)】

All necessary performance testing was conducted oxygenated and deoxygenated hemoglobin characterization testing on the subject device to support a determination of substantial equivalence to the predicate device in accordance with ISO 80601-2-61.

7.2 Electrical Safety and EMC Testing

The laboratory tests of electrical safety, electromagnetic compatibility, and reliability testing were conducted and showed that the subject device complied with 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, 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 home healthcare environment, and ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.

7.3 Biocompatibility testing

The biocompatibility evaluation for the subject device was in accordance with the FDA Biocompatibility guidance (Use of International Standard ISO10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"). The standards below are tested and met the acceptance criteria.

- Biological evaluation (ISO10993-1)
- Cytotoxicity (ISO10993-5)
- Sensitization (ISO10993-10)
- Irritation (ISO10993-23)

7.4 Software Verification and Validation

Software verification and validation were provided in compliance with FDA Guidance "The Content of the Premarket Submission for Software Contained in Medical Devices". The verifications and validations demonstrate that the subject device work functionally. The software for the subject device is considered as a "moderate" level of concern, which is identical to the predicate device. A failure or latent flaw in the software could not directly cause serious injury or death to the patient or operator, but a non-serious injury could occur. According to FDA Guidance document, the software validation documentation summarized the required for a Moderate level of concern device.

7.5 Cleaning Validation

Cleaning validation was executed in accordance with FDA Guidance "Reprocessing Medical Device in Health Care Setting: Validation Methods and Labeling" The performance of the subject device will not be affected after multiple cleaning procedures as illustrated in user manual.

7.6 Clinical Performance

Clinical performance was conducted per ISO 80601-2-61. The clinical validation testing of the SpO2 performance under no motion on healthy, adult volunteers in the range of 70% to 100%. The ARMS for SpO2 under no motion was found to be 1.89%. No adverse effects and complications happened during the clinical study.

8 SUBSTANTIAL EQUIVALENCE

Based upon equivalences in: intended use, patient population, site of application, conditions of use, operating principles, and the non-clinical performance data, the subject device have been shown to be safe and effective and to perform equivalently as compared to the legally marketed predicate device. Therefore, the subject devices are substantially equivalent to the legally marketed predicate device.