February 19, 2025

AViTA Corporation
Maggie Chao
Adm. Manager
9F, No.78, Sec.1, Kwang Fu Road, Sanchong Dist.,
New Taipei City, 24158
Taiwan

Re: K242455
Trade/Device Name: AViTA Pulse Oximeter (SP62B)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 22, 2025
Received: January 22, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Anesthesia,
Respiratory, and Sleep 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)*
K242455

Device Name
AViTA Pulse Oximeter (SP62B)

Indications for Use *(Describe)*
The Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adults as non-invasive spot checking in 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. 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.

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

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AVITA CORPORATION

510(K) Submission for
AViTA Pulse Oximeter

510(K) Summary

1 APPLICANT INFORMATION

Applicant:	AViTA Corporation
Address:	9F, No.78, Sec.1, Kwang-Fu Rd., San-Chung District, New Taipei City 24158, Taiwan
Applicant Establishment Number:	9617543
Applicant Contact:	Maggie Chao
Email:	Maggie_chao@avita.com.tw
Phone Number:	+886-2-8512-1568
Fax Number:	+886-2-8512-1347
Date of Submission:	August 19, 2024

2 SUBJECT DEVICE

Trade/Proprietary Name:	AViTA Pulse Oximeter
Common Name:	Pulse Oximeter
Review Panel:	Anesthesiology
Classification Product Code:	DQA
Regulation Number:	870.2700
Device Class:	II

3 PREDICATE DEVICE

510(k) Number:	K223399
Manufacturer:	AViTA Corporation

4 DEVICE DESCRIPTION

The subject device AViTA Pulse Oximeter with Bluetooth is non-invasive spot checking, not provided sterile, multi-use device, which can measure and display user's oxygen saturation of arterial hemoglobin (SpO_2) 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. 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 SpO_2 and PR. It is software-driven and does not

include alarms.

5 INDICATIONS FOR USE

The Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adults as non-invasive spot checking in 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. The device is prescription only.

6 TECHNOLOGICAL CHARACTERISTICS

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 (SpO_2).

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.

7 DEVICE COMPARISON TABLE

Item	Proposed Device	Predicate Device	Predicate Device
Product Name	AViTA Pulse Oximeter	AViTA Pulse Oximeter	Beijing Choice Pulse Oximeter
Model No.	SP62B	SP61	MD300C228
510(k) Information			
Regulation Number	870.2700	870.2700	870.2700
Classification	Class II	Class II	Class II
Product Code	DQA	DQA	DQA
K. No.	-	K223399	K232975
Indication for Use			
Statement	The Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adults as non-invasive spot checking in 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.	The Fingertip Pulse Oximeter are intended for measuring functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate for adults as non-invasive spot checking in 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.	The Pulse Oximeter is a handheld non-invasive device intended for spot-checking of oxygen saturation of arterial hemoglobin (SpO_2) and Pulse Rate of adult, adolescent child and infant patients in hospitals, hospital-type facilities and homecare. The device can be used by the people whose finger thickness is between 8mm and 22mm (0.3 inches to 0.9 inches).
Population	adults	adults	adult, adolescent, child and infant patients
Application site	finger	finger	finger
Performance	normal condition	normal condition	normal condition

Stand-alone or module	stand-alone	stand-alone	stand-alone
Single use or not	multiple use	multiple use	multiple use
Use environment	professional caring environment	professional caring environment	hospitals, hospital-type facilities and homecare
Comparison	The proposed device and the predicated device have the same intended use and classification. All changes in indications for use would not affect the safety and effectiveness. The AViTA Pulse Oximeter SP62B is substantially equivalent to the predicate device (K223399) concerning the same intended use.		

Test Principle			Traditional 510(k)
Principle	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 (SpO_2). 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	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 (SpO_2). 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	The pulse oximeter works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660nm, which is red light; the other is 905nm, which is infrared-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO_2.

	recommended to use the pulse oximeter before or after engaging in sports activities rather than during physical exercise. Do not use for continuous monitoring. The proposed devices of this submission do not differ from the predicate device.	recommended to use the pulse oximeter before or after engaging in sports activities rather than during physical exercise. Do not use for continuous monitoring. The proposed devices of this submission do not differ from the predicate device.	Traditional 510(k)
Measurement Method	Wavelength	Wavelength	Wavelength
Comparison	The proposed device and the predicated device have the same principle. There is no additional question of safety and effectiveness as compared to the predicate device. AViTA Pulse Oximeter SP62B is substantially equivalent to the predicated device K223399) concerning the test principle.		
Energy			
Type	Battery	Battery	Battery
Battery	AAA Alkaline battery x 1	AAA Alkaline battery x 1	AAA Alkaline battery x 2
Comparison	There is no additional question of safety and effectiveness as compared to the predicate device raised by the battery. The AViTA Pulse Oximeter SP62B is substantially equivalent to the predicate device (K223399) concerning the energy source.		
Operation Features			
On/Off	Automatic turn on and off	Automatic turn on and off	Automatic turn on and off
Display	Two color OLED	Two color OLED	LCD
Input Key	A 4-directional key	A 4-directional key	A 2-directional key
Warning /Indicator	Visual indicator	Visual indicator	Visual indicator
Warning / Indicator Function	Reading starts to flash when detects user SpO_2 and Pulse rate. Display shows “Finger Out” when no measurement detects.	Reading starts to flash when detects user SpO_2 and Pulse rate. Display shows “Finger Out” when no measurement detects.	the device will power off automatically in 8 seconds when "Finger out" is displayed
Display Rotation	Yes	Yes	Yes
Bluetooth	**BLE 4.2**	N/A	**BLE 5.0**
Comparison	The proposed device is configured the Bluetooth 4.2 module which predicate		

	device is configured the Bluetooth 5.0 module. The Bluetooth is the independent function module, it would not affect other function module of the device. In addition, the embedded software could meet the requirements of Submissions for Software Contained in Medical Devices, the related document of software could refer to Software Document section of this submission. Therefore, this difference does not affect substantially equivalence between proposed device and predicate device on safety and effectiveness.		
General Specification			
Operating Temp	5 ºC to 40 ºC (41 ºF to 104 ºF)	5 ºC to 40 ºC (41 ºF to 104 ºF)	0 ºC to 40 ºC (32 ºF to 104 ºF)
Storage Temp.	-30ºC to 70 ºC (-22 ºF to 158 ºF)	-30ºC to 70 ºC (-22 ºF to 158 ºF)	-25~70℃ (-13~158 ℉)
Humidity	10% - 90% (non-condensing)	10% - 90% (non-condensing)	15% to 93%, non-condensing for both operating and storage
Atmospheric Pressure	700 hPa - 1060 hPa for both operating and storage	700 hPa - 1060 hPa for both operating and storage	70kPa~106kpa for both operating and storage
Water Resistance	IP22	IP22	IEC 60601-1-11
Comparison	There's no difference in usage life and atmospheric pressure. The AViTA Pulse Oximeter SP62B is substantially equivalent to the predicate device (K223399) concerning the technological characteristics.		
Classification			
Applied Part	Type BF	Type BF	Type BF
Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2
Harmonized Standard	ISO 80601-2-61	ISO 80601-2-61	ISO 80601-2-61
Mode of Operation	Spot checking	Spot checking	Spot checking
Appearance			
Weight	weight without battery: 26.5g	weight without battery: 25g	weight without battery: 50g
Size	L68 mm x W37.8 mm xH28.5 mm	L68 mm x W37.8 mm xH27.7 mm	L58 mm x W32mm x H34 mm
Comparison	The differences of general specification and appearance will not be considered as a NSE between the proposed device and the predicate device. The AViTA Pulse Oximeter SP62B is substantially equivalent to the predicate device (K223399) concerning the general specification and appearance.		
Pulse Oximetry Specification			

Range	0% to 100%	0% to 100%	0% to 100%
Resolution unit	1%	1%	1%
Accuracy	70% to 100% range ± 2%, less than 70% are unspecified	70% to 100% range ± 2%, less than 70% are unspecified	70% to 100% range ± 2%, less than 0~69% no definition
Comparison	The AViTA Pulse OximeterSP62B is substantially equivalent to the predicate device (K223399) concerning the general specification and appearance.		
Biocompatibility Testing			
cytotoxicity	In accordance with ISO 10993-1	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	In accordance with ISO 10993-1
skin irritation	In accordance with ISO 10993-1	In accordance with ISO 10993-1	In accordance with ISO 10993-1
Material used	Enclosure material: ABS Lens: PMMA Mylar: PET	Enclosure material: ABS Lens: PMMA Mylar: PET	Battery Cover: ABS Enclosure: ABS Screen protect Film: PMMA Power Button: ABS
Comparison	The AViTA Pulse Oximeter SP62B is substantially equivalent to the predicate device (K223399) concerning the general specification and appearance.		
Pulse Rate Specification			
Range	30 to 250 bpm	30 to 250 bpm	30 to 250 bpm
Resolution unit	1 bpm (no decimal)	1 bpm (no decimal)	1 bpm (no decimal)
Accuracy	±2 bpm or ±2%, whichever is greater	±2 bpm or ±2%, whichever is greater	30 bpm~99 bpm, ± 2 bpm; 100 bpm~250 bpm, ± 2%
Comparison	The AViTA Pulse Oximeter SP62B is substantially equivalent to the predicate device (K223399) concerning the performance specification.		

8 PERFORMANCE TESTING

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.

8.1 Performance Data

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.

8.2 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.

8.3 Biocompatibility testing

The biocompatibility evaluation for the subject device with surface contact and prolonged duration 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)

8.4 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.

8.5 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.

8.6 Clinical Performance

Clinical performance was conducted per ISO 80601-2-61. The clinical validation testing of the SpO_2 performance under no motion on healthy, adult volunteers in the range of 70% to 100%. The ARMS for SpO_2 under no motion was found to be 1.89%. No adverse effects and complications happened during the clinical study.

9 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.