February 27, 2026

Avita Corporation
Hsieh Rex
Regulatory Affairs
9F, No.78, Sec.1, Kwang Fu Road, Sanchong Dist.
New Taipei City, 24158
China

Re: K252448
Trade/Device Name: AViTA Pulse Oximeter (SP61)
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: January 28, 2026
Received: January 28, 2026

Dear Hsieh Rex:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252448

Device Name
AViTA Pulse Oximeter (SP61)

Indications for Use *(Describe)*
The AViTA Pulse Oximeter is intended for spot check monitoring of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adults, adolescents and child in home and professional healthcare facility settings. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches ~0.9 inches) and intended for use 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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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:	Rex Hsieh
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Phone Number:	+886-2-8512-1568 ext.5306
Fax Number:	+886-2-8512-1347
Date of Preparation:	Feb 25, 2026

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:	K193350
Trade Name:	Leadtek Fingertip Pulse Oximeter
Manufacturer:	Leadtek Research Incorporation

Reference Device

510(k) Number:	K152563
Trade Name:	Pulse Oximeter MD300M
Manufacturer:	Beijing Choice Electronic Technology Co., Ltd.

4 DEVICE DESCRIPTION

The AViTA Pulse Oximeter is a non-invasive, prescription-use medical device intended for spot-check monitoring measurement of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate in adult, adolescent, and child users in home and professional healthcare environment settings.

The device operates using spectrophotometry by emitting red and infrared light through a pulsatile vascular bed, such as a fingertip, and detecting the light transmitted through the tissue to determine the relative concentrations of oxygenated and deoxygenated hemoglobin.

The device is designed for use on fingers with a thickness range of approximately 0.8 cm to 2.3 cm (0.3 inches to 0.9 inches) and is intended for use under no-motion conditions. The device is intended for spot-check measurements only and is not intended for continuous monitoring.

5 INTENDED USE

The AViTA Pulse Oximeter is intended for spot check monitoring of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adults, adolescents and child in home and professional healthcare facility settings. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches ~0.9 inches) and intended for use during no-motion condition. The device is prescription only

6 TECHNOLOGICAL CHARACTERISTICS

The AViTA Pulse Oximeter operates based on the principles of spectrophotometry.
The device emits two wavelengths of light, typically red and infrared, through a pulsatile vascular bed, such as a fingertip. A photodetector positioned opposite the light source detects the transmitted light after it passes through the tissue.

Functional oxygen saturation (SpO_2) is determined by analyzing the differential absorption of red and infrared light by oxygenated hemoglobin (HbO_2) and deoxygenated hemoglobin at specific wavelengths. The ratio of oxygenated hemoglobin to total hemoglobin is calculated to derive the SpO_2 value, while pulse rate is derived from the pulsatile component of the detected signal. The technological characteristics, measurement principle, and signal processing approach of the subject device are consistent with those of legally marketed pulse oximeters and the previously cleared AViTA Pulse Oximeter (K223399).

7 DEVICE COMPARISON TABLE

Item	Subject Device	Predicate Device	Reference Device	Difference / Rationale
Product Name	**AViTA Pulse Oximeter**	**Leadtek Fingertip Pulse Oximeter**	**Pulse Oximeter (MD300M)**	
Model No.	**SP61**	**8D01B and 8D01C**	**MD300M**	
510(k) Information				
Regulation Number	870.2700	870.2700	870.2700	same
Classification	Class II	Class II	Class II	same
Product Code	DQA	DQA	DQA	same
Indication for Use				
Statement	The AViTA Pulse Oximeter is intended for spot check monitoring of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate for adults, adolescents and child in home and professional healthcare facility settings. It is designed for fingers between 0.8cm and 2.3cm (0.3 inches ~0.9 inches) and intended for use 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.	The MD300M pulse oximeter is intended for continuous monitoring, spot-checking ... of single adult, adolescent, child and infant patients in hospitals and clinics	Note 1
Population	adults and adolescent and child	adults and adolescent	Adult, Adolescent, Child, Infant	Note 1
Application site	Finger	Finger	Finger	same
Performance	normal condition	normal condition	normal condition	same
Stand-alone or module	stand-alone	stand-alone	stand-alone	same
Single use or not	multiple use	multiple use	multiple use	same
Use environment	Home use and professional caring environment	home and professional caring environment	Professional (Hospital/Clinics)	**Same as Primary.** Subject device matches Leadtek for home use.

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.	Principle of the oximeter is as follows: A mathematic formula is established making use ion—Section III 510(k) Summary III-5 of Lambert Beer Law according to Spectrum Absorption Characteristics of Reductive hemoglobin (RHb) and Oxyhemoglobin (HbO2) in red and near-infrared zones. Operation principle of the instrument: Photoeletric Oxyhemoglobin Inspection Technology is adopted in accordance with Capacity Pulse Scanning and Recording Technology, so that two beams of different wavelength of lights (660nm red and 905nm near infrared light) can be focused on a human nail tip through a clamping finger-type sensor. A measured signal obtained by a photosensitive element, will be shown on the oximeter's display through process in electronic circuits and microprocessor.	Note 2
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	Dual wavelength LED (660 nanometers @ 3.2mW and 905 nanometers @2.4mW; both as max average	Note 2
Energy				

Type	Battery	Battery	Battery / AC Adapter	Same as Primary
Battery	AAA Alkaline battery x 1	AAA Alkaline battery x 1	AA Alkaline x 3 or Adapter	Same as Primary
Operation Features				
On/Off	Automatic turn on and off	Automatic turn on and off	Automatic turn on and off	Same
Display	Two color OLED	Full color OLED	TFT Color	Same as Primary
Input Key	A 4-directional key	A 5-directional key (**8D01B)** or a single push-down (**8D01C)** key	Menu / Navigation keys	Note 3
Warning /Indicator	Visual indicator	**8D01B:** Audio and visual warning **8D01C:** Visual indicator	Audio and Visual	same
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	Audio and Visual Alarm. Limits: Adjustable. Indicates low power, probe off, finger out, and exceeding limits.	. The Subject Device is intended for Spot-Checking, during which the user is expected to be present and looking at the display. Therefore, a visual indicator is sufficient. The Reference Device (MD300M) includes audio alarms because it is intended for continuous monitoring. The Primary Predicate (specifically model 8D01C) also utilizes visual indicators. Thus, the absence of an audio alarm is appropriate for the spot-check intended use and is substantially equivalent.
Display Rotation	Yes	Yes	No (Handheld)	Same as Primary
General Specification				

Usage Life	> 24 hrs typical operation under default setting	> 24 hrs typical operation under default setting	> 24 hrs	same
Operating Temperature	5 ºC to 40 ºC (41 ºF to 104 ºF)	5 ºC to 40 ºC (41 ºF to 104 ºF)	5°C to 40°C	same
Storage Temperature	-30~70°C (-22~158 °F)	-30ºC to 70 ºC (-22 ºF to 158 ºF)	-20°C to 55°C	Comparable
Humidity	10% - 90% (non-condensing)	10% to 90%, non-condensing for both operating and storage	≤ 80% (Operating)	Same as Primary
Atmospheric Pressure	700 hPa – 1060 hPa for both operating and storage	700 hPa – 1013 hPa for both operating and storage	860 - 1060 hPa	Same as Primary
Water Resistance	IP22	IP22	IPX1	Same as Primary
Classification				
Applied Part	Type BF	Type BF	Type BF	same
Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	same
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	same
Harmonized Standard	ISO 80601-2-61	ISO 80601-2-61	ISO 80601-2-61	same
Mode of Operation	Spot checking	Spot checking	Continuous / Spot check	Same as Primary
Appearance				
Weight	weight without battery: 26g (0,92 ounces)	weight without battery: 26g (0,92 ounces)	Handheld (Heavier)	NA
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”)	Handheld (Larger)	NA
Pulse Oximetry				
Range	0% to 100%	0% to 100%	0% - 100%	Same
Resolution	Resolution	Resolution	Resolution	Same
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 70% are unspecified	Same
Biocompatibility Testing				
Cytotoxicity	In accordance with ISO 10993-1	In accordance with ISO 10993-1	In accordance with ISO 10993-1	Same
Skin sensitization	In accordance with ISO 10993-1	In accordance with ISO 10993-1	In accordance with ISO 10993-1	Same
Skin irritation	In accordance with ISO 10993-1	In accordance with ISO 10993-1	In accordance with ISO 10993-1	Same
Heart Rate Specification				

Range	30 to 250 bpm	30 to 250 bpm	30 to 250 bpm	Same
Resolution	1 bpm	1 bpm	1 bpm	Same
Accuracy	±2 bpm or ±2%, whichever is greater	±1 bpm or ±1%, whichever is greater	±2 bpm or ±2%	Note 4

Note 1: Intended Use and Patient Population The Subject Device is substantially equivalent to the **Primary Predicate (Leadtek)** regarding the **Use Environment (Home & Professional)** and **Mode of Operation (Spot-check)**.

- **Population Expansion:** The Subject Device expands the patient population to include **"Child"**, which differs from the Primary Predicate but is substantially equivalent to the **Reference Device (MD300M)**, which is cleared for adult, adolescent, child, and infant use.
- **Safety Verification:** The Subject Device's suitability for children (finger thickness 0.8 cm – 2.3 cm) has been verified through bench testing using pediatric-representative tools (anthropometric data validation and ProSim 8 functional testing). This demonstrates that the device effectively accommodates the anatomical and physiological characteristics of the child population.

Note 2: Technological Characteristics (Wavelength) The Subject Device utilizes Red (660nm) and Infrared (**905nm**) wavelengths.

- **Comparison:** While the Primary Predicate uses 940nm for Infrared, the Subject Device's wavelength specification is identical to the **Reference Device (MD300M)**, which also uses **905nm**.
- **Rationale:** All three devices operate on the same fundamental physical principle of spectrophotometry (Beer-Lambert Law). The difference in the specific infrared wavelength does not affect the fundamental measurement principle and has been validated via **ISO 80601-2-61** performance testing. Therefore, this difference does not raise new questions of safety or effectiveness.

Note 3: User Interface (Input Keys) The Subject Device uses a 4-directional key, while the Primary Predicate uses a 5-directional key or single button, and the Reference Device uses menu keys.

- **Rationale:** This is solely a difference in **User Interface (UI)** design and implementation. It does not affect the device's measurement algorithm, performance, or operating principle. Usability testing confirms that the 4-directional key allows users to effectively navigate and operate the device for its intended use.

Note 4: Heart Rate (PR) Accuracy The Subject Device specifies a Pulse Rate accuracy of **±2 bpm or ±2%**.

- **Comparison:** The Primary Predicate specifies a tighter accuracy (±1 bpm), whereas the Subject Device's specification is identical to the **Reference Device (MD300M)**.
- **Rationale:** The accuracy of ±2 bpm or ±2% fully complies with the particular standard **ISO 80601-2-61** for pulse oximeters. Bench testing confirms the Subject Device meets this requirement. Since the device is

intended for spot-checking rather than critical care continuous monitoring, this accuracy level is clinically acceptable and substantially equivalent to legally marketed devices.

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 as safe and as effective as the predicate device.

8.1 Performance Data【807.92(b)】

Performance testing was conducted on the subject device, AViTA Pulse Oximeter (Model SP61), to evaluate the accuracy of oxygen saturation (SpO2) and pulse rate measurements using laboratory bench testing methods. The testing was performed in accordance with **ISO 80601-2-61:2017**, *Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*, to support a determination of substantial equivalence to the predicate device.

8.2 Electrical Safety and EMC Testing

Electrical safety, electromagnetic compatibility (EMC), and essential performance testing were conducted on the subject device, **AViTA Pulse Oximeter (Model SP61)**, to evaluate compliance with applicable safety and performance standards for the intended home and professional healthcare environments.

Testing demonstrated that the subject device complies with the following standards:

- **IEC 60601-1 (Relied upon from K223399)**: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- **IEC 60601-1-2 (Relied upon from K223399)**: 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 (Relied upon from K223399)**: Medical electrical equipment – Part 1-11: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- **IEC TR 60601-4-2**: Guidance on assessing the reliability of medical device essential performance under electromagnetic disturbances

During EMC immunity testing, **oxygen saturation (SpO_2) and pulse rate measurement functions were defined as essential performance** and were actively monitored to verify continued performance under electromagnetic disturbance conditions. Performance acceptance criteria were established in accordance with **ISO 80601-2-61**, and the device was required to maintain SpO_2 and pulse rate measurement accuracy within the specified limits throughout testing.

The test results confirmed that the subject device maintained its essential performance during exposure to electromagnetic disturbances representative of the intended use environments. No degradation or loss of SpO_2 or pulse rate measurement performance was observed that would impact the device's intended use or result in unacceptable risk to the patient.

Based on the results of electrical safety and EMC testing, the subject device demonstrates compliance with applicable standards and performs as intended under the specified electromagnetic

environments. Detailed test methods and results are provided in the corresponding electrical safety and EMC test reports.

8.3 Biocompatibility testing (Relied upon from K223399)

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)

8.4 Software Verification and Validation (Relied upon from K223399)

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 Basic Documentation Level.

8.5 Cleaning Validation (Relied upon from K223399)

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 (Relied upon from K223399)

Clinical Test Results Clinical performance evaluation of the subject device, AViTA Pulse Oximeter (Model SP61), was conducted in accordance with **ISO 80601-2-61:2017** and the **FDA Guidance for Pulse Oximeters** to assess SpO_2 accuracy under steady-state, no-motion conditions.

A controlled desaturation study was performed with **12 healthy adult volunteers** (6 male and 6 female) out of 17 screened subjects. The subject pool represented a diverse range of skin pigmentation (light, medium, and dark), fulfilling the demographic requirements of ISO 80601-2-61.

SpO_2 Accuracy Results (Comparison to SaO_2 Reference) SpO_2 accuracy was evaluated by comparing the SpO_2 readings from the subject device to functional arterial oxygen saturation (SaO_2) measured by a **reference Co-oximeter** (Gold Standard) from arterial blood samples. The accuracy was quantified using the Accuracy Root Mean Square (Arms) metric.

A total of **255 valid paired data points** were collected across the required SpO_2 range of 70% to 100%. The aggregate results demonstrated high accuracy:

- **Overall Arms (70-100%): 1.89%**

This result falls well within the FDA recommended acceptance criterion of **≤ 3.0%** and the device's labeled specification of ±2%. Subgroup analysis further confirmed performance consistency:

- $SpO_2 \geq 85\%$: 166 valid data points, Arms = 1.31%
- $SpO_2 < 85\%$: 89 valid data points, Arms = 2.66%

Conclusion The clinical evaluation demonstrates that the AViTA Pulse Oximeter (SP61) meets the essential performance requirements for SpO_2 accuracy as defined in ISO 80601-2-61. The calculated Arms of 1.89% confirms the device's clinical accuracy in the range of 70-100%. No device-related adverse events were observed during the study.

9 SUBSTANTIAL EQUIVALENCE

Determination of Substantial Equivalence Based on a comprehensive comparison of intended use, patient population, technological characteristics, and performance data, the subject device, AViTA Pulse Oximeter (Model SP61), has been demonstrated to be substantially equivalent to the predicate device.

Therefore, the AViTA Pulse Oximeter (Model SP61) is substantially equivalent to the legally marketed predicate devices.