May 9, 2025

Avidhrt Inc.
℅ Prabhu Raghavan
Principal Consultant
MDQR, LLC
1790 Montemar Way
San Jose, California 95125

Re: K241086
Trade/Device Name: Avidhrt Sense SpO2
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: DQA
Dated: May 5, 2025
Received: May 6, 2025

Dear Prabhu Raghavan:

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,

Jennifer W. Shih -S

Jennifer Kozen
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular 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)*
K241086

Device Name
Avidhrt Sense SpO2

Indications for Use *(Describe)*
Avidhrt Sense is a handheld spot-checking measurement device, indicated to do the following:
• Non-invasive spot checking of functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse waveform (when prescribed by a physician).

Avidhrt Sense SpO2 is intended for use in adult patients in the home environment. The Avidhrt Sense SpO2 is not for continuous monitoring, use during motion or for patients with low perfusion. The Avidhrt Sense SpO2 is not intended for pediatric 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 for K241086

Prepared in accordance with the requirements of 21 CFR 807.92

Submitter Information [807.92(a)(1)]

Submitter/Applicant	Avidhrt Inc. 325 E. Grand River Avenue #225 East Lansing, MI 48823 *Applicant Contact*: Prabode Weebadde Email: prabode@avidhrt.com Phone: (517) 214-9041
Primary Contact Person	Prabhu Raghavan Regulatory Consultant for Avidhrt Inc. Principal Consultant, MDQR LLC. 1790 Montemar Way San Jose, CA 95125 Phone: 408-316-5707 Email: prabhu@mdqr.solutions
Date Prepared	May 09, 2025

Device Information [807.92(a)(2)]

Trade Name	Avidhrt Sense SpO2
Common Name	Oximeter
Regulation	21 CFR §870.2700
Device Class	II
Product Code	DQA
Subsequent Product Code	N/A

Predicate Information [807.92(a)(3)]

Predicate(s)	K181956, Masimo MightySat Rx Fingertip Pulse Oximeter by Masimo Corporation
Common Name	Oximeter
Regulation	21 CFR §870.2700
Device Class	II
Product Code	DQA
Subsequent Product Code	BZQ

Device Description [807.92(a)(4)]

Avidhrt Sense SpO2 is a handheld spot-checking measurement device designed for non-invasive spot checking of functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse

waveform (when prescribed by a physician). Avidhrt Sense SpO2 is used in conjunction Avidhrt Sense SpO2 smart phone app that displays the SpO2.

Indications for use [807.92(a)(5)]
Avidhrt Sense SpO2 is a handheld spot-checking measurement device, indicated to do the following:

- Non-invasive spot checking of functional oxygen saturation of arterial hemoglobin (% SpO2) and pulse waveform (when prescribed by a physician).

Avidhrt Sense SpO2 is intended for use in adult patients in the home environment. The Avidhrt Sense SpO2 is not for continuous monitoring, use during motion or for patients with low perfusion. The Avidhrt Sense SpO2 is not intended for pediatric use.

Substantial Equivalence
Avidhrt utilizes the Masimo MightySat Rx Fingertip Pulse Oximeter (K181956) as a predicate for pulse oximetry functions.

Comparison of intended use and indications for use
The Avidhrt Sense SpO2 is indicated for noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) using pulse oximetry. The Masimo MightySat Rx Fingertip Pulse Oximeter is "indicated for the noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR) for adult and pediatric patients during both no motion and motion conditions, and for patients who are well or poorly perfused" and is also "indicated for the noninvasive spot checking of respiration rate (RRp) for adult patients". As such, the subject device has a subset of intended use of the predicate device, i.e., "noninvasive spot checking of functional oxygen saturation of arterial hemoglobin (SpO2) in adults".

With regards to the intended use patient population, the subject device is intended for use by adults. This is a subset of the intended use population of the K181956 predicate, which includes both adults and pediatric patients. Both devices are intended for use by adult lay users independently or guided by health care professionals (HCPs) in home and non-acute clinical environments. The predicate includes additional use in acute environments, which is not present in the subject device. The predicate device's SpO2 function is intended for use during both motion and no motion, and for patients who are well and poorly perfusion. The subject device is indicated for a subset of the predicate's functions, i.e., during conditions of no motion and for patients who are well perfused.

The predicate is also indicated for noninvasive spot checking of respiration rate of adult patients, which is not included in the subject device.

As such, the subject device has the same intended use and substantially equivalent indications for a subset of the indications for use of the predicate device.

Comparison of technological characteristics [807.92(a)(6)]
Technological characteristics of the Avidhrt Sense SpO2 pulse oximetry functions closely align with those of the MightySat device. They both use pulse oximetry, with the primary difference being the minor differences in the method (reflectance vs. transmittance) used to perform this measurement. The difference of method of the pulse oximetry between the Avidhrt Sense SpO2 and MightySat devices do not raise different questions of safety or effectiveness. The technological characteristic difference is addressed by performance testing using the consensus standard ISO 80601-2-61, and FDA Guidance: Pulse Oximeters-Premarket Notification Submissions: Guidance for Industry and Food and Drug Administration Staff.

In conclusion, Avidhrt Sense SpO2 has the same intended use as the predicate device, and any differences in technological characteristics do not raise different questions of safety or effectiveness.

Performance Data [807.92(b)]
All necessary testing was conducted on Avidhrt Sense SpO2 to support a determination of substantial equivalence to the predicate device, which included:

- Electrical safety per IEC 60601-1 and IEC 60601-1-11,
- Electromagnetic compatibility per IEC 60601-1-2, wireless coexistence testing per ANSI C63.27,
- Biocompatibility testing per ISO 10993-1,
- Pulse oximetry testing per IEC 80601-2-61, which included clinical performance testing to evaluate the accuracy of the SpO2 measurement (hypoxia study per IEC 80601-2-61),
- Evaluating the performance of the subject device to reject conditions of low perfusion,
- Evaluating the ability of the users to safely operate the device in a human factors study.

As noted above, a clinical study was performed to support the device:

- A controlled hypoxia or desaturation study, was conducted to provide human validation data of pulse oximeters according to ISO 80601-2-61:2017 and FDA guidance on pulse oximeters. The study included fourteen (12) healthy volunteer subjects, ages 21 - 49, with 8 subjects identified as female (67%) and 4 subjects as male (33%). The subjects included a range of ethnicities. The 12 subjects had a range of skin tones, including at least 25% (3/12) with dark skin tones, thus exceeding the requirements in the standard and FDA guidance of at least 2 or 15%. Hypoxia was then induced to different and stable levels of oxyhemoglobin saturation (between 70-100%) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide. Each plateau level of oxyhemoglobin saturation was maintained for at least 30 seconds or until reference pulse

oximeters readings were stable. Two arterial blood samples were then obtained, approximately 30 seconds apart. Each stable plateau therefore was maintained for at least 60 seconds with SpO2 fluctuating by less than 2-3%. The plateaus were nominally at 100%, room air saturation, 93%, 90%, 87%, 85%, 82%, 80%, 77%, 75% and 70%. A total of 291 samples were obtained at the saturation plateaus across this span.

Avidhrt Sense SpO2 oximeter data were taken as 5-second averages at each plateau to arterial blood analysis for comparison. According to equation 1 in ISO 80601-2-61:2017, A_{RMS} for the Avidhrt Sense SpO2 was calculated for each range of the following SaO2 ranges of 70-80%, 80- 90%, 90-100% and 70-100%. The results were 2.44%, 1.49%, 1.43%, and 1.82%, respectively, which satisfied the prespecified performance criteria.

Conclusions [807.92(b)(3)]

The results of these testing therefore demonstrate that the device performs as intended and confirm that the technological differences between the subject device and the predicate device do not raise different questions of safety and effectiveness, and that the device is as safe and as effective for its intended use as the predicate device.