June 18, 2026

Presage Security, Inc. d/b/a Presage Technologies, Inc.
Michael Kenney
General Counsel and Secretary
50 Catoctin Cir NE #101
Office 114
Leesburg, Virginia 20176

Re: K254169
Trade/Device Name: SmartSpectra Vital Signs Monitor 1.0
Regulation Number: 21 CFR 870.2785
Regulation Name: Software For Optical Camera-Based Measurement Of Pulse Rate, Heart Rate, Breathing Rate, And/Or Respiratory Rate
Regulatory Class: Class II
Product Code: QME
Dated: December 22, 2025
Received: December 23, 2025

Dear Michael Kenney:

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 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 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,

KIMBERLY N. CROWLEY -S

Digitally signed by KIMBERLY N. CROWLEY -S
Date: 2026.06.18 15:30:06 -04'00'

For: Jennifer Kozen
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254169

Please provide the device trade name(s).

SmartSpectra Vital Signs Monitor 1.0

Please provide your Indications for Use below.

The Presage SmartSpectra Vital Signs Monitor is intended for non-invasive spot measurement of pulse rate and respiratory rate in healthy individuals during routine interactions with healthcare professionals such as during routine checkups. It is software assessing video footage from a fixed-installation solution (smartphone mounted in a static-mount) in admissions and examination areas of hospitals, clinics, general care, or other secured environments, where a single human face can be maintained in view, with professional healthcare oversight. The SmartSpectra system is intended for use by trained healthcare professionals and should not be used by untrained users. The SmartSpectra Vital Signs Monitor is intended for use on humans 18 to 70 years old who do not require critical care or continuous vital signs monitoring. The device is not intended to be the sole method of checking the physical health of a subject or for use on patients that have been admitted to hospitals or in ICUs.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

Contact Details

Applicant Name: Presage Security, Inc. d/b/a Presage Technologies, Inc.
Applicant Address: 50 Catoctin Cir NE #101 Office 114 Leesburg VA 20176 United States
Applicant Contact Telephone: 312-278-3013
Applicant Contact: Mr. Jeremy Moore
Applicant Contact Email: jeremy@presagetech.com

Device Name

Device Trade Name: SmartSpectra Vital Signs Monitor 1.0
Common Name: Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate
Classification Name: Software For Optical Camera-Based Measurement Of Pulse Rate, Heart Rate, Breathing Rate, And/Or Respiratory Rate
Regulation Number: 870.2785
Product Code(s): QME

Legally Marketed Predicate Device

K211906 Oxehealth Vital Signs

Device Description Summary

The SmartSpectra device is a software development kit (“SDK”) which uses software algorithms to analyze optical camera-based video signals for estimation of pulse rate and respiratory rate. It is a software-only medical device (“SaMD”) verified and validated to run within the SmartSpectra Vital Signs software application (“App”), installed on a Samsung Galaxy S24 or Apple iPhone 16 Pro. The device’s operating system must be kept up-to-date with the latest security patches and must not be rooted, jailbroken, or otherwise modified beyond the manufacturer’s standard configuration. Access to the SmartSpectra device is controlled via the Presage Technologies Mobile Device Manager (MDM) Service, ensuring the host application with the SDK device is only installed on verified and validated hardware and utilized by the intended user population.

The SmartSpectra device is intended for prescription only use (“POU”) in hospitals, clinics, general care and secured environments, from a statically mounted position installed by trained and certified Presage personnel. The Presage technician verifies the use environment prior to mounting the device in the clinical area. Such verification includes assuring that the clinical area is properly illuminated and that the device’s mount will not be subjected to excessive vibration. Following environment verification and static mounting of the device, the Presage technician validates the device was properly installed, is operating effectively, and documents evidence of proper installation.

Intended Use/Indications for Use

The Presage SmartSpectra Vital Signs Monitor is intended for non-invasive spot measurement of pulse rate and respiratory rate in healthy individuals during routine interactions with healthcare professionals such as during routine checkups. It is software assessing video footage from a fixed-installation solution (smartphone mounted in a static-mount) in admissions and examination areas of hospitals, clinics, general care, or other secured environments, where a single human face can be maintained in view, with professional healthcare oversight. The SmartSpectra system is intended for use by trained healthcare professionals and should not be used by untrained users. The SmartSpectra Vital Signs Monitor is intended for use on humans 18 to 70 years old who do not require critical care or continuous vital signs monitoring. The device is not intended to be the sole method of checking the physical health of a subject or for use on patients that have been admitted to hospitals or in ICUs.

Indications for Use Comparison

As set forth by Presage Technologies, Inc. (“Presage”) in the Substantial Equivalence Table (DOC - 0024) included with this 510(k) submission, Presage’s SmartSpectra Vital Signs Monitor (the “SmartSpectra device” or “the device”) and the identified predicate, Oxehealth’s Vital Signs (K211906) are substantially similar.

The two are considered software as a medical device (“SaMD”), and share the same regulatory classification, device class, and classification name. Both are intended for non-invasive, spot-check physiological measurements using optical, camera-based technology; both measure signals obtained from humans 18 to 70 years of age, who do not require critical care or continuous vital signs monitoring. Both rely on generally comparable hardware compatibility requirements, and present results through substantially similar user interfaces.

There are differences, but they are minor and limited to details such as specific hardware compatibility or user interaction features. Such distinctions neither alter performance expectations nor raise different questions of safety or effectiveness. The SmartSpectra device is therefore substantially equivalent to the Oxehealth Vital Signs device.

Technological Comparison

The Presage SmartSpectra Vital Signs Monitor and the Oxehealth Vital Signs device employ the same fundamental technological characteristics to achieve their intended use. Both devices utilize optical, camera-based, non-contact technology combined with software algorithms to analyze video imagery and derive physiological measurements, specifically pulse rate and respiration rate. Pulse is determined based on subtle changes in skin coloration associated with blood flow. Respiration is determined based on movements of the subject's upper torso. Each device is software-driven, operates in a fixed installation environment, and performs spot measurements without requiring direct physical contact or wearable sensors. The devices rely on comparable data acquisition, signal processing, and result output principles, and include similar limitations indicating that the measurements are not intended to be used as the sole method for assessing physical health. Any minor differences in description related to installation context, supervision, or user qualifications reflect labeling clarifications and do not alter the underlying technology, operating principles, or performance, nor do they raise new questions of safety or effectiveness.

	Subject Device	**Predicate Device**	**Discussion**
	SmartSpectra Vital Signs Monitor	Oxehealth Vital Signs *(K211906)*	
Product Code	QME	QME	Same
Regulation Number	21 CFR 870.2785	21 CFR 870.2785	Same
Class	Class 2	Class 2	Same
Classification Name	Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate	Software for optical camera-based measurement of pulse rate, heart rate, breathing rate, and/or respiratory rate	Same
Intended Use	Non-invasive spot check measurements of pulse rate and respiratory rate	Non-invasive spot check measurements of pulse rate and breathing rate (chest wall movements)	Same

Indications for Use	The Presage SmartSpectra Vital Signs Monitor is intended for non-invasive spot measurement of pulse rate and respiratory rate in healthy individuals during routine interactions with healthcare professionals such as during routine checkups. It is software assessing video footage from a fixed-installation solution (smartphone mounted in a static-mount) in admissions and examination areas of hospitals, clinics, general care, or other secured environments, where a single human face can be maintained in view, with professional healthcare oversight. The SmartSpectra system is intended for use by trained healthcare professionals and should not be used by untrained users. The SmartSpectra Vital Signs Monitor is intended for use on humans 18 to 70 years old who do not require critical care or continuous vital signs monitoring. The device is not intended to be the sole method of checking the physical health of a subject or for use on patients that have been admitted to hospitals or in ICUs.	The Oxehealth Vital Signs device is intended for non-invasive spot measurement of pulse rate and estimated breathing rate (chest wall movements) when the subject is still. It is software assessing video footage from a fixed-installation solution for use within single occupancy rooms within hospitals, general care and secured environments with professional healthcare oversight and where a framework exists which mandates periodic checks by a trained professional to ensure subject safety. The Oxehealth system is intended for use by appropriately trained staff with a duty of care, and should not be used by untrained users. The Oxehealth Vital Signs device is indicated for use on humans 18 years of age or older who do not require critical care or continuous vital signs monitoring. The device is not intended to be the sole method of checking the physical health of a subject.	Substantially Equivalent
Intended Use Population	Healthy patients 18 to 70 years of age who do not require critical care or continuous vital signs monitoring.	Humans 18 years of age or older who do not require critical care or continuous vital signs monitoring.	Substantially Equivalent. The subject device has a narrower intended population which does not raise different questions of safety and effectiveness.

Use Environment	Healthcare facilities where a single human face can be maintained in view, with professional healthcare oversight. The device is not intended for use on patients that have been admitted to hospitals or in ICUs.	For use within single occupancy rooms within hospitals, general care and secure environments.	Substantially Equivalent
Installation Procedure	System installation requires unit-by-unit verification of all hardware and environmental conditions to be installed at a customer site by Presage as well as verifying adequate performance at maximum usage load of the solution before handover to the customer.	System installation requires unit-by-unit verification of all hardware and environmental conditions to be installed at a customer site by Oxehealth as well as verifying adequate performance at maximum usage load of the solution before handover to the customer.	Same
Compatibility with Hardware - Computing	Samsung Galaxy S24 or Apple iPhone 16 Pro smartphone installed by Presage Technologies, and validated during installation. Installation will be carried out by a Presage Technologies trained installer, according to installation instructions and verification procedures provided by Presage Technologies.	Standard, off-the-shelf computers and mobile tablets, specified and installed by Oxehealth, and validated during installation. Installation will be carried out by an Oxehealth approved installer, according to installation instructions and verification procedures provided by Oxehealth.	Substantially Equivalent
Compatibility with Hardware - Camera and Accessories	Samsung Galaxy S24 or Apple iPhone 16 Pro	Standard, off-the-shelf machine vision camera and infrared illuminators, exact specification determined by Oxehealth and validated during installation	Substantially Equivalent
Device Measurements	Non-invasive spot check measurements of pulse rate and respiratory rate.	Non-invasive spot check measurements of pulse rate and breathing rate (chest wall movements).	Substantially Equivalent
CO_2 Sensor Technology	N/A	N/A	Same
User Interface	Software medical device designed to extract signals from video and measure pulse rate and breathing rate from a	Software medical device designed to extract signals from video to and measure pulse rate and breathing rate from a	Substantially Equivalent

	patient. Smartphone application user interface designed to allow users to take spot check measurement of pulse rate and breathing rate.	patient. Software user interface designed to allow users to take spot check measurement of pulse rate and breathing rate, and to see previously obtained measurements.	
Software	The platforms use a combination of C++, Kotlin, Java, Swift, Objective-C, and Python; use of third party libraries	C++ and Node.js; use of third party libraries	Substantially Equivalent
Human Factors	Operation of Software User Interface	Operation of Software User Interface	Same
Power	Power supply	Power supply	Same
Pulse Rate Range and Accuracy	Pulse rate measurement 50-150 beats per minute within a 30 second window. Pulse rate measurement RMSE is 3 beats per minute.	Pulse rate measurement 50-130 beats per minute within a 9 second window. Pulse rate measurement RMSE is 3 beats per minute.	Substantially Equivalent
Respiratory Rate Range and Accuracy	Respiratory rate measurement range is 8-26 breaths per minute within a 30 second window. Respiratory rate measurement accuracy is 3 breaths per minute based on RMSE and Bland-Altman analysis and 95% CI of Limits of Agreement (LoA).	Estimated breathing rate (chest wall movements) measurement range is 8-31 breaths per minute within a 30 second window. Breathing rate measurement RMSE is 2 breaths per minute.	Substantially Equivalent

Non-Clinical Performance Testing

Nonclinical testing was conducted to support a determination of substantial equivalence for the SmartSpectra Vital Signs Monitor. The primary nonclinical evaluations consisted of software verification and validation (V&V) testing, cybersecurity testing, interoperability testing, and human factors/usability testing. Software verification and validation activities were performed for the SmartSpectra software, which is classified as Basic Documentation Level, in accordance with IEC 62304:2006 + A1:2015 and FDA guidance Content of Premarket Submissions for Device Software Functions. Verification and validation testing included unit testing, integration testing, system-level testing, and user acceptance testing. These activities confirmed that the software performs as intended, meets its specified requirements, and supports safe and

effective operation of the device. Interoperability testing was conducted to confirm compatibility and proper data exchange with supported third-party devices and systems. Testing demonstrated reliable communication and correct functionality when operating in the intended interoperable environment. Cybersecurity testing was conducted in accordance with FDA guidance Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions. Testing addressed potential cybersecurity risks and verified implementation of appropriate controls to protect device functionality and data integrity. Human factors and usability testing was performed and documented in DOC-0084, Human Factors Testing Report. The testing evaluated representative users performing critical tasks in the intended use environment. Results demonstrated that users were able to safely and effectively operate the SmartSpectra Vital Signs Monitor and that identified use-related risks were adequately mitigated. Collectively, these nonclinical tests support that the SmartSpectra Vital Signs Monitor performs as intended and is substantially equivalent to the predicate device.

Clinical Performance Testing

Clinical testing was conducted and relied upon to support a determination of substantial equivalence for the SmartSpectra Vital Signs Monitor. The clinical evidence consists of a prospective clinical evaluation study conducted in a hospital setting and a separate clinical validation study conducted under IRB oversight, both comparing SmartSpectra measurements to FDA-cleared reference devices.

The primary clinical evaluation study (DOC-0080 and DOC-0081) was conducted at Baylor College of Medicine and enrolled 112 adult subjects (111 evaluable) aged 18 years and older. The SmartSpectra Vital Signs Monitor was evaluated for non-contact measurement of pulse rate and respiratory rate using statically mounted mobile devices (iOS and Android). Measurements were compared against ECG-derived heart rate and $etCO_2$-derived respiratory rate. Respiratory rate was validated against the accepted gold standard – blinded, manually-counted etCO2 waveform. The study assessed accuracy, robustness, and agreement using RMSE, capture rate, Bland-Altman analysis, and Deming regression. Performance was consistent across demographic subgroups including sex, age, body mass index, and Fitzpatrick skin tone.

A separate clinical validation study (DOC-0090) was conducted under IRB oversight with informed consent to evaluate SmartSpectra performance across varying physiological and environmental conditions, including resting and elevated heart rates, lighting conditions, and camera distances. 99 evaluable subjects were included in the final analysis. SmartSpectra measurements were compared against BIOPAC MP160 reference measurements using ECG, respiratory belt (RSPU), and $etCO_2$ signals. Bland-Altman and Deming regression analyses demonstrated strong agreement with reference measurements and minimal bias.

For pulse rate, during the elevated heart rate (EHR) Pre (resting) timepoint, Android achieved an RMSE of 1.34 bpm [95% CI: 1.08, 1.62] (N=85) and iPhone achieved 1.52 bpm [95% CI: 1.26, 1.77] (N=62). During the EHR Post (elevated heart rate) timepoint, Android achieved an RMSE of 1.51 bpm [95% CI: 1.25, 1.79] (N=77) and iPhone achieved 1.81 bpm [95% CI: 1.39, 2.21] (N=59). Similarly, in the Clinical Evaluation Study, the SmartSpectra Vital Signs Monitor demonstrated pulse rate RMSE values well below the 3 bpm performance threshold across both platforms. Android achieved an RMSE of 1.73 bpm [95% CI: 1.49, 1.95] (N=96) and iPhone achieved an RMSE of 1.77 bpm [95% CI: 1.50, 2.04] (N=92).

For respiratory rate, across all platforms, protocols, and timepoints in the Clinical Validation Study, the SmartSpectra Vital Signs Monitor met the 3.0 breaths/min respiratory rate acceptance criteria within the 8-26 breaths/min range, based on the outer bounds of the 95% confidence intervals of the Limits of Agreements (LoAs) calculated from Bland-Altman analyses. When respiratory rate data was pooled (95 unique subjects, 555 observations) across the Tidal Volume (TV) and Elevated Heart Rate (EHR) protocols bias between the device and reference devices was 0.03 (95% CI: [-0.09, 0.16]), with a lower LoA of -2.17 (95% CI: [-2.37,-1.99]) and upper LoA of 2.23 (95% CI: [2.06, 2.43]).

Presage designed and conducted a human factors engineering study (“HF Study”) with simulated use testing for the purpose of evaluating user interaction with the Device. The design of the HF study was based on a use related risk analysis (“URRA”) compliant with the FDA’s 2016 guidance and expectations for comprehensive scope, naive use and critical task coverage. The results of the HF Study provided evidence that the software interface, user manual, and tutorial training reliably guide users to identify and implement appropriate use conditions. Anticipated user-related risks were mitigated by user training and software algorithms. Users were able to understand the required interventions to ensure critical tasks could be performed properly to operate the Device safely and effectively under realistic environmental and physical conditions. 30 out of 30 users were able to obtain a successful measurement using the Device across all challenge sets. The results demonstrate that the user interface, labeling, and training adequately mitigate use-related risks and enable safe and effective operation of the Device by intended users under expected use conditions.

Based on the totality of the nonclinical and clinical evidence, the SmartSpectra Vital Signs Monitor (“the Device”) is as safe, as effective, and performs as well as the legally marketed predicate device, Oxehealth Vital Signs, and raises no new questions of safety or effectiveness.