



September 25, 2026

Life Detection Technologies
% Michael Nilo
President, Principal Consultant
Nilo Medical Consulting Group
3706 Butler St.
Suite #313
Pittsburgh, Pennsylvania 15201

Re: K254058

Trade/Device Name: DistaSense(TM) (v1)
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: DRT, BZQ
Dated: August 21, 2026
Received: August 24, 2026

Dear Michael Nilo:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JENNIFER W. SHIH -S

Jennifer Kozen
Assistant Director
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.

K254058

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Please provide the device trade name(s).

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DistaSense(TM) (v1)

Please provide your Indications for Use below.

?

The DistaSense(TM) System is a contactless medical device intended to measure heart rate and respiration rate in healthy adult patients, at rest or during sleep (in a non-motion condition) the DistaSense(TM) System is intended to be used by healthcare professionals, caregivers, and patients, with recordings performed in either a clinical setting or in a home environment. The DistaSense(TM) web application is intended for use by healthcare professionals only. This device is not indicated for active patient monitoring, rather, it is intended for retrospective data review in healthy patients. The device is not indicated for use in pregnant women or patients with active implantable devices.

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](#))

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510(k) Summary

510(k) #	K254058
Date Prepared	09/23/2026

1. Contact Details: 21 CFR 807.92(a)(1)

Applicant Name	Life Detection Technologies
Applicant Address	440 N Wolfe Rd, STE WL 265 Sunnyvale, CA 94085
Applicant Contact	Peter Rule
Applicant Contact Telephone	650-279-5261
Applicant Contact Email	prule@distasense.com

2. Device Name: 21 CFR 807.92(a)(2)

Device Trade Name	DistaSense™ System
Common Name	Monitor, Cardiac / Monitor, Breathing Frequency
Regulation Number	870.2300 / 868.2375
Product Codes	DRT, BZQ

3. Legally Marketed Devices: 21 CFR 807.92(a)(3)

Predicate Number	K223163
Predicate Trade Name	Sleepiz One+
Product Code	DRT, BZQ

4. Device Description Summary: 21 CFR 807.92(a)(4)

The DistaSense™ system is a contactless medical device intended to measure heart rate and respiration rate in healthy adult patients 22 years or older, at rest or during sleep (in a non-motion condition). The DistaSense™ system is intended to be used by healthcare professionals, caregivers, and patients, with recordings performed in either a clinical setting or in a home environment. The five major components in the system are the bed sensor, adjustable bed strap, analog front end, smart data hub, and the web portal with data analytics. The bed sensor is a non-contact, near-field antenna that, when used in conjunction with the analog front end, detects the patient's change in body impedance. This information is then passed to the smart data hub, which securely transfers the data to the web portal. The web portal gives healthcare professionals several different administrative and processing capabilities. All patient data is then encrypted and stored on a non-device Medical Device Data System.

5. Intended Use/Indications for Use: 21 CFR 807.92(a)(5)

The DistaSense™ system is a contactless medical device intended to measure heart rate and respiration rate in healthy adult patients, at rest or during sleep (in a non-motion condition). The DistaSense™ system is intended to be used by healthcare professionals, caregivers, and patients, with recordings performed in either a clinical setting or in a home environment. The DistaSense™ web application is intended for use by healthcare professionals only. This device is not indicated for active patient monitoring, rather, it is intended for retrospective data review in healthy patients. The device is not indicated for use in pregnant women or patients with active implantable devices.

6. Indications for Use Comparison: 21 CFR 807.92(a)(5)

The Indications or Use of the DistaSense and Sleepiz One+ are nearly identical. The medical indications related to heart rate and respiration rate are the same for both the subject and predicate device.

7. Technological Comparison: 21 CFR 807.92(a)(6)

While the biometric data collection technology differs, the interpretation, use of, and conveyance of the data is equivalent to the predicate device. Both the predicate and subject devices are used for the contactless collection of respiration rate (RR) and heart rate (HR) of patients during rest in a clinical or home healthcare environment.

The DistaSense system uses a near-field antenna to measure capacitance changes to collect and interpret data on the RR and HR of the patient. Likewise, the Sleepiz One+ uses local radar detection to perceive movements and interpret the data to determine and display the RR and HR of the patient.

The differences in technology do not raise different questions of safety or effectiveness. The questions are the same, and existing test methods have been used to demonstrate substantial equivalence and a reasonable assurance of safety and effectiveness.

The table below summarizes the technological characteristics of the subject device compared to the stated predicate.

510(k) Summary

Detail and Technological Characteristic	Subject Device DistaSense v1	Primary Predicate Sleepiz One+ (K223163)	Comparison
Device	DistaSense v1	Sleepiz One+	
510k Number	K254058	K223163	
Manufacturer	Life Detection Technologies 440 N. Wolfe Rd Sunnyvale, CA 94085 USA	Sleepiz AG Hornbachstrasse 23 Zurich Zurich 8008 DE	
Classification & Product Code	21 CFR 870.2300 DRT, BZQ	21 CFR 870.2300 DRT, BZQ	Same
Indications for Use	The DistaSense™ system is a contactless medical device intended to measure heart rate and respiration rate in healthy adult patients, at rest or during sleep (in a non-motion condition). The DistaSense™ system is intended to be used by healthcare professionals, caregivers, and patients, with recordings performed in either a clinical setting or in a home environment. The DistaSense™ web application is intended for use by healthcare professionals only. This device is not indicated for active patient monitoring, rather, it is intended for retrospective data review in healthy patients. The device is not indicated for use in pregnant women or patients with active implantable devices.	Sleepiz One+ is a contactless medical device intended to measure heart rate and respiration rate in adult patients, at rest or during sleep (in non-motion condition). The Sleepiz One+ hardware unit is intended to be used by a healthcare professional when the recordings are performed in a clinical setting, or by patients or their caregivers when the recordings are performed in a home environment. The Sleepiz One+ web application is intended for use by healthcare professionals. Sleepiz One+ device can also detect the presence of patients and their body movements at rest or during sleep. This device is not indicated for active patient monitoring, as it does not provide alarms for timely response in life-threatening situations. It is not indicated for use on pregnant women or patients with active implantable devices.	Similar – DistaSense measures heart and respiratory rate with the data used by healthcare professionals to inform patient care and can be used at home or in a clinical setting, including long-term care facilities. The DistaSense does not collect information on patient movement or presence.

510(k) Summary

Device Description	The DistaSense system is a wireless remote patient monitoring system intended for use by healthcare professionals for the measurement of respiration rate and heart rate, in an automatic contact-less manner. The system is designed for installation by trained LDT service technicians. The system consists of the following components: - Bed Sensor; - Adjustable Bed Strap; - Analog Front End; - Smart Data Hub with power supply; - Healthcare professional-facing Web Portal with data analytics. The non-contact Bed Sensor, in conjunction with the Analog Front End (AFE), detects the body capacitance changes associated with breathing and circulation in the patient's torso. The	<u>Outputs:</u> The following parameters are estimated: - Breathing pattern; - Instantaneous breathing rate [breaths per minute]; - Breathing rate statistics (10th, 50th, and 90th quantiles) [breaths per minute]; - Body movement; - Time in bed [hours]; - Presence detection; - Heart rate [beats per minute]; - Heart rate statistics (10th, 50th, 90th quantiles) [beats per minute]. <u>Major Components:</u> 1. Sleepis One+ Hardware unit: The Sleepiz One+ hardware unit uses radar technology that allows contactless detection of heart rate and respiration rate by sensing chest displacements originating from heartbeats and breathing activity of patients at rest or during sleep. The hardware unit can be used by a healthcare professional when the recordings are performed in a	Similar – DistaSense does not include as many features or outputs as the predicate devices. But the combination of a non-contact monitoring system with data transferred wirelessly to a cloud service for data to be accessed by a healthcare professional is the same between all devices. The DistaSense uses near-field antenna capacitance measurements instead of radar to collect data.
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510(k) Summary

	Smart Data Hub (SDH) securely transmits the body capacitance data to the Web Portal for processing into respiration rate (RR) and heart rate (HR). Data is transmitted safely via cellular signal to an AWS cloud service that is accessed via the Web Portal The Web Portal provides for user administration and patient management, as well as processing and display of patient data. The Web Portal displays the RR and HR data plot for each daily sleeping bout. The SDH signal quality and any status or data transmission faults are displayed on the Web Portal.	clinical setting, or by patient or their caregiver when the recordings are performed in home environment. The signals recorded by Sleepiz One+ hardware unit is then transferred via Wi-Fi to the cloud software where it is interpreted and displayed on the web application. 2. Sleepiz One+ Web Application: The Sleepiz One+ web application is intended to display the vital signs that have been interpreted from the derived signals by the Sleep Analytics Software on the secured Sleepiz Cloud software. The displayed data can then be accessed by a healthcare professional for retrospective analyses to remotely monitor the patient's physiological status. The intended users of the Sleepiz One+ web application are physicians and other healthcare professionals in a clinical setting. The web application allows the annotation of the data, compilation of results into reports, the management of Sleepiz One+ hardware units and to perform other administrative functions that do not involve vital signs. <u>Accessories:</u> Sleepiz hardware unit is supplied with the following components which are intended to be used in combination with it: - Power supply; -Tablet with pre-installed application to enable data transfer via Wi-Fi and display the connectivity status Support structure to allow easy positioning of the device.	
Intended Use	The intended use is to contactlessly measure patient heart rate and respiration rate.	The intended use is to contactlessly measure heart rate and respiration rate and detect patient motion.	Same

510(k) Summary

Intended User	Patients and healthcare professionals	Patients and healthcare professionals	Same
Site of Use	Clinical and home environment	Clinical and home environment	Same
Patient Population	Adults	Adults	Same
TECNOLOGICAL CHARACTERISTICS			
Data Collection Method	Near-field Antenna capacitance measurement	Continuous-wave radar	Primary difference between predicates and subject device.
Data Transfer Method	Wireless (Cellular)	Wireless (Wi-Fi, LTE via accessory tablet)	Similar; no impact to safety and effectiveness
Outputs	HR, RR	HR, RR, Presence Detection	Similar – DistaSense does not provide presence or motion detection
Heart Rate Measurement Range and Accuracy	40-150 beats/min ± 5 bpm	40-120 beats/min ± 5 bpm	Similar; no impact to safety and effectiveness
Respiratory Rate Measurement Range and Accuracy	4-35 breaths/min ± 3 bpm	5-40 breaths/min ± 3 bpm	Similar; no impact to safety and effectiveness

8. Performance Testing: 21 CFR 807.92(b)

Life Detection Technologies has performed robust verification and validation activities in order to support its substantial equivalence when compared to the primary predicate and the reference devices. This testing includes both non-clinical and clinical testing. The following sections outline the testing completed on the subject device in the order they appear in the eSTAR.

8.1 Non-Clinical Testing

8.1.1 Distribution Testing

The packaging of the DistaSense System was evaluated according to the distribution cycles and assurance level of ASTM D4169. All testing was passed and no deviations were reported.

8.1.2 Biocompatibility Testing

For the DistaSense System, there is no patient contact. As such, no biocompatibility testing was required for the subject device.

8.1.3 Software Testing

The software used in the DistaSense System has been developed in accordance with IEC 62304:2006/Amd 1:2015. To verify that all software requirements have been met, both static and dynamic testing have been completed. Integration testing, system-level testing, and performance testing were also completed. All testing was passed.

8.1.4 Cybersecurity Testing

For cybersecurity testing, Life Detection Technologies has completed all testing as required by the published FDA guidance titled “*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions.*” This testing includes security requirement verification and validation, threat mitigation, vulnerability testing, and penetration testing.

8.1.5 Electromagnetic Compatibility and Electrical Safety

Appropriate electromagnetic compatibility testing was completed to show that the performance of the device did not degrade in the presence of external phenomena, ensuring the real-world resilience of the device. EMC testing was done according to IEC 60601-1-2:2014+AMD1:2020 with performance during emissions testing evaluated per IEC 60601-4-2.

EMT safety testing was performed in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020, and IEC 60601-1-11:2015+AMD1:2020. All acceptance criteria were passed during and after testing, and no deviations were reported.

8.1.6 Bench Testing

Life Detection Technologies performed testing to show the durability of the bed sensor across the use-life of the DistaSense system. This testing was performed at both T=0 and after accelerated aging simulating one year of use. The sample size of this testing was n=4, and all acceptance criteria were met without any deviations.

Testing to demonstrate sensors do not drift with continuous and repeated use was also performed to support that measurements and outputs remain accurate.

8.2 Clinical Testing

Life Detection Technologies performed clinical testing to evaluate the performance of the DistaSense system compared to standard polysomnography-based respiratory effort belt and electrocardiography (ECG) recordings to assess the respiration rate and heart rate accuracy, respectively, in patients who were observed continuously overnight. The enrolled patient population was representative of the intended population (i.e., healthy subjects).

The respiratory rate accuracy was found to meet the prespecified passing criteria of ± 3 breaths per minute for both the overnight average dataset and the high frequency dataset, with 95% limits of agreement of -0.42 to 0.25, and -1.91 to 1.77 breaths per min, respectively, compared to manually scored respiratory rate from respiratory effort belt (n=26). The heart rate accuracy was found to meet the prespecified passing criteria of ± 5 beats per minutes for both the overnight average dataset and the high frequency dataset, with 95% limits of agreement of -0.48 to 0.18, and -3.83 to 3.37 beats per minute, respectively, compared to manually scored heart rate from ECG (n=26). The mean biases for the overnight average RR and the high frequency RR are -0.08 and -0.06 breaths per minute, respectively. The mean biases for the overnight average HR and the high frequency HR are 0.15 and -0.23 beats per minute, respectively. The Deming regression slope values for RR and HR are 1.008 and 1.002, respectively.

RR Validation Reference Device Gap Analysis

As the clinical performance testing was not performed with the accepted gold standard for RR validation (blinded, manually counted etCO₂ waveforms with an FDA-cleared capnogram) a gap analysis was performed that compared the gold standard to the reference device (RIP belt) over the entire claimed RR range. The 95% limits of agreement were -1.334 to 0.868 and 0.715 to 1.069. This data supports that for the claimed RR range in the intended population (exclusively healthy patients) that clinical testing with an alternative ground truth is scientifically sound and

can support RR functionality.

Device performance was also assessed by subgroups according to BMI, sex at birth, age, and race. The results of all subgroup analysis demonstrate reasonably distributed sample size within each subgroup, as well as consistent performance across all subgroups analyzed.

Thus, the performance of the DistaSense system supports substantial equivalence to the predicate device.

9. Conclusion 21 CFR 807.92(b)(3)

This 510(k) submission demonstrates that the DistaSense system is substantially equivalent to the predicate device.