July 9, 2026

LifeLens Technologies, Inc.
% Endri Angjeli
Regulatory Consultant
MEDIcept, Inc.
200 Homer Ave.
Ashland, Massachusetts 01721

Re: K260157
Trade/Device Name: LifeLens Physiological Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Electrocardiograph, ambulatory (without analysis)
Regulatory Class: Class II
Product Code: MWJ, DRG, DQA, BZQ, FLL,
Dated: June 6, 2026
Received: June 8, 2026

Dear Endri Angjeli:

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 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
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.	K260157

Please provide the device trade name(s).

LifeLens Physiological Monitor

Please provide your Indications for Use below.

The LifeLens Physiological Monitor is intended for spot-check monitoring and continuous data storage of physiological data in home and healthcare settings. Data could include ECG, oxygen saturation of arterial hemoglobin (Sp02), heart rate (HR), heart rate variability (HRV), skin temperature (TEMP), respiration rate (RR). Data are securely transmitted from the device for storage, review, analysis, and display. Data from the device are intended as an aid to diagnosis, disease management, and treatment. The device is intended for use on adults (18 years of age or older). The LifeLens Physiological Monitor also reports wellness data including activity level, body position, step count, and gait analysis.

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)

K260157 510(K) SUMMARY

510(k) Owner: LifeLens Technologies, Inc.
Address: 1 Ivybrook Blvd, Suite 100
Ivyland, PA 18974
Phone: (215) 622-4715

Contact Person: Matt Walenciak, VP of Quality & Project Management
Prepared by: Endri Angjeli, Regulatory Consultant

Prepared Date: January 16, 2025

Trade Name: LifeLens Physiological Monitor
Classification:

Common Name	Regulations Number	Product Code
Electrocardiograph, ambulatory (without analysis)	21 CFR 870.2800	MWJ
Radiofrequency physiological signal transmitter and receiver	21 CFR 870.2910	DRG
Oximeter	21 CFR 870.2700	DQA
Monitor, breathing frequency	21 CFR 868.2375	BZQ
Continuous measurement thermometer	21 CFR 880.2910	FLL

Predicate Devices:

Predicate 510(k) Number	Predicate Device Name	Device Type
Primary K203168	LifeLens Wireless ECG Monitor	DSH
Secondary K242018	UbiqVue 2A Multiparameter System (UX2550)	DRG, DQA, MHX, FLL

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Indications For Use:

The LifeLens Physiological Monitor is intended for spot-check monitoring and continuous data storage of physiological data in home and healthcare settings. Data could include ECG, oxygen saturation of arterial hemoglobin (SpO2), heart rate (HR), heart rate variability (HRV), skin temperature (TEMP), respiration rate (RR). Data are securely transmitted from the device for storage, review, analysis, and display. Data from the device are intended as an aid to diagnosis, disease management, and treatment. The device is intended for use on adults (18 years of age or older). The LifeLens Physiological Monitor also reports wellness data including activity level, body position, step count, and gait analysis.

Device Description:

The LifeLens Physiological Monitor is an ambulatory physiological monitoring system intended to measure oxygen saturation (SpO2), heart rate, respiration rate, electrocardiogram (ECG) data, skin temperature, and heart rate variability. In addition, the device also calculates and displays the following wellness metrics: Posture, Balance, Activity, and Steps.

The system consists of a disposable Patch, a reusable Hub, a reusable Recharger, and a Mobile Application.

The Skin Attachment Component, referred to as the SAC or Patch, is a single-use disposable, passive, hypoallergenic, thin, and breathable skin interface to which the Hub connects hermetically.

The Hub is a small, reusable, battery powered component including an electrical interface for coupling to the Patch, and hardware to record, store, and transmit physiological data from the subject during use. Additionally, the Hub includes microphones and tap detection circuitry to facilitate annotation (i.e., audio recordings) of symptoms by the user. The hub is a multi-patient use device.

The Recharger is a battery-powered, multi-purpose, reusable device for storing and charging two Hubs, interfacing with the Hub(s) during use, storing patient data, and allowing data offload after use. The recharger is a multi-patient use device.

The LifeLens mobile application connects to LifeLens Hub via Bluetooth to display device data output and status.

The device is not intended for automated analysis or active patient monitoring and is not intended to generate alarms or be used with alarm systems.

Substantial Equivalence:

	Subject Device LifeLens Physiological Monitor	**Primary Predicate K203168** LifeLens Wireless ECG Monitor	**Secondary Predicate K242018** UbiqVue 2A Multiparameter System (UX2550)	**Comparison to both Predicates**
Product Code	DSH, DRG, DQA, BZQ, FLL	DSH	DRG, MHX, FLL, DQA	Similar
Regulation Classification (Primary)	21 CFR 870.2800 Class II	21 CFR 870.2800 Class II	21 CFR 870.2910 Class II	Same
Indications For Use	The LifeLens Physiological Monitor is intended for spot-check monitoring and continuous data storage of physiological data in home and healthcare settings. Data could include ECG, oxygen saturation of arterial hemoglobin (SpO2), heart rate (HR), heart rate variability (HRV), skin temperature (TEMP), respiration rate (RRp) and wellness data (activity level, body position, step count, and gait analysis). Data are securely transmitted from the device for storage, review, analysis, and display. Data	LifeLens Wireless ECG Monitor is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light headedness, pre-syncope, syncope, fatigue, chest pain and/or anxiety. The LifeLens Wireless ECG Monitor is intended for use by patients 18 years or	The UbiqVueTM 2A Multiparameter System is a wireless remote patient monitoring system intended for use by healthcare professionals for continuous collection of physiological data at home and in healthcare settings. This shall include electrocardiography, heart rate, SpO2%, respiration rate, pulse rate, photoplethysmography waveform, skin temperature, body temperature, body posture, body motion, R-R Interval, heart rate variability (HRV) and Blood Pressure (optional). Data is transmitted wirelessly near real time from UbiqVue 2A Wearable	Similar

	Subject Device LifeLens Physiological Monitor	**Primary Predicate K203168** LifeLens Wireless ECG Monitor	**Secondary Predicate K242018** UbiqVue 2A Multiparameter System (UX2550)	**Comparison to both Predicates**
	from the device are intended as an aid to diagnosis, disease management, and treatment. The device is intended for use on adults (18 years of age or older).	older. The LifeLens Wireless ECG Monitor is not intended to be worn during defibrillation.	Biosensor and 3rd party device (for Blood Pressure only) to Remote Central server for display, storage, and analysis. The UbiqVueTM 2A Multiparameter System is intended for non-critical, adult population. The UbiqVueTM 2A Multiparameter System shall include the ability to notify healthcare professionals through alerts when Physiological parameters fall outside the set limits, manual trigger by patient and to display multiple patient's physiological data for remote monitoring at home and with visual alarm for active monitoring at hospitals and out of hospital patient care settings (such as clinics, outpatient surgery facilities, long-term care facilities and physician offices) in which care is administered by healthcare professionals.	
Intended Population	Non- Critical patient 18 years or older	Non- Critical patient 18 years or older	Non- Critical adult patient	Same

	Subject Device LifeLens Physiological Monitor	**Primary Predicate K203168** LifeLens Wireless ECG Monitor	**Secondary Predicate K242018** UbiqVue 2A Multiparameter System (UX2550)	**Comparison to both Predicates**
Intended Use Environment	Home and Healthcare setting	Home and Healthcare setting	Home and Healthcare setting	Same
Monitored Parameters				
ECG	1 lead	1 lead	N/A	Same
Heart Rate	Range: 30-220 bpm Accuracy: ± 3 bpm	N/A	30-250 bpm Accuracy: ± 3 bpm or 5% whichever is greater	Similar
Respiration Rate	Range: 4-60 rpm Accuracy: ± 3 rpm	N/A	Range: 5-60 rpm Accuracy: ≤ 3 rpm	Similar
Skin Temperature	Range: 24°C to 44°C Accuracy: ± 0.1°C	N/A	Range: 15°C to 43°C Accuracy: As per ASTM E1112-00	Similar
SpO2%	± 3.2 % (100 to 70%) Less than 70% unspecified	N/A	± 3 % (100 to 70%) Less than 70% unspecified	Similar

Summary of Technological Characteristics of Subject Devices Compared to Predicate Devices:

The subject device is a modified version of the primary predicate. The subject device incorporates additional physiological measurement capabilities. These additional measurement capabilities are similar to those of the secondary predicate. The subject device and both predicate devices have the same technological characteristics, including being battery powered, having dry-electrode electrocardiography (ECG), reflective photoplethysmography (PPG), and other comparable sensors. They are wireless, wearable devices with similar form factors, constructed with similar materials, which record and transmit physiological parameters. Any differences in features do not affect the safety or effectiveness of their intended use.

Non-Clinical Performance Testing:

Electrical Safety and electromagnetic compatibility (EMC)	EMC, Electrical, Mechanical, and Thermal Safety were verified in accordance with IEC 60601-1 (ed. 3.2), IEC 60601-1-2: 2020
Software Validation and Verification	Software verification and validation testing was conducted in accordance with FDA Guidance "Content of Premarket Submissions for Device Software Functions"
Multi-patient Use and Service Life testing	Multi-patient Use and Service Life testing was conducted in accordance with FDA Guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff"
Biocompatibility	The Patch, which is the skin-contact component, has been previously tested for cytotoxicity, irritation and skin sensitization, and has not changed from the predicate.
ECG	The ECG acquisition, has been previously tested in accordance with AAMI/ANSI/IEC 60601-2-47:2012 Medical Electrical Equipment – Part 2- 47: Particular Requirements for the Basic Safety and Essential Performance of Ambulatory Electrocardiographic Systems and has not changed from the predicate.
Cybersecurity	Cybersecurity testing and controls have been implemented in accordance with FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"
Human Factors	Human Factors verification was testing was conducted in accordance with FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices"
Heart Rate	Performance of heart rate measurements was verified in accordance to IEC 60601-2-47 Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
Skin Temperature	Performance of skin temperature measurement was verified with use of ASTM E111200(2018), Standard Specification for Electronic Thermometers for Intermittent Determination of Patient Temperature.

Non-clinical Performance Validation

Oxygen saturation performance was validated in a study using arterial blood draw reference measurements from 29 participants, spanning an SaO2 range of 70% to 100%. The study included data from participants of diverse sets of demographic and skin colors/tones. The primary endpoint was met at each placement location.

Heart Rate and Respiration Rate performance was validated through a study evaluating data from 94 participants compared to cleared reference devices. The study included data from participants from diverse sets of demographic and various reported medical history components, consistent with intended use population. The primary endpoints were met at each placement location.

This medical device product has functions subject to FDA premarket review as well as functions that are not subject to FDA premarket review. For this application, if the product has functions that are not subject to FDA premarket review, FDA assessed those functions only to the extent that they either could adversely impact the safety and effectiveness of the functions subject to FDA premarket review or they are included as a labeled positive impact that was considered in the assessment of the functions subject to FDA premarket review.

Conclusion:
Results of the testing show that the proposed subject device meets its intended use and support a determination that the proposed subject device does not raise new questions of safety or effectiveness as compared to the predicate devices. Therefore, the subject device is substantially equivalent to the predicate devices in terms of indications for use, design, technological characteristics, modes of operations, safety, and effectiveness.