July 20, 2021

LifeLens Technologies, Inc.
% Nicole Batista
Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K203168
Trade/Device Name: LifeLens Wireless ECG Monitor
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH
Dated: June 17, 2021
Received: June 17, 2021

Dear Nicole Batista:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Shih 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203168

Device Name
LifeLens Wireless ECG Monitor

Indications for Use *(Describe)*
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 older. The LifeLens Wireless ECG Monitor is not intended to be worn during defibrillation.

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

Device Trade Name: LifeLens Wireless ECG Monitor

Manufacturer:
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Date Prepared: June 17, 2021

Classifications: 21 CFR §870.2800

Class: II

Product Codes: DSH

Predicate Device: myPatch® sl

Table 1: Primary Predicate Devices

Manufacturer	Device Name	K Number
Dms-Service, LLC	myPatch®-sl	K163535

Indications for Use:

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 older. The LifeLens Wireless ECG Monitor is not intended to be worn during defibrillation.

Device Description:

The LifeLens Wireless ECG Monitor is an ambulatory electrocardiograph (ECG) monitor system intended to continuously capture a single channel electrocardiogram from a subject. The Monitor consists of three components, a) disposable skin adhesive component (SAC) (also referred to as the Patch), b) reusable Hub, and c) reusable Gateway (or Gateway Recharger Case).

The SAC is a single-use disposable, passive, hypoallergenic, thin, and breathable skin interface to which the Hub connects hermetically. It is placed vertically along the sternum of the subject during use.

The Hub is a small, reusable, battery powered component including an electrical interface for coupling to the SAC, and hardware to record, store, and transmit the electrocardiogram 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 Gateway Recharging Case is a battery-powered device for storing and charging two Hubs, interfacing with the Hub(s) during use, storing complete patient data, and allowing users to the data after use. The Gateway receives information wirelessly over the BLE communication channel from the Hub. The Gateway manages device use and coordinates any notifications to the user about hub power status, gateway power status, etc.

The system can interface wirelessly with a computer via Bluetooth LE to provide real-time data to assist in patient set-up by the Health Care Professional (HCP). The real-time data provides a means to confirm system function and signal quality. The system can also interface through the USB interface on the Gateway with a computer to offload ECG data for further archiving or analysis purposes. Only the ECG recording portion is part of this 510(k) application.

Performance Testing Summary:

The LifeLens Wireless ECG Monitor was designed and tested considering the Guidance for Industry and FDA Staff - Guidance for the content of premarket submissions for software contained in medical devices (May 11, 2005), and for compliance with the applicable clauses of the following standards:

- IEC 60601-1:2005/R(2012) and A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
- ANSI/AAMI/IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 4)

- 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.
- AAMI/ANSI/IEC 62366-1:2015 Medical device – part 1: Application of usability engineering to medical devices
- AAMI/ANSI/IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

The following non-clinical testing was performed on the LifeLens Wireless ECG Monitor system:

- Software verification and validation
- Performance verification and validation
- Biocompatibility Testing
    - Cytotoxicity
    - Irritation
    - Skin Sensitization
- Human Factors and Usability Testing
- Mechanical/Electrical Safety and Essential Performance Testing
- Wireless Co-Existence
- Electromagnetic Compatibility

The following clinical testing was performed on the LifeLens Wireless ECG Monitor system:

- Co-Monitoring Comparative study to reference ECG devices
  To assess signals recorded by the LifeLens Wireless ECG Monitor, a study was conducted on 15 subjects. ECG signals were captured and compared between the LifeLens Wireless ECG Monitor, the LifeLens Wireless ECG Monitor with off-the-shelf electrodes, and a reference 12-lead ECG recording device. Signals were compared analytically via Signal-Noise Ratio comparisons and found to be substantially equivalent. Cardiologists assessed the signals for signal quality, quantitative measurements, and rhythm interpretation and found significant correlation with no clinically relevant differences, supporting substantial equivalence.
- Wear and Comfort study
  To assess the long-term wear and comfort of the LifeLens Wireless ECG Monitor, a study was conducted on 18 subjects. The devices were applied to the subjects following the Instructions for Use and were worn for two days prior to removal. Subjects were questioned regarding the comfort of the device and any limitations

they experienced due to wearing the device. All subjects concluded that the device was comfortable and wearable. No issues with skin health or damage from the extended wear or removal of the device were noted. The acquired signals were analyzed by cardiologists, and all were deemed acceptable. The battery life, connectivity, and available memory of the LifeLens Wireless ECG Monitor were also analyzed and found to be acceptable.

In summary, testing of the LifeLens Wireless ECG Monitor indicated no new risks and demonstrated substantial equivalence in performance compared to the legally marketed predicate. The nonclinical testing supported the biocompatibility, performance, usability, mechanical/electrical safety, and wireless coexistence of the LifeLens Wireless ECG Monitor and the clinical testing supported the substantial equivalence of the acquired ECG signal and the wearability of the device.

Substantial Equivalence:

Comparative information presented in the 510(k) supports the substantial equivalence of the LifeLens Wireless ECG Monitor to the primary predicate device. Comparisons were designed to show the indications, intended use, design, and performance are equivalent between the subject device and primary predicate device.

Conclusion:

The information and performance data demonstrate that the device is as safe and as effective as the primary predicate device. This 510(k) submitted on behalf of the LifeLens Wireless ECG Monitor has shown to be substantially equivalent to legally marketed predicate based on indications for use, technological characteristics, performance testing, and comparison to predicate device.