November 15, 2023

LifeWatch Services, Inc
Stefanie Martinez-Koenig
Sr. Director Regulatory and Clinical Trials
10255 W Higgins Road
Suite 100
Rosemont, Illinois 60018

Re: K170565
Trade/Device Name: LifeWatch Mobile Cardiac Telemetry 3 Lead LifeWatch MCT 3L
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: QYX, DSI

Dear Stefanie Martinez-Koenig:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated August 1, 2017. Specifically, FDA is updating this SE Letter because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jennifer Kozen, OHT2: Office of Cardiovascular Devices, 301-796-5813, jennifer.kozen@fda.hhs.gov.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 1, 2017

LifeWatch Services, Inc.
Stefanie Martinez-Koenig
Sr. Director Regulatory and Clinical Trials
10255 W Higgins Road
Suite 100
Rosemont, Illinois 60018

Re: K170565
Trade/Device Name: LifeWatch Mobile Cardiac Telemetry 3 Lead LifeWatch MCT 3L (CG-6108 ACT-3L)
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including ST-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: DSI
Dated: June 30, 2017
Received: July 3, 2017

Dear Stefanie Martinez-Koenig:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170565

Device Name
LifeWatch Mobile Cardiac Telemetry 3 Lead LifeWatch MCT 3L (CG-6108 ACT-3L)

Indications for Use *(Describe)*
The MCT 3L (CG-6108 ACT-3L) Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alert triggered by an arrhythmia detection algorithm, or generates an alert manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

The MCT 3L (CG-6108 ACT-3L) Continuous ECG Monitor and Arrhythmia Detector is intended to be prescribed for patients who have demonstrated a need for cardiac monitoring and are at low risk of developing life-threatening arrhythmias. Conditions where the system should not be used include patients likely to experience primary Ventricular Fibrillation or Ventricular Tachycardia and patients who have other co-morbid cardiovascular conditions where an arrhythmia could be potentially life threatening.

The device has been validated for use on patients 6 years of age and older.

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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Department of Health and Human Services
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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This document contains the 510(k) summary for the LifeWatch Mobile Cardiac Telemetry 3 Lead Continuous ECG Monitor and Arrhythmia Detector. The content of this summary is based on the requirements of 21 CFR Section 807.92(c)

Submission Date: February 24, 2017

Submitter Information:

Submitted By: Stefanie Martinez-Koenig, Senior Director, Regulatory and Clinical Trials
10255 W Higgins Rd Suite 100
Rosemont, IL 60018
Email: SMartinezKoenig@LifeWatch.com

Contact Person: Robin Martin, Regulatory Consultant
10255 W Higgins Rd Suite 100
Rosemont, IL 60018
Email: CT-RMartin@LifeWatch.com

Device Information:

Trade Name: LifeWatch Mobile Cardiac Telemetry 3 Lead LifeWatch MCT 3L (CG-6108 ACT-3L)

Common Name: MCT 3L

Classification Name: Detector and Alarm, Arrhythmia
Transmitters and Receivers, Electrocardiograph, Telephone

Device Classification: 870.1025
870.2920

Predicate Device(s): K143359 CG-6108 ACT 3L Continuous ECG Monitor and Arrhythmia Detector
LifeWatch Technologies, Ltd. (DSI and DXH)

Device Description: The MCT 3L Continuous ECG Monitor and Arrhythmia Detector is designed for self-testing by patients at home and for analysis by medical professionals at a remote Monitoring Center.

The chest-worn sensor is used for the acquisition, recording, and transmission of the ECG signal. The device is equipped with 4 electrodes on a harness and it houses a 3.6V AA battery, a Bluetooth transceiver and a patient alert buzzer.
The ECG signals are transmitted via Bluetooth to a handheld device with a proprietary interactive application, configured to process and transmit the ECG recordings. The handheld device is a mobile computing device with a display and a touch input such as a cell phone. It has sufficient memory and processing capability to run the proprietary application.
When an arrhythmia event is detected, the handheld device transmits the recorded ECG information automatically via cellular link, to the Monitoring Center for professional analysis. When cellular service is unavailable the patient has an option to transmit via a landline telephone.

The MCT 3L does contain software. The device is not supplied sterile or intended to be sterilized by the operator prior to use, and is not intended for single use.

Indications for Use:

The MCT 3L (CG-6108 ACT-3L) Continuous ECG Monitorand Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alert triggered by an arrhythmia detection algorithm, or generates an alert manually triggered by the patient, and transmits the recorded data transtelephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

The MCT 3L (CG-6108 ACT-3L) Continuous ECG Monitor and Arrhythmia Detector is intended to be prescribed for patients who have demonstrated a need for cardiac monitoring and are at low risk of developing life-threatening arrhythmias. Conditions where the system should not be used include patients likely to experience primary Ventricular Fibrillation or Ventricular Tachycardia and patients who have other co-morbid cardiovascular conditions where an arrhythmia could be potentially life threatening.
The device has been validated for use on patients 6 years of age and older.

Comparison to Predicate: The Indications for Use for the proposed MCT 3L device are identical to those of the predicate device with the exception that use for pediatrics age 6 and older is not excluded in the MCT 3L labeling. Bench testing of the proposed MCT 3L was conducted to demonstrate substantial equivalence to the predicate device. Insignificant historical changes are listed within the device description. No changes have been made to the user interface, device algorithms, or applications software compared to the predicate device.

The proposed device has the same intended use and employs the same fundamental scientific technology.

Performance Testing:

Non-Clinical: The design and development of the MCT 3L device conforms to LifeWatch Service's Quality System. Because the subject of this premarket notification is a labeling change, and certain predicate standards test reports remain applicable to the device, testing to only the following voluntary standards are submitted to support substantial equivalence to the predicate device:

- IEC 62366-1:2015, including human factors validation testing related to the use of the device in the pediatric patient population (age 6 to 21) with adult caregivers, where appropriate.
- ISO 14971:2012, including evaluation of use-related risks
- ANSI/AAMI/IEC 60601-1-2 Edition 4:2014-02, Electromagnetic Compatibility
- Wireless Coexistence Testing in accordance with FDA's guidance entitled, "Radio Frequency Wireless Technology in Medical Devices", dated August 14, 2013

Clinical: No clinical data was necessary to support substantial equivalence of the proposed device compared to the predicate.

Conclusion: The above testing supports that the proposed device is as safe, effective and performs as well as the legally marketed predicate in its intended use. Therefore, the proposed device is substantially equivalent to the predicate.