**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

September 11, 2015

LifeWatch Technologies Ltd.
Stephen Slavens
Head of RA and QA
10255 W Higgins Road, Suite 100
Chicago, Illinois 60018

Re: K143359
Trade/Device Name: Cg-6108 Act-3l Continuous ECG Monitor and Arrhythmia Detector
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, DXH
Dated: August 23, 2015
Received: August 25, 2015

Dear Stephen Slavens,

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.

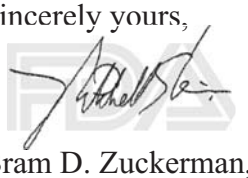
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 yours,



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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K143359

Device Name
CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector

Indications for Use *(Describe)*
The 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 trans-telephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.
The 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.
This device has not been tested for and it is not intended for pediatric use.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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*"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."*

# Section 005: 510(k) Summary

# 510(k) Summary: CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector with SW Version 6.

## Introduction

This document contains the 510(k) summary for the CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector with Software (SW) Ver. 6.1.17. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

## I. Submitter

| | | |
|---|---|---|
| **Submitter** | LifeWatch Technologies Ltd. | |
| **Establishment Registration Number** | 9681879 | |
| **Address** | 2 Pekeris St., P.O.B. 527, Rehovot, 7610303, Israel | |
| **Submitter:** | Asher Kassel, Director of RA & QA, LifeWatch Technologies Ltd. | |
| **Phone:** | 972-8-9484010 (direct) | Fax: 972-8-9484044 |
| **E-mail:** | akassel@lifewatch.com | |
| **Application Correspondent** | Stephen Slavens, Acting Head of Corporate RA & QA, LifeWatch | |
| **Phone:** | (847) 8134-625 | Fax: (847)720-2111 |
| **E-mail** | CT-SSlavens@lifewatch.com | |
| **Date Prepared:** | Nov 20, 2014 | |

## II. Device

| | |
|---|---|
| **Trade Name:** | CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector |
| **Classification:** | Detector and alarm, arrhythmia<br>Transmitters and receivers, electrocardiograph, telephone |
| **Product Code:** | DSI,<br>DXH |
| **Regulation No:** | 870.1025<br>870.2920 |
| **Class:** | II |

## III. Predicate Device

| | |
|---|---|
| **Predicate device** | K110499 cleared on 6th April 2011<br>CG-6108 ACT-3L Continuous ECG Monitor and Arrhythmia Detector |

## IV. Device Description

The CG-6108 ACT-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 modification that led to this submission was the change from a mobile platform with a Windows-based OS to one with an Android-based OS.

## V. Indications for Use

The 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 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 not been tested for and it is not intended for pediatric use.

## VI. Summary of the Technological Characteristics / Principles of Operation

The technological characteristics and principles of operation of the ACT device with SW Ver. 6.1.17 are the same as the predicate device. The chest-worn ECG sensor transmits signals via Bluetooth to the handheld device equipped with the Medical Application, which incorporates an algorithm for detection of cardiac events: Atrial Fibrillation, Tachycardia, Bradycardia and Pause.
A detected artifact triggers transmission of the signal to the Monitoring Center for analysis.

## VII. Performance data – Non Clinical for the CG-6108 ACT-3L with SW Ver. 6.1.17

In order to support the new SW Version, the following testing has been performed and passed:

- Wireless co-existence testing of the ACT-3L system, LifeWatch Technologies, VATR-0163
- SW Validation Test Report, LifeWatch Technologies, STR-0112-61170
- Testing of the ACT-3L algorithm, LifeWatch Technologies, VATR-0164

## Performance data - Standards:

This submission was written according to and in conformance with FDA Guidance “Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003.” This submission was also prepared per “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005”.

The design of the CG-6108 ACT-3L conforms to the following voluntary standards:

i. IEC 60601-1:2005 3rd edition / Cor. 1:2006, Cor. 2:2007, Medical electrical equipment – General requirements for safety
ii. ISO 14971:2007, Medical devices - Application of risk management to medical devices
iii. IEC 62304:2006, Medical Device Software – Software Lifecycle Processes
iv. ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
v. ANSI/AAMI EC57:2012: Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms
vi. IEC 60601-1-2: 2014 Ed. 4, Part 1: Medical electrical equipment, Part 1-2; Electromagnetic compatibility - Requirements and tests
vii. IEC 60601-1-8:2012, General Requirements for basic safety and essential performance – Collateral standard: General Requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

**Performance data - Clinical**

The FDA Guidance document "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003" states the Agency will rely on well-designed bench and/or animal testing rather than requiring clinical studies so long as the studies do not have dissimilar designs, new technology, or dissimilar indications for use. The modifications in this submission do not make changes that require clinical studies.

**VIII. PeConclusion of Substantial Equivalence:**

The CG-6108 ACT-3L device with SW Ver. 6.1.17 is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate device.