



Food and Drug Administration  
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January 15, 2016

Lifewatch Technologies Ltd.  
% Donna-Bea Tillman  
Senior Consultant  
Biologics Consulting Group, Inc.  
400 N. Washington St. Suite 100  
Alexandria, Virginia 22314

Re: K151269

Trade/Device Name: ECG Mini System 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: December 10, 2015

Received: December 14, 2015

Dear Donna-Bea Tillman:

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,

**Kenneth J. Cavanaugh -S**

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known)

N/A K151269

Device Name

ECG Mini System Continuous ECG Monitor and Arrhythmia Detector

Indications for Use (Describe)

The ECG Mini System 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 alarm triggered by an arrhythmia detection algorithm, or generates an alarm 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 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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## 510(k) Summary

### Introduction

This document contains the 510(k) summary for the ECG Mini System Continuous ECG Monitor and Arrhythmia Detector. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

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<b>Prepared By:</b>	Donna-Bea Tillman, Ph.D. Senior Consultant Biologics Consulting Group, Inc. 400 N. Washington St. Suite 100 Alexandria, VA 22314 dtillman@bcg-usa.com Phone: 410-531-6542 Fax: 703-548-7457
<b>Predicate device</b>	CG 6108-ACT1Lead system (K101639)
<b>Trade Name:</b>	ECG Mini System Continuous ECG Monitor and Arrhythmia Detector
<b>Classification:</b>	Detector and Alarm, Arrhythmia / Telephone Electrocardiograph Transmitters and Receivers
<b>Product Code:</b>	DSI / DXH
<b>Regulation No:</b>	870.1025 / 870.2920
<b>Class:</b>	II

### Device Description

The ECG Mini System Continuous ECG Monitor and Arrhythmia Detector (“ECG Mini”) is a system that records ECG data and detects defined arrhythmias. It is comprised of a disposable 1-lead ECG Patch which includes a processing/transmitting module called a “Brain”, and a cellular device (also called “Gateway”). The ECG Patch has 3 electrodes which are used to obtain a 1-lead ECG that is used for arrhythmia detection. The ECG Patch is placed on the upper left side of the chest according to the instructions and guidance in the Patient User Guide (UG-00105).

The ECG Mini system consists of following three components:

- Patch: Disposable 1-lead Patch with ECG electrodes
- Brain: Reusable processing and transmitter device
- Gateway Cellular Device: Communicates data to the Monitoring Center



### Indications for Use

The ECG Mini System 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 alarm triggered by an arrhythmia detection algorithm, or generates an alarm 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 device has not been tested for and it is not intended for pediatric use.

### Sterilization and Shelf Life

The ECG Mini is not provided sterile and is non-sterile when used.

The ECG Mini has been tested for accelerated aging and real time shelf life. The shelf life of the ECG Mini is 6 months from the date of manufacture.

### Biocompatibility

The ECG Mini System patch is intended for single patient use only, for about 5-7 days, after which it can be replaced by a new ECG Mini System patch. According to the classification of "duration category" in Table 1 in ISO 10993-1, the ECG Mini System patch is classified as a surface device, in contact with the skin for a prolonged exposure (B), i.e. a device whose single, multiple or long-term use or contact is likely to exceed 24 hours but not 30 days.

The patient contacting materials of the ECG Mini patch have been tested for cytotoxicity, sensitization and skin irritation per the following standards:

- Cytotoxicity ISO 10993-5
- Sensitization ISO 10993-10
- Irritation ISO 10993-10

### Software

Similar to the predicate device, the software level of concern for the ECG Mini is MAJOR.

This determination was reached by a careful review of the FDA guidance "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff" (5/11/2005).

### Electromagnetic Compatibility and Electrical Safety

The following Electrical Safety and EMC Testing was performed on the ECG Mini:

- IEC 60601-1:2005, 3rd edition, plus CORR. 1 (2006) + CORR. 2 (2007) - Medical electrical equipment – General requirements for safety
- IEC 60601-1-2:2014, General requirements for safety, Collateral Standard - Medical electrical equipment, Part 1-2; Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-11 Edition 1.0 2010-04, 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
- CFR 47 FCC: Rules and Regulations; Part 15. "Radio frequency devices"; Subpart C: "Intentional radiators" (2015). Section 15.209. "Radiated emission limits, general requirements". "Radiated Emission Limits, Additional Provisions"; Section 15.249. "Operation within the bands 902 – 928 MHz, 2400 –2483.5 MHz, 5725 – 5875 MHz and 24.0 - 24.25 GHz"



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## Performance Testing

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The following performance testing was conducted on the ECG Mini:

- ECG Performance - The ECG Mini has been tested and was shown to comply with the requirements of ANSI/AAMI/IEC 60601-2-47: 2012 (60601-2-47 in short); Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems.
- Arrhythmia Detection - The algorithm used by the ECG Mini for arrhythmia detection has been tested in accordance with the requirements of the FDA recognized standard ANSI/AAMI EC57: 2012 - Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms.
- Human Factors - LifeWatch conducted a Usability Validation Study of the ECG Mini in accordance with Section 5.9 of IEC 62366:2007. This study focused on the ability of a test population that meets the device's indicated user population to initiate the use of the device and to understand the user feedback signals while using the device. The study simulated Lifewatch's existing user support model, which is to provide instructions in the form of a Quick Start Guide and a User Guide, coupled with a Monitoring call center, which the user must contact in order to start signal collection and monitoring.
- ECG Electrode - In accordance with FDA's Guidance Document for ECG Electrodes, the ECG electrode assembly of the ECG Mini was tested in accordance with PART 4.2.2 (Electrical performance) of ANSI/AAMI EC12:2000/(R)2010: Disposable ECG electrodes.
- Alarms - Lifewatch has conducted an assessment demonstrating that the ECG Mini complies with the applicable requirements of IEC 60601-1-8, ed. 2.1:2012: 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.
- ICD Use - LifeWatch had conducted testing to demonstrate that the ECG Mini is compatible with Implantable Cardioverter Defibrillators (ICDs).
- Wireless Co-Existence - Lifewatch has assessed the ECG Mini for Wireless Coexistence in accordance with the FDA guidance document Radio Frequency Wireless Technology in Medical Devices (August 14, 2013).

## Performance Standards and Guidance Documents

This 510(k) submission was written in accordance with the following FDA Guidance documents:

- Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005
- Class II Special Controls Guidance Document: Electrocardiograph Electrodes, July 21, 2011

The design of the ECG Mini System Continuous ECG Monitor and Arrhythmia Detector conforms to the following voluntary standards:

- IEC 60601 1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012, Medical electrical equipment – General requirements for safety

- IEC 60601-1-2 Edition 4: 2014, Part 1: Medical electrical equipment, Part 1-2; Electromagnetic compatibility - Requirements and tests
- IEC 60601-1-11 Edition 1.0 2010-04, 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
- IEC 60601-1-8 Edition 2.1 2012-11 Medical electrical equipment – Part 1-8: 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
- AAMI/ANSI/ISO 60601-2-47:2012, Medical electrical equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices
- IEC 62304 First edition 2006-05, Medical Device Software – Software Lifecycle Processes
- ANSI/AAMI/ISO EC57:2012, Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
- AAMI ANSI EC12:2000/(R)2010 Disposable ECG electrodes
- ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.

### Substantial Equivalence Discussion

The predicate device is the CG 6108-ACT1Lead system (ACT or CG 6108 in short) cleared in K101639 on June 25, 2010, as an arrhythmia detector and alarm system.

The only difference in the Indications for use is that the subject ECG Mini explicitly states that it is not intended for pediatric use. The difference does not raise any issues of safety or effectiveness.

The subject device and the predicate device are both intended to be used by patients who experience transient symptoms that may suggest cardiac arrhythmia. Both devices continuously monitor patient ECG, and either automatically generate an event triggered by an arrhythmia detection algorithm or generates an event manually triggered by the patient. Both devices transmit the event and the recorded data over a cellular network to a monitoring center, where the data is provided to a medical practitioner for evaluation. The device therefore have the same intended use.

The subject device and the predicate device both use three electrodes to obtain a 1-lead ECG that is stored on a smartphone for transmission to a remote monitoring system. Both devices include an arrhythmia detection algorithm that is capable of detecting the following types of arrhythmias:

- Pause
- Tachycardia
- Bradycardia
- Atrial Fibrillation

Both devices also allow the user to manually trigger an event.

The two significant differences between the subject ECG Mini and the predicate ACT1 system are the design of the electrode component and the mobile platform used as the Gateway device.

The differences between the CG 6108-ACT1Lead (K101639) and the subject device are minimal and pose no new questions to safety and effectiveness. The Indications for Use, and system



components (monitoring device, data transmission device and Monitoring Center) of both devices are substantially equivalent.

**Substantial Equivalence Conclusion**

The ECG Mini System Continuous ECG Monitor and Arrhythmia Detector is substantially equivalent with respect to the indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate device.