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

February 5, 2016

LifeWatch Technologies Ltd.
Mr. Asher Kassel
Director of RA & QA
2 Pekeris St.
Rehovot, 7670202 Israel

Re: K151835
Trade/Device Name: Vital Signs Patch System
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, MHX, DQA, FLL
Dated: January 5, 2016
Received: January 6, 2016

Dear Mr. Asher Kassel:

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.

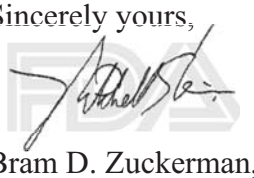
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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)*
K151835

Device Name
Vital Signs Patch System (VSP)

Indications for Use *(Describe)*
The Vital Signs Patch (VSP) system is intended to be used on patients in a clinical environment for the continuous, non-invasive monitoring of ECG, Heart Rate (HR), respiration rate, surface temperature, and arterial blood oxygen saturation (intended use group adults 21 and above), when prescribed by a physician or other qualified healthcare professional.
Contraindications:
• The VSP is not intended for use by persons with any type of defibrillator, external or internal (ICD); the VSP must be detached from the patient before using a defibrillator on the patient
• The VSP is not to be used in a magnetic resonance imaging (MRI) environment. The VSP device must be removed from the patient's skin before he/she undergoes MRI procedure
• The VSP is not a "life-saving" or therapeutic device; the VSP supplies vital signs data to a doctor or technician for the purpose of diagnosis by such (or other qualified) personnel
• The VSP is not intended for use on patients with unhealed surgical incision/dressings on the thoracic or abdominal regions
• The VSP is not intended for use on patients with skin or soft tissue damage on the area where the VSP is placed (such as burns, irritation, infections, wounds, etc.)
• The VSP is not intended for use in the diagnosis of myocardial infarction or for chest pain monitoring.
Warning: The temperature function of the Vital Signs Patch measures and reports surface temperature on the upper chest. Where direct measurements of body core temperature are required, it is recommended to utilize appropriate core temperature monitoring devices for this purpose.

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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K151835

510(k) Summary: Vital Signs Patch

Introduction

This document contains the 510(k) summary for the revised Vital Signs Patch system. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Submitter	LifeWatch Technologies Ltd.
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Date Prepared:	July 1, 2015
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Predicate device	Vital Signs Patch (K132407)
Trade Name:	Vital Signs Patch System
Classification:	Class II
Product Codes:	DSI – Arrhythmia Detector and Alarm MHX – Physiological Patient Monitor DQA – Oximeter FLL –Clinical Electronic Thermometer
Regulations:	21 CFR 870.1025 - Arrhythmia Detector and Alarm 21 CFR 870.2700 – Oximeter 21 CFR 880.2910 - Clinical Electronic Thermometer
Panel:	Cardiovascular

Device Description

The Vital Signs Patch (VSP in short) system is designed to monitor selected vital signs of patients in a clinical environment.

The VSP system is comprised of the following components:

- Physical Patch
- Brain - VSP Transmitter
- Gateway mobile device
- Clinical Backend

The Patch is attached to the patient's chest. The Brain plugs into a cradle on the Patch and is connected to the Patch with a 16-pin connector. The Brain receives the power from the Patch's battery; the data from the sensors are transmitted using the 16-pin connector. The Gateway includes a dedicated, medical SW application (also known as the Gateway application) designed by LifeWatch Technologies. The Brain transmits data to the Gateway application using the RF component. The patient can manually trigger an event by the pressing a button on the Brain.

In addition, the Brain contains a 32MB Flash memory chip that can store 6-10 hours of data in case of communication failure with the Gateway.

All data received from the Brain is recorded and stored on the Gateway. In addition, the Gateway can be used to view vital sign signals received from the Brain and to transmit the data to a Monitoring Center via the internet by the Wi-Fi network.

The VSP is not intended for use on patients with life threatening arrhythmias; hence it is not intended for patients in the ICU.

The internal LifeWatch Technologies Ltd. Part Number of the Vital Signs Patch system is CG-1101B; this model serves also as the predicate device (cleared in K132407) for this Special submission.

Device Modifications

The purpose of this Special 510(k) is a modification of the submitter's own previously cleared 510(k). The modification does not change the fundamental scientific technology or the intended use and is therefore appropriate for review as a Special 510(k).

There are two modifications being made to the VSP that are the subject of this 510(k):

1. The VSP can now interface with a Clinical Console Tablet.
2. A Patient Posture Sensor has been added.

Indications for Use

The Vital Signs Patch system is intended to be used on patients in a clinical environment for the continuous, non-invasive monitoring of ECG, Heart Rate (HR), respiration rate, surface temperature, and arterial blood oxygen saturation (intended use group adults 21 and above), when prescribed by a physician or other qualified healthcare professional.

Contraindications:

- The VSP is not intended for use by persons with any type of defibrillator, external or internal (ICD); the VSP must be detached from the patient before using a defibrillator on the patient
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Warning: The temperature function of the Vital Signs Patch measures and reports surface temperature on the upper chest. Where direct measurements of body core temperature are required, it is recommended to utilize appropriate core temperature monitoring devices for this purpose.

Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm, October 28, 2003" and the device conforms to the applicable performance requirements contained in and referenced in this document.

Performance Testing:

A risk analysis was performed by assigning a Risk Priority Number (RPN) to each defined hazard, based on the Frequency of Occurrence (F) and the Degree of Severity (S). The result of that analysis showed that after mitigation and characterization of each remaining risk's severity, frequency and detectability, all remaining risk was ALARP (As Low as Reasonably Possible) or BA (Broadly Acceptable).

As required by the risk analysis and in accordance with design control procedures, design verification and validation testing of the modified device have been performed. The 510(k) summarizes the testing that was performed, the acceptance criteria and the results of the testing.

Substantial Equivalence:

The minor device modifications to the VSP System, as described in this 510(k), do not alter the fundamental scientific technology of the predicate device and summary level information is adequate to assess the modifications. The verification testing demonstrated that the device continues to meet its performance specifications and the results of the testing did not raise new issues of safety or effectiveness. Therefore the modified VSP System can be found substantially equivalent to the predicate device as cleared in K132407.