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

December 19, 2014

Lifewatch Technologies Ltd.
Asher Kassel
Director of RA and QA
2 Pekeris Street
Rehovot, 7670202, Israel

Re: K132407
Trade/Device Name: Vital Signs Patch System (VSP)
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: December 10, 2014
Received: December 11, 2014

Dear 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,

Melissa A. Torres -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): K132407

Device Name: Vital Signs Patch

Indications for Use

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.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use _____**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary: Vital Signs Patch system

Introduction

This document contains the 510(k) summary for the Vital Signs Patch system, Part Number CG-1101B. The content of this summary is based on the requirements of 21 CFR Section 807.92(c).

Submitter	LifeWatch Technologies Ltd.	
Establishment Registration Number	9681879	
Address	2 Pekeris St., P.O.B. 527, Rehovot, 7610303, Israel	
Contact person:	Asher Kassel, Director of RA & QA, LifeWatch Technologies Ltd.	
Phone:	972-8-9484010 (direct)	Fax: 972-8-9484044
E-mail:	asherk@lifewatch.com	
Date Prepared:	June 14, 2014	
Primary predicate device	PROPAQ LT Vital Signs Monitor, manufactured by Welch Allyn Protocol, Inc. and cleared in K033378 on March 1st, 2004.	
Secondary predicate device	VS200 Aingeal Physiological Patient Monitor manufactured by Intelesens Ltd.; cleared in K110015 on May 20, 2011.	
SP02 predicate device	MD300W4 Beijing Wrist Pulse Oximeter Choice Electronic Technology Co., Ltd. cleared in **K122046**	
Trade Name:	Vital Signs Patch system	
Regulation No:	21 CFR 870.1025; 870.2700 and 880.2910	
Classification:	Class II	
Product Codes:	DSI; MHX; DQA; FLL	

1.1. Device Description and Summary of the Technological Characteristics / Principles of Operation

The Vital Signs Patch (**VSP**) system is designed to monitor vital signs of patients. The internal LifeWatch Technologies Ltd. (**LWT** in short) Part Number of the VSP is CG-1101B. The VSP system consists of the following components:

Vital Signs Patch

A **Vital Signs Patch (VSP Patch)** – A Polyethylene substrate coated with biocompatible adhesive with an ECG sensor with four electrodes (3 leads), a temperature sensor, a blood oxygen saturation sensor, a respiration rate sensor (utilizes the ECG electrodes for impedance measurement), a 3.0V Li-MnO2 battery to activate the Brain and a cradle to hold the Brain.

VSP transmitter ("Brain")

The VSP transmitter (also called "Brain") is the main Processing & Transmitting Unit of the VSP device**;** the Brain has a 16-pin connector that is plugged into the cradle of the Patch. Once the Brain is inserted into the cradle of the Patch, it receives power from the battery installed in the Patch and starts to operate. The Brain

acquires all signals coming from the sensors embedded in the Patch.

The Brain integrates a low power RF component (*Nordic)* for short-range communication with the Gateway. The Brain is also equipped with Red and Green LED's and a buzzer to visually and audibly indicate system status.

Gateway

The Gateway is a dedicated SW application designed by LifeWatch Technologies (LWT) that runs on a LifeWatch Technologies approved mobile device running Android OS v 2.3.5 or above, and equipped with Nordic nRF24L series 2.4 GHz RF communication chip. The Gateway includes a user interface for alarms (such as low arterial oxygen saturation) and monitoring. Communication with the Clinical Backend is performed using wireless (3G cellular or Wi-Fi) technology.

Clinical Backend

The VSP **Clinical Backend (**VSP CBE or CBE) receives vital signs data from the VSP Gateway, processes them and presents the data on a Clinical console.
The VSP system is capable of processing and storing patient vital signs in a centralized database; the length of the recording is limited by the available storage capacity.

1.2. Indications for Use

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

1.3. Contraindications

Contraindications for Use:

- 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.

1.4. Clinical and non-clinical performance data for the Vital Signs Patch system

The Vital Signs Patch system has been subjected to extensive verification / validation testing. Final testing of the system included various performance tests and software validation tests designed to ensure that the device meets all of its functional and performance requirements and is fit for its intended use. The following list summarizes the testing performed on the device:

- Software Verification and Validation
  - Software Functional Unit Verification
  - System Level Software Validation
  - Arrhythmia Detection Algorithm Performance Validation
- Hardware Verification
- Clinical trial of the SPO2 function
- Electrical Safety, EMC, SPO2 and FCC testing by an independent, certified, external test laboratory.

1.5. Voluntary Performance Standards:

This 510(k) submission was written in accordance with the FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11 2005". The design of the Vital Signs Patch system conforms to the following voluntary standards:

1. ANSI/AAMI/ISO EC57:1998 (R) 2008: Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms (FDA Recognition Number: 3-73)
2. ANSI/AAMI EC38:2007: Ambulatory Electrocardiograph (FDA Recognition Number:
   3-65)
3. ISO 14971:2007: Medical devices – application of risk management to medical devices (FDA Recognition Number: 5-40**)**
4. IEC 60601-1:2005, 3rd edition: Medical electrical equipment; Part 1: General requirements for safety (FDA Recognition Number: 5-4)
5. ISO 10993-1:2009: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (FDA Recognition Number: 2-179)
6. IEC 60601-1-2:2007, Medical electrical equipment; Part 1: 2. Collateral Std.: EMC; requirements and tests (FDA Recognition Number: 5-53)
7. ISO 80601-2-61:2011: Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (FDA Recognition Number: 1-85**)**

8. ISO 80601-2-56:2009, Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature (FDA Recognition Number: 6-232)
9. IEC 62304:2006, Medical Device Software – Software Lifecycle Processes (FDA Recognition Number: 13-8)

Substantial Equivalence:

The Vital Signs Patch system is substantially equivalent with respect to indications for use, technological characteristics and performance characteristics to the identified legally marketed predicate devices.