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 17, 2015

Healthwatch Ltd.
% Yoram Levy
Qsite General Manager
31 Haavoda Street
Binyamina, 30500 IL

Re: K142476
Trade/Device Name: Master Caution Device (MCD)
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II
Product Code: DXH
Dated: December 31, 2014
Received: January 7, 2015

Dear Yoram Levy,

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

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)*
K142476

Device Name
Master Caution Device (MCD™)

Indications for Use *(Describe)*
Master Caution Device (MCD) is intended to condition an electrocardiographic signal, so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location. The Master Caution Device (MCD) is designed to be used by a patient to transmit a 12 lead ECG, posture and motion , respiration and skin temperature (IR) signals, in near real-time to enable review at a physician's office, hospital or other remote medical receiving center. Master Caution Device (MCD) target population is adults above the age of 21.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Food and Drug Administration
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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."

510(K) SUMMARY

HealthWatch Master Caution Device (MCD™)

510(k) Number K142476

Applicant's Name: HealthWatch Ltd.
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Contact Person: Yoram Levy, Qsite
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Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: ***Master Caution Device MCD™***

Summary Preparation Date: February 09, 2015

Classification:
Name: Telephone electrocardiograph transmitter and receiver
Product Code: DXH
Regulation No: 21 CFR 870.2920
Class: II
Classification Panel: Cardiovascular

Device Description:

The ***HealthWatch Master Caution Device*** (MCD) is a personal, hand-held battery powered, ECG device that can be connected to any approved and market cleared, ten standard ECG electrodes, configuring a 12-lead ECG device.

The MCD is a miniature ECG device with an embedded processor containing data acquisition, data storage, data processing accelerometers, respiration, skin temperature (IR) and BT (Bluetooth) capabilities. The ***HealthWatch Master Caution Device*** (MCD) acquires ECG data via the connected electrodes. The ***HealthWatch Master Caution Device*** (MCD) transmits the data in

near real time to a suitable Bluetooth communication device for forwarding to a remote location for professional review.

A communication device is defined as any device that is capable of receiving the ECG data via Bluetooth and forwarding it via WIFI or cellular network (3G/4G). Communication devices can be cell-phones, computers or other dedicated communication modems.

Intended Use Statement:

Master Caution Device (MCD) is intended to condition an electrocardiographic signal, so that it can be transmitted digitally via Bluetooth technology and cell-phone or communication device to a remote location. The Master Caution Device (MCD) is designed to be used by a patient to transmit a 12 lead ECG, posture and motion , respiration and skin temperature (IR) signals, in near real-time to enable review at a physician's office, hospital or other remote medical receiving center. Master Caution Device (MCD) target population is adults above the age of 21.

Predicate Device:

Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
SHL Smartheart	K113514	February 22, 2012
MotionWatch and Pro-Diary	K132764	January 21, 2014
Avivo Mobile Patient Management System	K083287	February 3, 2009
Hospira vital Signs wireless monitoring system	K090610	December 22, 2009

Substantial Equivalence to Predicate Device

The ***HealthWatch Master Caution Device*** (MCD) utilizes the same transmission method using Bluetooth module and communication device, as its predicate devices.

Any minor differences in the human interface and features do not raise any new questions of safety and effectiveness issues, as verified by performance testing.

Results of tests and validations, performed with the proposed ***HealthWatch Master Caution Device*** (MCD) demonstrates that substantial equivalence has been determined, without raising any new safety and/or effectiveness concerns.

Therefore, the ***HealthWatch Master Caution Device*** (MCD) is substantially equivalent to its predicate device.

Follows is a comparison of the technology features:

Feature	HealthWatch Master Caution Device	SHL Smartheart (K113514)	AVIVO Mobile patient management system (K083287)	Hospira vital Signs wireless monitoring system (K090610)	MotionWatch (K132764)
Physiological parameters transfer	Bluetooth	Bluetooth	Bluetooth	Bluetooth	Bluetooth
Bluetooth class	Class II	Class II	Class II	Class II	Class II
ECG measures	Yes	Yes	Yes	Yes	N/A
Acceleration sensor	Yes	N/A	Yes	N/A	Yes
Respiration sensor	Yes	N/A	Yes	N/A	N/A
Skin temperature sensor	Yes	N/A	Yes	N/A	N/A

Performance Standards:

The ***Healthwatch Master Caution Device (MCD™)*** device complies with the following standards:

- ***IEC 60601-1*** Medical Electrical Equipment-Part 1: General Requirements for Safety. Collateral Standard: Safety Requirements for Medical Electrical Systems.

- ***IEC 60601-1-2*** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.

- ***IEC 60601-2-25*** Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

- ***ISO 62304*** Medical device software- Software life cycle processes

- ***ISO 14971*** Medical Devices- Application of risk management to medical devices

- ***ISO 15223-1*** Medical Devices- Symbols to be used with medical device labels, labeling and information to be supplied- Part 1.

- ***ASTM D4169*** Standard Practice for Performance Testing of Shipping Containers and Systems

Performance Bench Tests

Bench testing demonstrated that the ***HealthWatch Master Caution Device (MCD™)*** is as safe and effective as the cleared predicate device.

Summary of Pre-Clinical and clinical study

The ***HealthWatch Master Caution Device (MCD™)*** implies the exact same intended use, clinical indication and technology as its predicate device. The substantial equivalence o fthe ***HealthWatch Master Caution Device (MCD™)*** is shown by the predicate devices using the same parameters. Due to the comprehensive clinical studies already performed by the predicate and other devices, published in scientific literature, and since the performance testing shows its substantial equivalence, HealthWatch believes that animal and clinical studies are not necessary to determine the substantial equivalence of the ***HealthWatch Master Caution Device (MCD™)***