DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

August 18, 2014

Commwell Ltd.
c/o Mr. Jonathan S. Kahan
Regulatory Counsel
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, DC 20004

Re: K133703
Trade/Device Names: PhysioGlove ET System
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH, DPS
Dated: July 29, 2014
Received: July 29, 2014

Dear Mr. Kahan:

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.

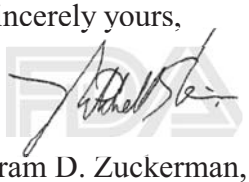
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

INDICATIONS FOR USE

510(k) Number (if known): __K133703_____

Device Name: PhysioGlove ET

Indications for Use:

The PhysioGlove ET is intended for self-testing by patients and by health care professionals at home and at medical settings. This 12-lead electrocardiogram (ECG), allows remote patients to display and transmit their ECG data to medical professionals via a mobile platform (communication device) to a remote server.

Specifically, the PhysioGlove ET is intended for patients who are concerned about their heart health and have the following problems that are suggestive of abnormal heart function:

- Skipped beats
- Pounding heart (palpitations)
- Heart racing or irregular pulse
- Lightheadedness or faintness
- Chest discomfort
- Shortness of breath
- High risk for heart problems
- History of heart problems
- Recipient of heart medications

The system only provides waveform parameters for healthcare provider interpretation and does not provide suggested interpretations.

Prescription Use (Part 21 CFR 801 Subpart D)	__√____	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY

510(k) Number K_____

6.1 Applicant's Name

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6.2 Contact Person

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6.3 Date Prepared

December 3, 2013

6.4 Trade Name

PhysioGlove ET

6.5 Classification Name

Transmitters and receivers, electrocardiograph, telephone

6.6 Product Code

DXH

6.7 Device Class

Class II

6.8 Regulation Number

21 CFR 870.2920

6.9 Panel

Cardiovascular

6.10 Predicate Devices

- PMP4 SelfCheck ECG [Card Guard Scientific Survival Ltd.] cleared under K042254
- PhysioGlove ES-1 with ECG Analysis Program [Commwell Ltd.] cleared under K103791

6.11 Intended Use / Indication for Use

The PhysioGlove ET is intended for self-testing by patients and by healthcare professionals at home and in medical settings. This 12-lead electrocardiogram (ECG) allows remote patients to display and transmit their ECG data to medical professionals via a mobile platform (communication device) to a remote server.

Specifically, the PhysioGlove ET is intended for patients who are concerned about their heart health and have the following problems that are suggestive of abnormal heart function:

- Skipped beats
- Pounding heart (palpitations)
- Heart racing or irregular pulse
- Lightheadedness or faintness
- Chest discomfort
- Shortness of breath
- High risk for heart problems
- History of heart problems
- Recipient of heart medications

The system only provides waveform parameters for healthcare provider interpretation and does not provide suggested interpretations.

6.12 Device Description

The PhysioGlove ET system is a 12-lead electrocardiograph capable of recording and transmitting standard ECGs for the purpose of cardiac monitoring and diagnosis in a remote location. The PhysioGlove ET system consists of the following 3 primary components:

The PhysioGlove - a glove that incorporates a system of Ag/AgCl electrodes for use in recording 12-lead ECGs. The PhysioGlove of the ET system is a modification of the cleared PhysioGlove ES-1 system (originally cleared under K083677 and later incorporated under K103791). In the ET system, however, the PhysioGlove encompasses also electronic elements (mainly a data acquisition circuitry and software packed into the glove, based on the cleared PhysioGlove ES-1) and a recording and transmitting circuitry to permit the transfer of the ECG data to a mobile platform.

The Mobile Platform Software - designed to be downloaded to a compatible mobile platform such as a smart cell-phone, a tablet computer, or another communication device. The proprietary Mobile Platform Software is responsible to provide the user with the PhysioGlove ET system operational instructions, as well as to receive the ECG data from the PhysioGlove and to transfer them to the receiving center. No graphical presentation of the acquired ECG is enabled on the mobile platform.

The Mercury Telemedicine System (MTS) - proprietary software designed to be installed on a computer in the PhysioGlove ET receiving center (e.g., Nurse Station). The MTS is responsible to receive the recorded ECG data, save it in a database and present it to a

medical professional who is capable of interpreting the results. The MTS is based on the PhysioGlove ES-1 software (originally cleared under K050674 and later incorporated under K103791).

The PhysioGlove ET system operates as follows:

The PhysioGlove records the patient's ECG and sends the data via Bluetooth to a mobile platform. Then, the recorded data is automatically transferred via the Internet using Wi-Fi to connect to a modem or via GPRS cellular communication. The data is sent to a receiving center (e.g., Nurse Station) to be reviewed by a medical professional who is capable of interpreting the ECG data.

6.13 Substantial Equivalence

The PhysioGlove ET System is substantially equivalent to the SelfCheck and PhysioGlove ES-1 with regard to intended use and indications for use. All three devices are reusable 12-Lead ECG examination systems, intended for recording of ECG. Both the PhysioGlove ET and the SelfCheck device are designed to be used by a patient or a health care professional who are concerned about their heart health and have problems that are suggestive of abnormal heart function.

Also, all three devices, the PhysioGlove ET, the SelfCheck Device, and the PhysioGlove ES-1 System, include hardware (HW) and software (SW) elements responsible for the collection and conditioning of the ECG signal so that it can be transmitted to another location for display. In the PhysioGlove ET, and similarly in the SelfCheck Device, the ECG recording may be conducted at home while the data display is performed at a remote location such as hospital, physician's office or a monitoring center.

The PhysioGlove ET System and the SelfCheck Device both use a Mobile Platform (e.g., a smart cell-phone, a compatible generic PDA or another communication device). The platform receives the ECG signal from the ECG acquisition element (the PhysioGlove or the PMP4 SelfCheck ECG) via Bluetooth and transmits it to the receiving center via cellular communication. Both devices contain methods for error testing and retransmission of the data.

The essential functionality of the SW elements included in the PhysioGlove ET system and its two predicates is substantially similar, i.e., receive the ECG data generated from the electrodes and transfer the digitized ECG data to the receiving center. Specifically, the PhysioGlove ET SW is a modification of the cleared PhysioGlove ES-1 SW (K103791) and thus, substantially equivalent the company's cleared device.

6.14 Performance Testing

Performance testing was conducted in order to demonstrate the performance, safety and usability of the PhysioGlove ET system. The testing plan included electrical safety and electromagnetic compatibility testing (according to IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, and IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests), compliance with performance standards (IEC 60601-1-11, 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, and IEC 60601-2-25,

Particular requirements for the basic safety and essential performance of electrocardiographs), SW validation testing and a usability study.

Test results indicated that the PhysioGlove ET functions as expected and is substantially equivalent to the predicate devices for its intended use. Therefore, it is concluded that the PhysioGlove ET system is substantially equivalent to its predicate devices without raising any new questions of safety and/or effectiveness.