K050674

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510(k) SUMMARY

COMMWELL LTD.'s PHYSIOGLOVE ES MODEL I

A. General Information

1. Submitter's Name:	**COMMWELL Ltd.**
2. Address:	Rechov Yad Harutzim 4 Kfar Saba, Israel 44641
3. Telephone Number:	9729-766-8094
4. Fax number:	9729-766-8099
5. Contact Person:	Irving Levy
6. Date Prepared:	January 31, 2005

B. Device

1. Name:	PHYSIOGLOVE ES MODEL I
2. Trade Name:	PHYSIOGLOVE ES MODEL I
3. Common Name:	12-Lead Diagnostic ECG system
4. Classification Name:	Electrocardiograph system
5. Product Code:	DPS
6. Class:	II
7. Regulation Number:	21CFR 870.2340

C. Description of the Device

The PhysioGlove ES Model I is a diagnostic electrocardiograph for 12-Lead resting ECGs. The system has been tested to a variety of performance standards.

The PhysioGlove ES Model I consists of an electronics data acquisition unit and software that runs on a medical grade PC.

The PhysioGlove ES Model I uses a standard, FDA-cleared, 10-electrode ECG cable to obtain ECG data from the patient.

The electronics performs analog processing and analog to digital conversion of a 12 lead diagnostic ECG.

The digital packets from the front-end enter the PC via the USB port. The software for the PC performs a variety of functions, including patient registration, ECG display, and storage. Users may also vary ECG acquisition parameters.

D. Intended Use Statement

The **PhysioGlove ES Model I** is a reusable 12-Lead diagnostic ECG examination system. It is intended for use in resting diagnostic electrocardiograph examination of adults. It is intended for use in physician offices, hospitals, outpatient clinics, or similar settings by or on the order of a physician or similarly qualified healthcare professional. The device only provides waveform parameters for healthcare provider interpretation and does not itself provide suggested interpretations.

E. Components

- Electronic Unit
- USB Cable
- Software and driver CD
- User Guide

F. Discussion of Substantial Equivalence

The PhysioGlove ES Model I has a substantially similar intended use and indications for use as the QRS Diagnostic's EKGCard (K030535), and uses substantially similar technology. None of the minor differences between the devices raise new questions of safety or effectiveness. Accordingly, the PhysioGlove ES Model I is substantially equivalence to the EKGCard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 25 2006

Commwell, Inc.
c/o Dr. John Smith
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K050674
Trade Name: PhysioGlove ES Model I
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: March 7, 2006
Received: March 7, 2006

Dear Dr. Smith:

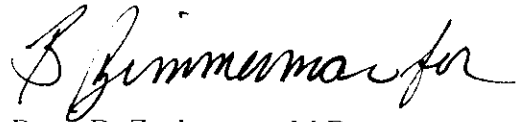
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K050674

Device Name: PhysioGlove ES Model I

Indications for Use:

The **PhysioGlove ES Model I** is a reusable 12-Lead diagnostic ECG examination system. It is intended for use in resting diagnostic electrocardiograph examination of adults. It is intended for use in physician offices, hospitals, outpatient clinics, or similar settings by or on the order of a physician or similarly qualified healthcare professional. The device only provides waveform parameters for healthcare provider interpretation and does not itself provide suggested interpretations.

Prescription Use _XX_ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K050674