APR 2 5 2012

Exhibit #1510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: K113485

1. Date of Submission:April 5, 2012

2. Sponsor
   Shenzhen Carewell Electronics Co., Ltd
   5A, Huating 3, TimeCity, Chuangye Road, Nanshan, Shenzhen 518054, P.R. China
   Contact Person: Jason Kang
   Position: General Manager
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023
   Shanghai, 200237, China
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   Fax: 240-238-7587
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4. Proposed Device Identification

   Proposed Device Name:Electrocardiograph
   Proposed Device Model:ECG-1101G(I), ECG-1103G(I), ECG-1103LW(I), ECG-1106L, ECG-1112 and ECG-1112D
   Classification: II
   Product Code: DPS
   Regulation Number: 21 CFR 870.2340
   Review Panel: Cardiovascular

Intended Use Statement:

Electrocardiographs, ECG-1101G(I), ECG-1103G(I), ECG-1103LW(I), ECG-1106L, ECG-1112 and ECG-1112D, are intended to acquire ECG signals from adult patients through body surface ECG electrodes. It could complete the ECG measurements of QRS detection, Heart Rate, ventricular ectopic beat (VEB), supraventricular ectopic beat (SVEB) and ST Segment Deviation. ECG with measurements is offered to clinician on an advisory basis only. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

5. Predicate Device Identification

510(k) Number:K101876
Product Name:Digital Electrocardiograph
Manufacturer:Digital Electrocardiograph

6. Device Description

Carewell Digital Electrocardiographs, ECG-1101G(I) / ECG-1103G(I)/ ECG-1103LW(I) / ECG-1106L /ECG-1112 / ECG-1112D, are designed to acquire, analyze, display and record ECG signals from patient body surface by ECG electrodes. After been amplified, filtered and analyzed, the ECG signal waveforms and analysis results are displayed on the LCD and recorded on the paper through thermal printer. ECG data, result and patient information could be stored in the memory of the device.

All the models, ECG-1101G(I) / ECG-1103G(I)/ ECG-1103LW(I) / ECG-1106L /ECG-1112 / ECG-1112D of the proposed device, Carewell Digital Electrocardiographs, have difference in appearance, but follow the same design principle and similar technical specifications:

They consist of three modules, which are power module, analog module and control module, and they have three operation modes, including AUTO Mode (automatic mode), MAN Mode (manual mode) and ANA Mode (analysis mode).

They are standard twelve leads, including bipolar limb leads, augmented unipolar limb leads and unipolar chest leads. And they are using the same accessories.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- IEC 60601-1:1988+A1:1991+A2:1995, Medical Electrical Equipment – Part 1: General requirements for safety;
- IEC 60601-1-2:2001 +A1: 2007, Medical Electrical Equipment – Part 1: General requirements for safety - Collateral Standard: Electromagnetic compatibility – Requirements and tests;
- IEC 60601-2-25: 1993+ A1:1999, Medical Electrical Equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers;
- ANSI/AAMI EC11:1991/(R)2007, Diagnosis electrocardiographic devices;
- ANSI/AAMI EC38:1998, Ambulatory electrocardiographs;
- ANSI/AAMI EC57:2003,Testing and Reporting performance results of cardiac rhythm and ST-segment measurement algorithms;
- AAMI EC53:1998, ECG cables and leadwieres;
- ISO 10993-5:2009 Standard,"Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity";
- ISO 10993-10:2002 Standard and Amendment 1:2006. "Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity AMENDMENT 1";

8. Substantially Equivalent Conclusion

The proposed device, Electrocardiographs, is determined to be Substantially Equivalent (SE) to the predicate device, Digital Electrocardiograph, K101876, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR 25 2012

Shenzhen Carewell Electronics Co., Ltd
c/o Diana Hong
Shanghai Mid-Link Business Consulting Co., Ltd
PO Box 237-023
Shanghai, 200030, China

Re: K113485
Trade/Device Name: Electrocardiograph ECG-1101G(I), ECG-1103G(I), ECG-1103LW(I), ECG-1106L, ECG-1112 and ECG-1112D
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: April 5, 2012
Received: April 9, 2012

Dear Ms. Hong:

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 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

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Exhibit #2Indications for Use

510(k) Number: K113485
Device Name:Electrocardiographs

Indications for Use:

Electrocardiographs, ECG-1101G(I), ECG-1103G(I), ECG-1103LW(I), ECG-1106L, ECG-1112 and ECG-1112D, are intended to acquire ECG signals from adult patients through body surface ECG electrodes. It could complete the ECG measurements of QRS detection, Heart Rate, ventricular ectopic beat (VEB), supraventricular ectopic beat (SVEB) and ST Segment Deviation. ECG with measurements is offered to clinician on an advisory basis only. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

☒PRESCRIPTION USE	☐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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113485