November 19, 2018

Shenzhen Carewell Electronics., Ltd
% Arthur Goddard
President
FDA Regulatory and Quality Systems Consultant
31853 Cedar Road
Mayfield Heights, Ohio 44124-4445

Re: K180432
Trade/Device Name: AI-ECG Platform
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: September 27, 2018
Received: October 3, 2018

Dear Arthur Goddard:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Arielle Drummond -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180432

Device Name
AI-ECG Platform

Indications for Use *(Describe)*

The AI-ECG Platform is designed to assist physicians in measuring and interpreting 12-lead resting ECG, and the interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. The program is intended for use by qualified healthcare professionals in hospitals and other healthcare facilities for the assessment of common cardiac abnormalities, including arrhythmias, myocardial infarction, ventricular hypertrophy, and abnormal ST-T changes. The AI-ECG Platform interpretation results are not intended to be the sole means of diagnosis for any abnormal ECG. They are offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

The AI-ECG Platform is qualified for use in the general adult population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities.

The AI-ECG Platform is used with compatible resting ECG devices which can export ECG recordings in Carewell ECG, HL7 aECG, DICOM ECG, SCP ECG, or MFER ECG data format. The AI-ECG Platform is not to be used for: patient monitoring, on ECG signals collected using non-standard leads, ECG signals not collected using electrodes with conductive paste/gel/fluid.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(K) Summary

This summary of 510(K) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1900 and 21 CFR 807.92.

The assigned 510(K) Number: K180432

5. 510(K) Summary

5.1. Date of Preparation: Feb., 12th, 2018

5.2. Sponsor

Shenzhen Carewell Electronics Co., Ltd.
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5.3. Submission Correspondent

Mr. Arthur Goddard
31853 Cedar Road, Ohio, 44124-4445, U.S.A.
Tel: (216) 233-5722
Email: asjgoddard@aol.com

5.4. Subject Device Identification

Subject Device Name: AI-ECG Platform
Edition: S Edition
Common name: ECG Analysis Software
Classification Name(s): Programmable Diagnostic Computer / Electrocardiograph
Product Code: DQK, DPS
Regulation Number: 21 CFR 870.1425
Review Panel: Cardiovascular
Classification: II

5.5. Predicate Devices

510(k) Number: K113485 (Secondary)
Device Name: Electrocardiograph

Manufacturer: Shenzhen Carewell Electronics Co., Ltd.

510(k) Number: K052883 (Primary)
Device Name: Datrix CardioServer ECG Management System
Manufacturer: Datrix, Inc

5.6. Indications for use:

The AI-ECG Platform is designed to assist physicians in measuring and interpreting 12-lead resting ECG, and the interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. The program is intended for use by qualified healthcare professionals in hospitals and other healthcare facilities for the assessment of common cardiac abnormalities, including arrhythmias, myocardial infarction, ventricular hypertrophy, and abnormal ST-T changes. The AI-ECG Platform interpretation results are not intended to be the sole means of diagnosis for any abnormal ECG. They are offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

The AI-ECG Platform is qualified for use in the general adult population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities.

The AI-ECG Platform is used with compatible resting ECG devices which can export ECG recordings in Carewell ECG, HL7 aECG, DICOM ECG, SCP ECG, or MFER ECG data format. The AI-ECG Platform is not to be used for: patient monitoring, on ECG signals collected using non-standard leads, ECG signals not collected using electrodes with conductive paste/gel/fluid.

5.7. Device Description

The AI-ECG Platform (S Edition) is a software package which is a distributed ECG auto analysis system designed to assist physician in measuring and interpreting 12-lead resting ECG with AI algorithm, the interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. The program is intended for use by qualified healthcare professionals in hospitals and other healthcare facilities for the assessment of common cardiac abnormalities, including arrhythmias, myocardial infarction, ventricular hypertrophy, and abnormal ST-T changes. The AI-ECG Platform interpretation results are not intended to be the sole means of diagnosis for any abnormal ECG. It is offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG.

The Carewell AI-ECG Platform is intended to be used in conjunction with Carewell ECG device or compatible ECG can export Carewell proprietary ECG data, HL7 aECG, DICOM ECG, SCP ECG, or MFER ECG data format. The AI-ECG Platform is not to be used for: patient monitoring, on ECG signals collected using non-standard leads, ECG signals not collected using electrodes with conductive paste/gel/fluid. The program receives ECG waveform data direct from device or user

manually uploaded, analyzes ECG data and automatically interprets on the computer server, the ECG measurement, interpretation and waveform data are then downloaded to a PC based physician's diagnosis client application to allow physician review, modify and confirm the analysis statements, and print the report. The original ECG waveform data is stored permanently in the server computer securely.

5.8. Predicate Devices and Subject Device Comparison

Table 3-1 Feature Comparison with Predicate Devices

Item	Subject Device K180432 AI-ECG Platform	Secondary Predicate K113485 Electrocardiograph	Primary Predicate K052883 Datrix CardioServer ECG Management System	Remark
Product Code	DQK, DPS	DPS	DQK	Discussion 1
Regulation Number	21 CFR 870.1425	21 CFR 870.2340	21 CFR 870.1425	
Regulation Description	Programmable diagnostic computer	Electrocardiograph	Programmable diagnostic computer	
Discussion 1: Predicate device Electrocardiograph, K113485 has ECG measuring functions and Datrix CardioServer ECG Management System, K052883 has ECG measuring and diagnostic functions. The subject AI-ECG Platform is a software package with automatically ECG measuring and diagnostic functions. The product codes of subject device can be covered by predicate devices K113485 and K052883.				
Classification	II	II	II	Same
Indications for use	The AI-ECG Platform is designed to assist physicians in measuring and interpreting 12-lead resting ECG, and the interpretation by the analysis program may then be confirmed, edited, or deleted by the physician. The program is intended for use by qualified healthcare professionals in hospitals and other healthcare facilities for the assessment of common cardiac abnormalities, including arrhythmias,	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	The CardioServer ECG Management System software is intended to be marketed to medical professionals and for point-of-care use. The software is designed to provide a database used through out the medical community to store, display, edit and print high resolution ECG data received from devices such as electrocardiographs. The CardioServer ECG Management System software allows medical	Discussion 2

Item	Subject Device K180432 AI-ECG Platform	Secondary Predicate K113485 Electrocardiograph	Primary Predicate K052883 Datrix CardioServer ECG Management System	Remark
	myocardial infarction, ventricular hyptrophy, and abnormal ST-T changes. The AI-ECG Platform interpretation results are not intended to be the sole means of diagnosis for any abnormal ECG. They are offered to physicians and clinicians on an advisory basis only in conjunction with the physician's knowledge of ECG. The AI-ECG Platform is qualified for use in the general adult population ranging from healthy subjects to patients with cardiac and/or non-cardiac abnormalities. The AI-ECG Platform is used with compatible resting ECG devices which can export ECG recordings in Carewell ECG, HL7 aECG, DICOM ECG, SCP ECG, or MFER ECG data format. The AI-ECG Platform is not to be used for: patient monitoring, on ECG signals collected using non-standard leads, ECG signals not collected using electrodes with conductive paste/gel/fluid.	(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.	professionals responsible for the diagnosis and treatment of patients (adult and pediatric) with heart disease to: review and edit specific patient ECG data including intervals such as QT measurements and algorithm generated preliminary interpretative statements. ECG records are all associated by patient ID and other demographic data. Secure access to the database is provided.	

Item	Subject Device K180432 AI-ECG Platform	Secondary Predicate K113485 Electrocardiograph	Primary Predicate K052883 Datrix CardioServer ECG Management System	Remark
Discussion 2: The subject device has smaller intended patient population scope, similar measuring functions, similar diagnostic functions scope and smaller supported ECG types scope. Others in the IFU are all the same. Therefore, the noted difference in indications for use does not raise any new issues of safety or effectiveness. It could be considered as substantially equivalent to that of the predicate devices.				
Algorithm	Carewell ECG Measurement Algorithm + Carewell ECG AI algorithm	Carewell ECG Measurement Algorithm	Glasgow ECG analysis for 12 lead ECG	Discussion 3
Discussion 3: The subject device AI-ECG Platform and the predicate device Electrocardiograph, K113485 are both produced by Shenzhen Carewell Electronics Co., Ltd. The measurement algorithm in the predicate device is also used in the subject device. AI algorithm is also used in junction with the previous algorithm. New algorithm is added into use to realize automatically interpreting ECGs and produce interpretation statement for the physician to reference. Though the subject device and predicate device K052883 use different algorithm, they are both intended to realize substantially equivalent intended use. It could be considered as substantially equivalent to that of the predicate device.				
Level of Concern of the software	Major	Moderate	Not specified in 510 (K) summary	Discussion 4
Discussion 4: The subject device K180432 AI-ECG Platform can provide diagnostic information about myocardial infarction (MI). The diagnostic information the software provided may result in a delayed response of appropriate medical care that would lead to serious injury or death. The Level of Concern of the software is Major. Predicate device K113485 doesn't provide diagnostic information and the software LoC is moderate. Though the level of concern of predicate device K052883 is not specified in 510 (K) summary, the predicate device K052883 can provide substantial equivalent diagnostic statement. The LoC of subject device K180432 is Major which is the highest level. So the software development is controlled as the strictest level. It could be considered as substantially equivalent to that of the predicate device.				
Fundamental scientific	The AI-ECG Platform performs the following functions:	--	CardioServer ECG Management System can realize the following	Discussion 5

Item	Subject Device K180432 AI-ECG Platform	Secondary Predicate K113485 Electrocardiograph	Primary Predicate K052883 Datrix CardioServer ECG Management System	Remark
technology	* Receive EGGs via local wired and/or wireless network, USBs, and other standard transmission methods; * Store, archive, and display EGGs; * Export EGGs in industry standard formats to electronic health records; * Print EGGs; * Utilize Windows standards; * Secure access to patient health information; * Log patient health information; * Provide clinical access to EGG data across the users local network; * Provide automatically measurements and interpretations of ECGs * Allow user editing of ECG interpretation; * Provide tools for user to manually measure EGGs; * Generate ECG reports Operating System requirement: Windows XP/7/8/10 32bit/64bit Operating System, Windows Server 2008/2012, Internet Information		functions: * Receive EGGs via wireless LAN, LAN, USB2, and other standard transmission modes; * Store, archive, and display EGGs; * Export EGGs in industry standard formats to electronic health records; * Print EGGs; * Utilize Windows standards; * Provide secure access to patient health information; * Log all interaction with patient health information; * Provide clinical access to EGG data across the users network; * Utilize the University of Glasgow EGG Algorithm for data interpretation; * Allow user editing of ECG interpretation; * Provide EGG measurements; * Gontain calipers for user edit of EGG measurements; * Generate management reports Hardware requirements: are Windows	

Item	Subject Device K180432 AI-ECG Platform	Secondary Predicate K113485 Electrocardiograph	Primary Predicate K052883 Datrix CardioServer ECG Management System	Remark
	Server 7/8, Microsoft Sql Server 2008 The four subsystems have different hardware requirements including processor, memory (RAM), Hard drive size, Nvidia GPU （optional）, screen resolution, printer etc.		2000 or 2003 Server operating system; Pentium IV, 2GHz (minimum); 512 MB RAM (minimum); 10/1 00 Ethernet (minimum); RAID 5 storage; 1024x768 monitor; and standard back-up technology.	
Discussion 5: The subject device AI-ECG Platform and the predicate device K052883 can realize similar functions including receiving, storing, analyzing, interpreting, exporting and printing ECG reports. They both have a user's interface for viewing, analyzing and interpreting ECG data, algorithms and APIs (Application Programming Interface) to access to the algorithms. They both have similar requirements for the operating system and hardware. The subject device is installed on the user's hardware and work or access through a local network. All the data processing and transmitting are in a secured local network environment. Both the devices use secured access technology. The subject device AI-ECG Platform therefore does not present any major technological innovations compared to predicate device.				

Table 3-2 Performance Comparison

Item	Subject Device K180432 AI-ECG Platform	Secondary Predicate K113485 Electrocardiograph	Primary Predicate K052883 Datrix CardioServer ECG Management System	Remark
Basic safety and essential performance	Comply with IEC 60601-2-25	Comply with IEC 60601-2-25	--	Same
Measurement performance	Comply with AAMI/ANSI EC57.	Comply with AAMI/ANSI EC57.	--	Same

5.9. Non-Clinical Test Conclusion

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

AAMI ANSI EC57:2012 Testing And Reporting Performance Results Of Cardiac Rhythm And ST-Segment Measurement Algorithms

IEC 60601-2-25:2011, Medical Electrical Equipment – Part 2-25: Particular requirements for the safety of electrocardiographs;

IEC 62304:2015, Medical device software - Software life-cycle

ISO 14971：2007, Medical devices-Application of risk management to medical device

5.10. Substantially Equivalent Conclusion

The subject device, AI-ECG Platform, is determined to be Substantially Equivalent (SE) to the predicate device, Electrocardiograph, K113485 and Datrix CardioServer ECG Management System, K052883.