March 20, 2020

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

Re: K200036
Trade/Device Name: AI-ECG Tracker
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK, DPS
Dated: January 3, 2020
Received: January 8, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

Jessica Paulsen
Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K200036

Device Name
AI-ECG Tracker

Indications for Use *(Describe)*
The AI-ECG Tracker is intended to be used by qualified healthcare professionals in hospitals and healthcare facilities for the assessment of arrhythmias using ECG data acquired from adults (age 22 and older) without pacemakers. The product supports downloading and analyzing data recorded from electrodes with conductive paste/gel placed on standard location in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12-lead ambulatory ECG devices when assessment of the rhythm is necessary. The AI-ECG Tracker provides ECG signal processing and analysis on a beat by beat basis, QRS detection, Supraventricular and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. The AI-ECG Tracker is not for use in life supporting or sustaining systems or ECG monitoring and Alarm devices.

The AI-ECG Tracker 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 patterns, patient background, clinical history, symptoms, and other diagnostic information.

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.

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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:K200036

5. 510(K) Summary

5.1. Date of Preparation: January 3rd, 2020

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 Tracker
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 Device

510(k) Number: K062282
Device Name: Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0
Manufacturer: Monebo Technologies, Inc.

5.6. Reference Device

510(k) Number: K113485

Device Name: Electrocardiograph

Manufacturer: Shenzhen Carewell Electronics Co., Ltd.

5.7. Indications for use

The AI-ECG Tracker is intended to be used by qualified healthcare professionals in hospitals and healthcare facilities for the assessment of arrhythmias using ECG data acquired from adults (age 22 and older) without pacemakers. The product supports downloading and analyzing data recorded from electrodes with conductive paste/gel placed on standard location in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12-lead ambulatory ECG devices when assessment of the rhythm is necessary. The AI-ECG Tracker provides ECG signal processing and analysis on a beat by beat basis, QRS detection, Supraventricular and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. The AI-ECG Tracker is not for use in life supporting or sustaining systems or ECG monitoring and Alarm devices.

The AI-ECG Tracker 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 patterns, patient background, clinical history, symptoms, and other diagnostic information.

5.8. Contraindications

Not suitable for diagnosis of non-cardiac abnormalities.

Not suitable for diagnosing patients with pacemakers.

Not suitable for diagnosing patients age 21 and under.

Not suitable for diagnosis other than cardiac arrhythmia.

The device must not be used as a physiological monitoring of vital signs.

5.9. Special Requirement

The input ECG data is required to contain at least one of leads I, II, III, V1, and V5.

5.10. Device Description

The AI-ECG Tracker is a distributed ECG auto analysis system designed to assist physicians and qualified healthcare professionals in measuring and interpreting ambulatory ECG data. The interpretations by the analysis program can be confirmed, edited, modified, or deleted by the physician and qualified healthcare professionals. The program is intended for use by qualified healthcare professionals in hospitals and other healthcare facilities for the assessments of common cardiac arrhythmias using ECG data acquired from adults (age 22 and older) without pacemakers.

The AI-ECG Tracker receives ECG waveform data uploaded by a user, analyzes ECG data and automatically interprets on a computer server. The ECG measurement, interpretation and waveform

data are then downloaded to the Physician Diagnostic Client for a physician to review, modify, confirm the analysis statements, and print the report. The original ECG waveform data is stored permanently in the user's server computer securely.

The system uses a machine learning based process (convolutional neural network or CNN) only for development of the AI ECG algorithm. The AI ECG algorithm is only used for beat classification. After the AI ECG algorithm is developed, the AI-based beat classification model is locked in the released product which means the marketed device doesn't have active machine learning or self-learning features.

5.11. Predicate Devices and Subject Device Comparison

Table 3-1 Feature Comparison with Predicate Devices

Item	Subject Device AI-ECG Tracker	Predicate Device K062282 Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0	Remark
Indications for use	The AI-ECG Tracker is intended to be used by qualified healthcare professionals in hospitals and healthcare facilities for the assessment of arrhythmias using ECG data acquired from adults (age 22 and older) without pacemakers. The product supports downloading and analyzing data recorded from electrodes with conductive paste/gel placed on standard location in compatible formats from any device used for the arrhythmia diagnostics such as Holter, event recorder, 12-lead ambulatory ECG devices when assessment of the rhythm is necessary. The AI-ECG Tracker provides ECG signal processing and analysis on a	The Automatic Analysis and Interpretation Software Library is intended for use by qualified medical professionals for the assessment of arrhythmias using historic ambulatory EGG data. The product supports downloading and analyzing data recorded in compatible formats from any device used for the arrhythmia diagnostics such as Holter, Event Monitor, 12 lead ambulatory or resting EGG devices, or other similar devices when assessment of the rhythm is necessary. The Automatic Analysis and Interpretation Software Library can also be electronically interfaced, and perform analysis with data	No substantial difference

Item	Subject Device AI-ECG Tracker	Predicate Device K062282 Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0	Remark
	beat by beat basis, QRS detection, Supraventricular and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis. The AI-ECG Tracker is not for use in life supporting or sustaining systems or ECG monitoring and Alarm devices. The AI-ECG Tracker 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 patterns, patient background, clinical history, symptoms, and other diagnostic information.	transferred from other computer based EGG systems, such as an EGG management system. The Automatic Analysis and Interpretation Software Library provides EGG signal processing and analysis on a beat by beat basis, QRS and Ventricular Ectopic Beat detection, QRS feature extraction, interval measurement, heart rate measurement, and rhythm analysis for up to sixteen(16) leads of captured data. The library is not for use in life supporting or sustaining systems or EGG monitoring and Alarm devices The product can be integrated into computerized EGG monitoring devices. In this case the medical device manufacturer will identify the indication for use depending on the application of their device.	
Algorithm	Proprietary Algorithm	Proprietary Algorithm	Different
Level of Concern of the software	Major	Moderate	Different
Diagnostic Statement	Heart rate determination for non-paced adult QRS Detection Non-paced arrhythmia interpretation for adult patients	Heart rate determination for non-paced adult QRS Detection Non-paced arrhythmia interpretation for adult patients	Same

Item	Subject Device AI-ECG Tracker	Predicate Device K062282 Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0	Remark
	Non-paced ventricular arrhythmia calls for adult patients Intervals measurement Ventricular ectopic beat detection	Non-paced ventricular arrhythmia calls for adult patients Intervals measurement Ventricular ectopic beat detection	
Fundamental scientific technology	The AI-ECG Tracker consists of: - Interfaces which provide tools to measure, analyze, interpret, review ECGs, and to generate and print reports. - Automated ECG interpretation algorithms that measure and analyze ECGs to provide supplementary information for ECG diagnosis. The device is developed in C# and C/C++ language, supported by Microsoft .Net framework and .Net Core runtime. Components and libraries can be accessed through the Application Programming Interface (API). Carewell AI-ECG Tracker requires local wired or wireless network.	The predicate device is a collection of callable functions that have been complied into machine code or IDL code of the computer on which they execute. The predicate device consists of a basic application for viewing, analyzing and annotating ECG data, and a callable object library built on the Microsoft .Net framework. An application software can be written to invoke some or all the functions in an object library. The library can be accessed through an Application program Interface (API) as a callable function. This allows the library to be used as an accessory to an ECG management application or as a stand-alone product.	No substantial difference. The subject device AI-ECG Tracker and the predicate device K062282 both built with Microsoft .Net framework with similar application architect, both have user's interface for viewing, analyzing and interpreting ECG data, and both allow the core algorithm library to be accessed via APIs.

Table 3-2 Performance Comparison

Item	Subject Device AI-ECG Tracker	Predicate Device K062282 Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0	Remark
Basic safety and essential	Comply with IEC 60601-2-25	Comply with IEC 60601-2-25	Same

Item	Subject Device AI-ECG Tracker	Predicate Device K062282 Monebo Automated ECG Analysis and Interpretation Software Library, Version 3.0	Remark
performance			
Measurement performance	Comply with AAMI/ANSI EC57 and IEC 60601-2-47.	Comply with AAMI/ANSI EC57 and IEC 60601-2-47.	Same

5.1. 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 60601-2-47:2012 Medical Electrical Equipment - Part 2-47: Particular Requirements For The Basic Safety And Essential Performance of Ambulatory Electrocardiographic Systems;

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

IEC 62304 Edition 1.1 2015-06, Medical device software - Software life-cycle;

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

5.2. Substantially Equivalent Conclusion

The subject device, AI-ECG Tracker, is determined to be Substantially Equivalent (SE) to the predicate device, Monebo Automated ECG Analysis and Interpretation Software Library, Monebo Technologies, Inc. K062282.