March 25, 2022

CAF Medical Solutions Inc.
% Juan Tezak
Consultant
Compliance 4 Devices
118 W Prive Cr.
Delray Beach, Florida 33445

Re: K220362
Trade/Device Name: LE-12CH
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: February 8, 2022
Received: February 8, 2022

Dear Juan Tezak:

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,

Jennifer Shih
Assistant 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

Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220362

Device Name

LE-12CH

Indications for Use *(Describe)*

The intended use of LE-12CH electrocardiograph is to acquire ECG signals from adult and pediatric patients (beginning at birth through 21 years of age) through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

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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510(k) Summary

LE-12CH
February, 2022

ADMINISTRATIVE INFORMATION

Applicant
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Establishment Registration Number

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DEVICE AND CLASSIFICATION NAME

Device Trade Name:	**LE-12CH**
Common Name:	Electrocardiograph
Classification Regulation:	21 CFR 870.2340
Classification Name:	Electrocardiograph
Device Classification:	Class II
Classification Panel:	Cardiovascular
Product Code:	DPS
Prior Submission:	No Prior Submission

Predicate Device Information

Predicate Device: K171942. Electrocardiograph with models SE-12, SE-12 Express, SE-1200 and SE-1200 Express. Edan Instruments, Inc.

Intended Use / Indications for Use

The intended use of LE-12CH electrocardiograph is to acquire ECG signals from adult and pediatric patients (beginning at birth through 21 years of age) through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

Device Description

CAF Medical's LE-12CH electrocardiograph device is a twelve-channel electrocardiograph, which features a user-friendly design, a high-resolution 8.4-inch (800*600) TFT LCD touch screen, an alphanumeric keypad and an optimized workflow.

The LE-12CH electrocardiograph can acquire 12-channel waveforms simultaneously, and can also print the 12-channel electrocardiograph waveforms simultaneously, using a 216 mm wide thermal printer.

An advanced digital filtering technique has been used in the LE-12CH device, including a baseline anti-drift filter, AC noise filter (50/60 Hz), EMG filter and low-pass filter, which can help the user record the ECG more clearly.

The LE-12CH electrocardiograph works by sampling the ECG signal from the patient's skin surface using special electrodes. This signal is then amplified and sampled in A/D format by the ECG board. The ECG board transfers the data to the system's MCU via UART. The MCU filters the data, sends it to the LCD, prints the waveforms on paper and stores the data in memory. This log can be stored in flash memory or sent to the PC via Ethernet, WIFI or RS232. During the examination, no substances are given to or removed from the patient. The LE-12CH electrocardiograph supports cardiac stress testing.

Contraindications:

There are no known contraindications for use.

Equivalence to Marketed Device

LE-12CH is substantially equivalent to the predicate device. In further support of a substantial equivalence determination, here-under is a comparison chart with the subject device and predicate device.

Table 1. Comparison with predicate device for Summary

ITEM	PREDICATE DEVICE SE-1200 EXPRESS	PROPOSED DEVICE LE-12CH	COMPARISON RESULT
K#	K171942	K220362	—
Intended Use / Indications for Use	The intended use of SE-12 series electrocardiograph is to acquire ECG signals from adult and pediatric patient (beginning at birth through 21 years of age) through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.	The intended use of LE-12CH electrocardiograph is to acquire ECG signals from adult and pediatric patient (beginning at birth through 21 years of age) through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.	Same
Safety Specifications			
Safety Standards	IEC 60601-1:2005/A1:2012 EN 60601-1:2006/A1:2013 IEC 60601-1-2:2007 EN 60601-1-2:2007/AC:2010 IEC/EN 60601-2-25	IEC 60601-1 ((2005) + Amd. 1 (2012)) IEC 60601-1-2 (Edition 4.0 2014) IEC 60601-2-25 (Edition 2.0 2011)	Same
Anti-electric-shock type:	Class I with internal power supply	Class I with internal power supply	Same
Anti-electric-shock degree:	Type CF	Type CF	Same
Degree of protection against harmful ingress of water:	Ordinary equipment (Sealed equipment without liquid proof)	Ordinary equipment (Sealed equipment without liquid proof)	Same
Disinfection/sterilization method:	Refer to the user manual for details	Refer to the user manual for details	Same
Degree of safety of application in the presence of flammable gas:	Equipment not suitable for use in the presence of flammable gas	Equipment not suitable for use in the presence of flammable gas	Same
Working mode:	Continuous operation	Continuous operation	Same
EMC:	CISPR 11 Group 1, Class A	CISPR 11 Group 1, Class A	Same
Ingress rating	IPX0	IPX0	Same
Environment Specifications			
Temperature			
Transport & Storage	-20ºC (-4ºF) ~ +55ºC (+131ºF)	-20ºC (-4ºF) ~ +55ºC (+131ºF)	Same
Working	+5ºC (+41ºF) ~ +40ºC (+104ºF)	+5ºC (+41ºF) ~ +40ºC (+104ºF)	Same
Relative Humidity:			
Transport & Storage	25%~93% Non-Condensing	25%~93% Non-Condensing	Same

ITEM	PREDICATE DEVICE SE-1200 EXPRESS	PROPOSED DEVICE LE-12CH	COMPARISON RESULT
Working	25% RH ~ 80% RH Non-Condensing	25% RH ~ 80% RH Non-Condensing	Same
Atmospheric Pressure:			
Transport & Storage	700 hPa ~1060 hPa	700 hPa ~1060 hPa	Same
Working	860 hPa ~1060 hPa	860 hPa ~1060 hPa	Same
Power Supply Specifications			
Mains Supply:	Operating Voltage =100V-240V~	Operating Voltage =100V-240V~	Same
	Operating frequency = 50 Hz / 60 Hz	Operating frequency = 50 Hz / 60 Hz	Same
	Input Current = 0.9-0.4A Or Input power = 96VA	Input Current = 0.9-0.4A Or Input power = 96VA	Same
Built-in Lithium Battery Pack:	Rated voltage = 14.8 V	Rated voltage = 14.8 V	Same
	SE-12 Express&SE-1200 Express: Rated capacity = 5000mAh SE-12& SE-1200: Rated capacity = 2500mAh	Rated capacity = 5000mAh	Same
	When the battery is fully charged, SE-12& SE-1200can work normally about4hours, and it can continually print about 1.5 hours in the manual mode or print about300 ECG reports of 3×4+1Rin the auto mode; SE-12 Express& SE-1200 Express can work normally about 5 hours, and it can continually print about 2.5 hours in the manual mode or print about 350 ECG reports of 3×4+1Rin the auto mode.	When the battery is fully charged, L-12 CH can work normally about 5 hours, and it can continually print about 2.5 hours in the manual mode or print about 350 ECG reports of 3×4+1Rin the auto mode.	Same
Performance Specifications			
Recording			
Recorder:	Thermal dot-matrix recorder	Thermal dot-matrix recorder	Same
Printing Density	8 dots per mm / 200 dots per inch (amplitude axes) 40 dots per mm / 1000 dots per inch (time axes, @25mm/s)	8 dots per mm / 200 dots per inch (amplitude axes) 40 dots per mm / 1000 dots per inch (time axes, @25mm/s)	Same
Recorder Paper:	Folded thermal paper: 210mm×295mm×100pages Folded thermal paper: 215mm×280mm×100pages (Optional) Rolled thermal paper: 210mm×30m (Optional)	Folded thermal paper: 210mm×295mm×100pages Folded thermal paper: 215mm×280mm×100pages (Optional) Rolled thermal paper: 210mm×30m (Optional)	Same
Effective Width:	210mm	210mm	Same
Paper Speed:	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (±3%)	5mm/s, 6.25mm/s, 10mm/s, 12.5mm/s, 25mm/s, 50mm/s (±3%)	Same
Accuracy of data:	±5% (x-axis), ±5%(y-axis)	±5% (x-axis), ±5%(y-axis)	Same

ITEM	PREDICATE DEVICE SE-1200 EXPRESS	PROPOSED DEVICE LE-12CH	COMPARISON RESULT
HR Recognition			
Technique:	Peak-Peak Detection	Peak-Peak Detection	Same
HR Range:	30 BPM ~ 300 BPM	30 BPM ~ 300 BPM	Same
Accuracy:	±1 BPM	±1 BPM	Same
Leads:	Standard 12 leads	Standard 12 leads	Same
Acquisition Mode:	Simultaneously 12 leads	Simultaneously 12 leads	Same
A/D	24 bits	24 bits	Same
Resolution:	2.52uV/LSB	2.52uV/LSB	Same
Time Constant:	≥ 3.2 s	≥ 3.2 s	Same
Frequency Response:	0.01Hz ~ 300 Hz (-3 dB)	0.01Hz ~ 300 Hz (-3 dB)	Same
Gain:	1.25,2.5, 5, 10, 20, 10/5, AGC (mm/mV)	1.25,2.5, 5, 10, 20, 10/5, AGC (mm/mV)	Same
Input Impedance:	≥100MΩ(10Hz)	≥100MΩ(10Hz)	Same
Input Circuit Current:	≤0.01μA	≤0.01μA	Same
Input Voltage Range	≤±5 mVpp	≤±5 mVpp	Same
Calibration Voltage:	1mV±2%	1mV±2%	Same
DC Offset Voltage:	±600 mV	±600 mV	Same
Noise:	≤12.5 μVp-p	≤12.5 μVp-p	Same
Multi-channel Crosstalk	≤0.5 mm	≤0.5 mm	Same
Filter	AC Filter: On / Off	AC Filter: On / Off	Same
	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	Same
	LOWPASS Filter:300Hz/ 270Hz/1 50Hz / 100Hz / 75Hz	LOWPASS Filter:300Hz/ 270Hz/1 50Hz / 100Hz / 75Hz	Same
CMRR	≥140dB (AC ON) ≥123dB (AC OFF)	≥140dB (AC ON) ≥123dB (AC OFF)	Same
Sampling Frequency	16000Hz	16000Hz	Same
Pacemaker Detection			
Amplitude	±750uVto ±700 mV	±750uVto ±700 mV	Same
Width	50μs to 2.0 ms	50μs to 2.0 ms	Same
Sampling Frequency	16,000/sec/channel	16,000/sec/channel	Same
Input	≥100 kΩ; Sensitivity 10 mm/V±5%; Single ended	≥100 kΩ; Sensitivity 10 mm/V±5%; Single ended	Same
Output	≤100Ω; Sensitivity 1 V/mV ±5%; Single ended	≤100Ω; Sensitivity 1 V/mV ±5%; Single ended	Same

Non-Clinical Testing Summary

The LE-12CH was tested to evaluate its performance based on the following standards:

Table 2. Standards compliance

	Standard	Title
Biocompatibility	ISO 10993-1	Biological Evaluation of Medical Device – Part 1: Evaluation and Testing within a Risk Management Process
	ISO 10993-5	Biological Evaluation of Medical Device – Test for in vitro cytotoxicity
	ISO 10993-10	Biological Evaluation of Medical Device – Part 10: Test for irritation and skin sensitization
EMC	IEC 60601-1	IEC Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
Bench Testing	IEC 60601-2-25	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
Software Validation		Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. **Level of Concern "Moderate"**

Clinical Testing Summary

Clinical testing was not required to demonstrate the substantial equivalence of the subject device to the predicate device.

Conclusion

Based on the information presented in this 510(k) premarket notification, the LE-12CH is considered substantially equivalent (as safe, as effective and performs as well as) to the currently marketed device, K171942 Electrocardiograph SE-1200 Express, cited in this submission. Any differences noted between the LE-12CH and the predicate device do not impact safety or effectiveness based on the successfully conducted testing of the subject device.