October 1, 2021

Edan Instruments, Inc
Ying Dai
Regulatory Engineer
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
Shenzhen, Guangdong 518122
China

Re: K210140
Trade/Device Name: Electrocardiograph: SE-1202
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, DYC
Dated: July 15, 2021
Received: July 20, 2021

Dear Ying Dai:

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

Jennifer Shih Kozen
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

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)*
K210140

Device Name
Electrocardiograph(SE-1202)

Indications for Use *(Describe)*
The SE-1202 12-lead electrocardiograph is intended to acquire ECG signals from adult and pediatric patients 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.

CONTRAINDICATIONS:
SEMIP algorithm is not intended for interpretive statements of neonatal patients from birth to 28 days.

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

Prepared in accordance with the content and format regulatory requirements of 21 CFR Part 807.92

1. Submitter:

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Tel: +86(0755) 26858736
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Contact person: Ying DAI

Preparing date: January 15, 2021

2. Device name and classification:

Trade Name: Electrocardiograph, model: SE-1202

Common/Usual Name: Electrocardiograph

Classification Name	**Product code**
21 CFR 870.2340 Electrocardiograph	DPS
21 CFR 870.2400 Vectorcardiograph	DYC

Regulatory Class: Class II

3. Predicate Device(s): Edan Instruments, Inc, Electrocardiograph: SE-12, SE-12 Express, SE-1200, and SE-1200 Express, K171942.

4. Device Description: The SE-1202 electrocardiograph features a 10.1" LCD touch screen, an operation panel, user-programmable reports, and the ability to operate on either battery or AC power. It is capable of simultaneous acquisition, display, and print of 12-lead ECG. It uses algorithm to generate measurements, data presentations, graphical presentations and interpretative statements. The record can be saved in flash memory or send to PC.

5. Indication for Use

The SE-1202 12-lead electrocardiograph is intended to acquire ECG signals from adult and pediatric patients 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.

CONTRAINDICATIONS:

SEMIP algorithm is not intended for interpretive statements of neonatal patients

from birth to 28 days.

6. Predicate Device Comparison

Comparison to the predicate devices, the subject device has the same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following tables:

Item	Predicate device (SE-12, SE-12 Express, SE-1200, and SE-1200 Express)	Proposed device (SE-1202)	Comparison Result
K#	K171942	K210140	—
Intended Use	The intended use of SE-12 series electrocardiograph is to acquire ECG signals from adult and pediatric patients 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 SE-1202 12-lead electrocardiograph is intended to acquire ECG signals from adult and pediatric patients 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
ECG functionality	Resting ECG, Exercise ECG	Resting ECG	Different
Algorithm	SEMIP or Glasgow	SEMIP or Glasgow	Same
The number of electrodes	10	10	Same
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
	Rated capacity = 5000mAh or 2500mAh	Rated capacity = 5000mAh or 2500mAh	Same

Performance Specifications			
Recorder:	Thermal dot-matrix recorder	Thermal dot-matrix recorder	Same
HR Range:	30 BPM ~ 300 BPM	30 BPM ~ 300 BPM	Same
ECG Unit			
Leads:	Standard 12 leads	9 or 12 standard leads	Different
Acquisition Mode:	Simultaneously 12 leads	9 or 12 leads acquisition simultaneously	
Processor Board	800 MHz CPU	1GHz CPU	
Sampling Frequency	16, 000 Hz	64,000 Hz	Different
Input Impedance:	≥100 MΩ(10 Hz)	≥100 MΩ(10 Hz)	Same
DC Offset Voltage:	±600 mV	±900 mV	Different
Noise:	≤12.5 μVp-p	≤12.5 μVp-p	Same
Filter	AC Filter	AC Filter	Same
	DFT Filter: 0.01Hz/0.05Hz/0.15Hz/0.25Hz/ 0.32Hz/0.5Hz/0.67Hz	DFT Filter: 0.01 Hz / 0.05 Hz / 0.32 Hz / 0.67 Hz	Different
	EMG Filter	EMG Filter	Same
	LOWPASS Filter: 300Hz/270Hz/150Hz/100Hz/75Hz	LOWPASS Filter: 350 Hz / 300 Hz / 270 Hz / 150 Hz / 100 Hz / 75 Hz	Different
Pacemaker Detection			
Sampling Frequency	16,000/sec/channel	80,000 /sec/channel, Rhythm Lead	Different
Connection			
Wireless connection	Wi-Fi	Wi-Fi	same

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

7. Performance Data:

Non-clinical data:

Electrical safety and electromagnetic compatibility (EMC)

The SE-1202 electrocardiograph were assessed for conformity with the relevant requirements of the following standards and found to comply:

- ANSI AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.

Performance testing-Bench

Edan has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification and meet relevant consensus standards.

- IEC 60601-2-25 Edition 2.0 2011-10 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- Performance validation via EDAN proprietary database

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Clinical data: Not applicable.

Summary

The non-clinical performance testing showed that the subject devices are as safe and as effective as the predicate device.

8. Conclusion

The bench testing data and software verification and validation demonstrate that Electrocardiograph SE-1202 is substantially equivalent to the predicate devices.