April 7, 2022

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

Re: K212278
Trade/Device Name: Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: February 28, 2022
Received: March 7, 2022

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,

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)*

Device Name
Electrocardiograph

Indications for Use *(Describe)*
The iSE series 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. The electrocardiograph is capable of network communications and supports the informatized management of workflows in hospital and healthcare facilities.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:	Edan Instruments, Inc. #15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, Shenzhen, 518122 P.R.China. Tel: +86(0755) 84513592
Contact person:	Joan.Wei
Preparing date:	June 25th, 2021
2. Device name and classification:	Electrocardiograph **Classification Name/ Product code:** 21 CFR 870.2340 Electrocardiograph, DPS **Regulatory Class:** Class II
3.Premarket Notification Class III Certification and Summary	Not applicable, the subject device is Class II.
4. Predicate Device(s):	1) Edan Instruments, SE-18 Electrocardiograph, cleared under K170995 (Primary) 2) Edan Instruments, SE-12, SE-12 Express，SE-1200, and SE-1200 Express Electrocardiograph, cleared under K171942(Reference)
5. Reason for Submission	By submission of the Traditional 510(k), Edan Instruments is requesting clearance for new devices iSE-1210 and iSE-1810 Electrocardiograph.
6.Pre-Submission, IDE	Not applicable, there is no pre-submission.
7. Device Description:	iSE-1210 and iSE-1810 Electrocardiograph can support ECG Data Sampling of maximum 12 leads and maximum 18 leads separately. iSE series electrocardiograph uses algorithm to generate measurements, data presentations, graphical presentations and interpretative statements. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals.

8. Indication for Use

The iSE series 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. The electrocardiograph is capable of network communications and supports the informatized management of workflows in hospital and healthcare facilities.

9. Predicate Device Comparison

Comparison to the predicate and reference 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:

Table 1: Comparison between iSE Series and SE-18

Item	**Predicate device (SE-18)**	**Proposed device (iSE Series)**	**Comparison Result**
K#	K170995	K212278	—
Indications for Use/ Intended Use	The SE-18 18-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.	The iSE Series 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. The electrocardiograph is capable of network communications and supports the informatized management of	Different

		workflows in hospital and healthcare facilities.	
Algorithm	SEMIP V1.8	SEMIP V1.92	Different
The number of electrodes	16	iSE-1810: 16 iSE-1210: 10	Different
Power Supply Specifications			
Mains Supply:	Operating Voltage = 100V-240V~	Operating Voltage = 100V-240V~	Same
	Operating Frequency = 50Hz/60Hz	Operating frequency=50Hz/60Hz	Same
	Input Current = 0.9A ~ 0.4A	Input current=1.1 A	Different
Lithium Battery Pack:	Rated voltage = 14.8 V	Rated voltage = 15.2 V	Different
	Rated capacity = 5000mAh	Rated capacity = 3550mAh	
	--	When the battery is fully charged, iSE can work (without printing) continuously at least 8 hours. 100% recharge time: ≤ 5 hours 90% recharge time: < 4 hours	
Performance Specifications			
Recording (Optional for iSE with thermal printer)			
Recorder:	Thermal dot-matrix recorder	Thermal dot-matrix recorder	Same
HR Recognition			
HR Range	30 BPM ~ 300 BPM	30 BPM ~ 300 BPM	Same
ECG Unit			
Leads:	Standard 18 leads	iSE-1810: 9, 12, 15, 16 or 18 standard leads iSE-1210: 9 or 12 standard leads	Different
A/D	24 bits	24 bits	Same
Sampling Frequency	16, 000 Hz	64,000 Hz	Different
Frequency Response:	0.01Hz～300Hz (-3 dB)	0.01 Hz ~ 350 Hz (-3 dB)	Different
Filter	AC Filter	AC Filter	Same
	DFT Filter	DFT Filter	Same
	EMG Filter	EMG Filter	Same
	LOWPASS Filter: 300Hz/270Hz/150Hz/100Hz/75Hz	LOWPASS Filter: 350Hz/300Hz/270Hz/150Hz/100Hz/75 Hz	Different
Pacemaker Detection			
Sampling Frequency	16,000Hz, Rhythm Lead	iSE-1810(DE18): 16,000Hz, Rhythm Lead iSE-1210(DE12): 80,000Hz, Rhythm Lead	Different
Connection			
Wireless connection	WiFi	WiFi, Bluetooth, 4G, NFC	Different

Table 2: Comparison between iSE Series and SE-12 Series

Item	Reference device (SE-12, SE-12 Express, SE-1200, and SE-1200 Express)	Proposed device (iSE Series)	Comparison Result
K#	K171942	K212278	—
Indications for Use/ 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 iSE Series 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. The electrocardiograph is capable of network communications and supports the informatized management of workflows in hospital and healthcare facilities.	Different
The number of electrodes	10	iSE-1210: 10	Same
Leads:	Standard 12 leads	iSE-1210: 9 or 12 standard leads	Different

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

10. Performance Data:

Non-clinical data:

Electrical safety and electromagnetic compatibility (EMC)

The iSE series electrocardiograph were assessed for conformity with the relevant requirements of the following standards:

- 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

Human Factors Engineering Testing

Edan has conducted usability testing to validate the usability of the devices. The results of usability testing show that the subject device safe and effective for the intended users, uses, and use environments and meet the requirement of following FDA s are Guidance and consensus standard:

- Applying Human Factors and Usability Engineering to Medical Devices, issued on February 3, 2016
- IEC 62366-1:2020 Medical Devices-Part 1:Application of usability engineering to medical devices

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 predicate devices.

11. Conclusion

The non-clinical data, bench testing data, and software verification and validation testing demonstrate that iSE series electrocardiograph are substantially equivalent to the predicate devices.