July 28, 2023

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

Re: K222902
Trade/Device Name: Electrocardiograph, model: SE-1200 Pro and SE-1201 Pro
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 28, 2023
Received: July 5, 2023

Dear Milin Wu:

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 Shruti N. Mistry -S

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

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)*
K222902

Device Name
Electrocardiograph(SE-1200 Pro, SE-1201 Pro)

Indications for Use *(Describe)*
The SE-1200 Pro&SE-1201 Pro 12-lead electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiographs are 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 content and format regulatory 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
Fax: +86(0755) 26882223

Liu Yongying

Contact person:

Preparing date:

September 19, 2022

2. Device name and classification:

Trade Name: Electrocardiograph, model: SE-1200 Pro, SE-1201 Pro
Common/Usual Name: Electrocardiograph

Classification Name	**Product code**
21 CFR 870.2340 Electrocardiograph	DPS

Regulatory Class: Class II

3. Predicate Device(s):

1) Edan Instruments, iSE-1210 Electrocardiograph, cleared under K212278 (Primary)
2) Edan Instruments, SE-1202 Electrocardiograph, cleared under K210140 (Reference)

4. Device Description:

SE-1201 Pro&SE-1200 Pro (2 models: SE-1201 Pro and SE-1200 Pro) features a 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-1200 Pro&SE-1201 Pro 12-lead electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiographs are 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.

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:

Table 2-1: Comparison between SE-1201 Pro&SE-1200 Pro and iSE-1210 (primary predicate device)

Item	Primary predicate device (iSE-1210)	Proposed device (SE-1201 Pro&SE-1200 Pro)	Comparison Result
K#	K212278	K222902	—
Intended 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.	The SE-1200 Pro&SE-1201 Pro 12-lead electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiographs are 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.	Different
Algorithm	SEMIP	SEMIP or Glasgow	Different
Number of electrodes	10	10	Same
Safety Specifications			
Safety Standards	IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014 IEC 60601-2-25:2011	IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014 IEC 60601-2-25:2011	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

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	
	Output Power：19V, 2.53A	Output Power：19V, 2.53A	
Built-in Lithium Battery Pack	Rated voltage = 15.2V	Rated voltage = 14.8 V	Different
	Rated capacity = 3550mAh	Rated capacity = 2500mAh	
	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	When the battery is fully charged, the SE-1200 Pro&SE-1201 Pro electrocardiograph can work for ⩾4 H in auto mode (printing a report once every 2 minutes), the SE-1200 Pro&SE-1201 Pro electrocardiograph can work for⩾2 H in manual mode, and print 3*4+1R copies of reports automatically ⩾ 250 copies. The battery takes just under 2 hours to charge from empty to 90%.	
Recording			
Recorder	Thermal dot-matrix recorder	Thermal dot-matrix recorder	Same
Effective Width	210mm	210mm	Same
ECG Unit			
HR Range	30 BPM ~ 300 BPM ±1 BPM	30 BPM ~ 300 BPM ±1 BPM	Same
A/D	24 bits	24 bits	Same
Sampling Frequency	64,000 Hz	64,000 Hz	Same
Frequency Response	0.01 Hz ~ 350 Hz (-3 dB)	0.01 Hz ~ 350 Hz (-3 dB)	Same
Input Impedance	≥100 MΩ(10 Hz)	≥100 MΩ(10 Hz)	Same
DC Offset Voltage	±900 mV	±960mV, ±5%	Different
Noise	≤12.5 μVp-p	≤12.5 μVp-p	Same
Filter	AC Filter: 50 Hz / 60 Hz / Off	AC Filter: 50 Hz / 60 Hz / Off	Same
	DFT Filter: 0.01 Hz / 0.05 Hz / 0.32 Hz / 0.67 Hz	DFT Filter: 0.01 Hz / 0.05 Hz / 0.32 Hz / 0.67 Hz	
	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	

	LOWPASS Filter: 350 Hz / 300 Hz / 270 Hz / 150 Hz / 100 Hz / 75 Hz	LOWPASS Filter: 350 Hz / 300 Hz / 270 Hz / 150 Hz / 100 Hz / 75 Hz	
CMRR	≥140 dB (AC filter on) ≥123 dB (AC filter off)	≥140 dB (AC filter on) ≥123 dB (AC filter off)	Same
Pacemaker Detection			
Amplitude	±500μV to ±700mV	±500μV to ±700mV	Same
Width	30μs to 2.0ms	30μs to 2.0ms	
Sampling Frequency	80,000 /sec/channel, Rhythm Lead	80,000 /sec/channel, Rhythm Lead	
Connection			
Wireless connection	WIFI, 4G, Bluetooth, NFC	WIFI, 4G, Bluetooth,	Different

Table 2-2: Comparison between SE-1201 Pro&SE-1200 Pro and SE-1202 (reference predicate device)

Item	**Reference predicate device (SE-1202)**	**Proposed device (SE-1201 Pro&SE-1200 Pro)**	**Comparison Result**
K#	K210140	Current Submission	—
Intended 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.	The SE-1200 Pro&SE-1201 Pro 12-lead electrocardiographs are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiographs are 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
Algorithm	SEMIP or Glasgow	SEMIP or Glasgow	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-1201 Pro&SE-1200 Pro 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

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-1201 Pro&SE-1200 Pro is substantially equivalent to the predicate devices.