July 2, 2026

Edan Instruments, Inc.
Tracy Yue
Regulatory Engineer
15 Jinhui Rd., Jinsha Community, Kengzi Sub-District,
Pingshan District,
Shenzhen, Guangdong 518122
China

Re: K252463
Trade/Device Name: SE-1202 Series Electrocardiograph (Model: SE-1202, SE-1202E)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 5, 2026
Received: June 5, 2026

Dear Tracy Yue:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

KIMBERLY N. CROWLEY -S

For: Jennifer 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252463

Please provide the device trade name(s).

SE-1202 Series Electrocardiograph (Model: SE-1202, SE-1202E)

Please provide your Indications for Use below.

The SE-1202 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

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

1. Submitter:

Applicant: Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community,
Kengzi Sub-District, Pingshan District,
Shenzhen, 518122 P.R.China.
Tel: +86(0755) 26858736
Fax: +86(0755) 26882223

Contact person: Tracy Yue

Preparing date: August 6th, 2025

2. Device name and classification:

Trade name: SE-1202 Series Electrocardiograph (Model: SE-1202, SE-1202E)
Common/Usual Name: Electrocardiograph
Classification Name: 21 CFR 870.2340 Electrocardiograph
Regulatory class: Class II
Primary product code: DPS - Electrocardiograph

3. Predicate Device(s): Primary Predicate Device: Edan Instruments, Inc., Electrocardiograph, Model: SE-1202 (K210140)

4. Device Description: The SE-1202 Series Electrocardiograph feature an 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 electrocardiogram. 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 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.

6. Predicate Device Comparison

The table below compares the indication for use and key technological feature of the subject devices to the predicate device.

Item	<Subject Device> Model: SE-1202, SE-1202E	<Predicate Device> Model: SE-1202	Comparison Result
K#	Current Submission	K210140	——
Regulation/ Product code	21 CFR 870.2340 Electrocardiograph DPS - Electrocardiograph	21 CFR 870.2340 Electrocardiograph DPS - Electrocardiograph	Same
Intended Use/Indications for Use			
Intended Use/Indications for Use	The SE-1202 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 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
Intended Patient Population	Adult and pediatric patients	Adult and pediatric patients	Same
Algorithm	SEMIP or Glasgow	SEMIP or Glasgow	Same
Physical Specifications			
Dimension	SE-1202: 400*360*90mm, ±2mm	SE-1202: 400*360*90mm, ±2mm	Similar
	SE-1202E: 400*360*183mm, ±5mm	/	
Weight	SE-1202: ≤6.5kg, ±0.3 kg	SE-1202: ≤6.5kg, ±0.3 kg	

Item	<Subject Device> Model: SE-1202, SE-1202E	<Predicate Device> Model: SE-1202	Comparison Result
	SE-1202E: ≤5.6kg, ±0.3 kg	/	
Display& Touchscreen	SE-1202: 10.1’’, 1280×800 multicolor LCD Screen (flippable screen with 0° or 25° forward tilt)	SE-1202: 10.1", 1280×800 multicolor LCD Screen (flippable screen with ≤25°forward tilt)	
	SE-1202E: 13.3’’, 1920×1080 multicolor LCD Screen (fixed 25° screen)	/	
Safety Specifications			
Safety Standards	IEC 60601-1:2015+A1:2012+A2:2020 IEC 60601-1-2:2014+A1:2020 IEC 60601-2-25:2011	IEC 60601-1:2005/A1:2012 IEC 60601-1-2:2014 IEC 60601-2-25:2011	Similar
Anti-electric-shock type	Class I with internal power supply	Class I with internal power supply	Same
Anti-electric-shock degree	Type CF with defibrillation-proof	Type CF with defibrillation-proof	Same
Working mode	Continuous operation	Continuous operation	Same
Performance Specifications			
Recorder	Thermal dot-matrix recorder	Thermal dot-matrix recorder	Same
HR Range	30 bpm ~300 bpm, ±1 bpm	30 bpm ~300 bpm, ±1 bpm	Same
Leads	9 or 12 standard leads	9 or 12 standard leads	Same
Acquisition Mode	9 or 12 leads acquisition simultaneously	9 or 12 leads acquisition simultaneously	Same
Frequency Response	0.01~500Hz	0.01~350Hz	Similar
DC Offset Voltage	±960 mV, ±5%	±900 mV, ±5%	Similar
Wireless Function	2.4 GHz & 5 GHz WiFi (Optional) 4G (Optional)	2.4 GHz & 5 GHz WiFi (Optional)	Similar
Environmental Specifications			

Item	<Subject Device> Model: SE-1202, SE-1202E	<Predicate Device> Model: SE-1202	Comparison Result
Working Temperature	+5ºC (+41ºF) ~ +40ºC (+104ºF)	+5ºC (+41ºF) ~ +40ºC (+104ºF)	Same
Transport /Storage Temperature	-20ºC (-4ºF) ~ +55ºC (+131ºF)	-20ºC (-4ºF) ~ +55ºC (+131ºF)	Same
Working Relative Humidity	15% RH~95% RH Non-Condensing	15% RH~95% RH Non-Condensing	Same
Transport /Storage Relative Humidity	15% RH~95% RH Non-Condensing	15% RH~95% RH Non-Condensing	Same
Working Atmospheric Pressure	70kPa ~106kPa	70kPa ~106kPa	Same
Transport /Storage Atmospheric Pressure	70kPa ~106kPa	70kPa ~106kPa	Same

As seen in the comparison tables, the subject and predicate device 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)

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

- IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014+A1:2020 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 60601-2-25:2011 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 Food and Drug Administration Staff, *"Content of Premarket Submissions for Device Software Functions"*.

Clinical data: Not applicable.

Summary

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

8. Conclusion

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