January 24, 2018

Edan Instruments, Inc.
% Doug Worth
Sr. Dir. US RA/QA
Edan Medical
1200 Crossman Ave.
Suite 200
Sunnyvale, California 94089

Re: K171942
Trade/Device Name: Electrocardiograph with models SE-12, SE-12 Express, SE-1200 and SE-1200 Express
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 21, 2017
Received: December 26, 2017

Dear Doug Worth:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K171942

Device Name

Electrocardiograph: SE-12, SE-12 Express, SE-1200, SE-1200 Express

Indications for Use *(Describe)*

The intended use of SE-12 series 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

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.: (0755) 28340011 Fax: +1 (408) 418-4059
Contact Person:	Alice Yang
Date prepared:	June 19, 2017
2. Device name and classification:	**Device Name:** Electrocardiograph **Model:** SE-12, SE-1200, SE-12 Express, SE-1200 Express **Classification Name:** 870.2340 Electrocardiograph Product code: 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, Inc., Electrocardiograph, models SE-12, SE-12 Express，SE-1200, and SE-1200 Express cleared under K160876 (Primary) 2. Edan Instruments, Inc., PC ECG, model SE-1515 cleared under K152427(Reference)
5. Reason for Submission	Modification for previous cleared product Electrocardiograph, models SE-12, SE-1200, SE-12 Express, SE-1200 Express.
6. Pre-Submission, IDE	Not applicable, there is no prior submission.

7. Device Description:

The SE-12/12 Express/1200/1200 Express Electrocardiograph gathers ECG signals of 12 leads simultaneously. It displays the operation menu, ECG parameters as well as electrocardiograms, and be powered by the mains supply or battery. And the system has advanced performance and high reliability due to high resolution thermal recorder, 32-bit processor and a large-capacity memorizer. Design of the system took much consideration on ergonomics so the size is suitable for clinic and hospital uses.

There are four selectable modes in the system, including manual, auto, rhythm, R-R analysis or VCG, and VCG is configured with SE-12 Express & SE-1200 Express.

SE-12 and SE-1200 share the same single-color LCD screen of which the resolution is 320×240 dot; and LCD screen of SE-12 Express and SE-1200 Express is 800×600 multicolor LCD screen.

Moreover, SE-12 Express is configured with stress ECG function, which will allow to diagnose concealed coronary heart disease and atypical angina pectoris, prescribe the workload for patients with myocardial infarction before leaving hospital, and assess the effect of the treatment.

8. Intended Use:

The intended use of SE-12 series 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.

9. 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	Predicatedevice (SE-12, SE-12Express, SE-1200, andSE-1200Express)	Proposed device (SE-12, SE-12Express, SE-1200, andSE-1200Express)	Comparison Result
K#	K160876	Current Submission	—
Intended Use	The intended use of the 12-channel electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only	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	Different

	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.	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.	
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/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	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
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	SE-12 Express&SE-1200 Express: Rated capacity = 5000mAh SE-12& SE-1200: Rated capacity = 2500mAh	Same
	When the battery is fully charged, SE-12&SE-1200 can work normally about 4 hours, and it can continually print about 1.5 hours in the manual mode or print about 300 ECG reports of 3×4+1R in 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+1R in the auto mode.	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.	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, @ 25 mm/s)	8 dots per mm / 200 dots per inch (amplitude axes) 40 dots per mm / 1000 dots per inch (time axes, @ 25 mm/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
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
ECG Unit			
Leads:	Standard12 leads	Standard12 leads	Same
Acquisition Mode:	Simultaneously12leads	Simultaneously12leads	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:	0.05 Hz ~ 150 Hz (-3 dB)	0.01Hz ~ 300 Hz (-3 dB)	Different
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:	≥50MΩ(10Hz)	⩾100MΩ(10Hz)	Different
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:	±600mV	±600 mV	Same
Noise:	≤12.5μVp-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
	DFT Filter: 0.05Hz / 0.15Hz / 0.25Hz / 0.32Hz / 0.5Hz / 0.67Hz	DFTFilter:0.01Hz/0.05Hz / 0.15Hz / 0.25Hz / 0.32Hz / 0.5Hz / 0.67Hz	Different
	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	Same
	LOWPASSFilter:150Hz / 100Hz / 75Hz	LOWPASSFilter:300Hz/270Hz/150Hz / 100Hz / 75Hz	Different
CMRR	≥115 dB	⩾140dB (AC ON) ⩾123dB (AC OFF)	Different
Sampling Frequency	10000Hz	16000Hz	Different
Pacemaker Detection			
Amplitude	±2 to ±700 mV	±750uVto ±700 mV	Different
Width	0.1 to 2.0 ms	50μs to 2.0 ms	Different
Sampling Frequency	10,000/sec/channel	16,000/sec/channel	Different
External Input/output			
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%;	≤100Ω; Sensitivity 1 V/mV ±5%;	Same

	Single ended	Single ended	

The subject device has similar intended use, similar product design, and same performance effectiveness, as the predicate device. There are no significant differences between the primary predicate. There are no new questions of safety and/or effectiveness. There are no changes to the intended use, indications for use, nor fundamental scientific technology.

10. Effectiveness and Safety Considerations:

Non-clinical data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing
The biocompatibility evaluation for SE-12/12 Express/1200/1200 Express ELECTROCARDIOGRAPH device is conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA and the results passed. The worst case of the whole system is considered surface contacting for duration of less than 24 hours. And the battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the SE-12/12 Express/1200/1200 Express ELECTROCARDIOGRAPH device, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012 standard for safety and the IEC 60601-1-2: 2007 standard for EMC and no changes conducted during the testing to comply with the standards. The results passed.

Bench Testing
Bench testing was conducted per IEC 60601-2-25: 2011 and all the results show pass. ECG interpretation features were also validated by database testing.

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." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software will not directly result in serious injury or death to the patient or operator, and the software device is an accessory to a medical device that has a Moderate Level of Concern.
Regression testing to previous releases was completed for existing functionality and bench testing was utilized to verify new features against documented requirements.

Clinical data: Not applicable.

Summary

Based on the non-clinical and clinical performance as documented in the system development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

11. Substantially Equivalent Determination

Verification and validation testing has been conducted on the Electrocardiograph, models SE-12, SE-1200, SE-12 Express, SE-1200 Express. This premarket notification submission demonstrates that Electrocardiograph, models SE-12, SE-1200, SE-12 Express, SE-1200 Express is substantially equivalent to the predicate devices.