DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 15, 2017

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

Re: K160876
Trade/Device Name: Electrocardiograph, 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: January 5, 2017
Received: January 9, 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.

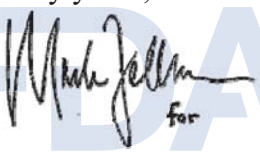
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160876

Device Name
Device Name: Electrocardiograph
Model: SE-12, SE-12 Express, SE-1200, and 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 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.

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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: Alice Yan
Preparing date: January 5, 2016

2. Device name and classification:

Device Name: Electrocardiograph
Model: SE-12, SE-12 Express, SE-1200, and SE-1200 Express
Classification Name/ Product code:
870.2340 Electrocardiograph/DPS
Regulatory Class: Class II

3. Predicate Device(s):

1) EDAN Instrument, Electrocardiograph, model SE-12, SE-12 Express, SE-1200, and SE-1200 Express, K102830
2) EDAN Instrument, Electrocardiograph, model SE-601, K131503
3) Cardiac Science Corporation, model Atria 6100, K060167
4) EDAN Instrument, PC ECG, model SE-1515, K152427

4. Reason for Submission

Technology change

5. Pre-Submission, IDE

Not applicable, there is no prior submission.

6. 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.

7. 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.

8. Predicate Device Comparison

The subject devices share the same characteristics in all items with the predicate device, concluding from using the same technology and principle. All the technological differences existed between the subject and predicate devices are only some performance parameters items, which are shown in the following tables in details.

Table 1: Comparison between the current SE-12 series and previous cleared system

Item	Predicate device (SE-12, SE-12 Express，SE-1200, and SE-1200 Express)	Proposed device (SE-12, SE-12 Express，SE-1200, and SE-1200 Express)	Comparison Result
K#	K102830	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 intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the	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	Same

	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.	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 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 60601-1-2: 2001+A1, IEC/EN60601-2-25 ANSI/AAMI EC11 IEC/EN 60601-2-51	IEC 60601-1:2005 EN 60601-1:2006 EN 60601-1-2:2007 IEC 60601-1-2:2007 IEC/EN60601-2-25:2011	Different
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 Power = 70VA	Input Current = 0.9-0.4A Or Input power = 96VA	Different
Built-in Lithium Battery Pack:	Rated voltage = 14.8 V	Rated voltage = 14.8 V	Same
	SE-12 Express&SE-1200 Express: Rated capacity = 4400mAh SE-12& SE-1200: Rated capacity =2200mAh	SE-12 Express&SE-1200 Express: Rated capacity = 5000mAh SE-12& SE-1200: Rated capacity = 2500mAh	Different
	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-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.	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:	203 mm	203mm	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:	Standard 12 leads	Standard 12 leads	Same
Acquisition Mode:	Simultaneously 12 leads	Simultaneously 12 leads	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)	0.05 Hz ~ 150 Hz (-3 dB)	Same
Gain:	2.5, 5, 10, 20, 10/5, AGC (mm/mV)	2.5, 5, 10, 20, 10/5, AGC (mm/mV)	Same
Input Impedance:	≥50 MΩ(10 Hz)	≥50 MΩ(10 Hz)	Same
Input Circuit Current:	≤0.01μA	≤0.01μA	Same
Input Voltage Range	≤±5 mVpp	≤±5 mVpp	Same
Calibration Voltage:	1 mV±3%	1 mV±3%	Same
DC Offset Voltage:	±600 mV	±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	DFT Filter: 0.05Hz / 0.15Hz / 0.25Hz / 0.32Hz / 0.5Hz / 0.67Hz	Same
	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	Same
	LOWPASS Filter:150Hz / 100Hz / 75Hz	LOWPASS Filter:150Hz / 100Hz / 75Hz	Same
CMRR	≥115 dB	≥115dB	Same
Sampling Frequency	1000 Hz	1000 Hz	Same
Pacemaker Detection			
Amplitude	±2 to ±700 mV	±2 to ±700 mV	Same

Width	0.1 to 2.0 ms	0.1 to 2.0 ms	Same
Sampling Frequency	10,000/sec/channel	10,000/sec/channel	Same
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%; Single ended	≤100Ω; Sensitivity 1 V/mV ±5%; Single ended	Same

Table 2: Comparison between SE-12 series and SE-601 series

Item	**Predicate device (SE-601C)**	**Proposed device (SE-12, SE-12 Express， SE-1200, and SE-1200 Express)**	**Comparison Result**
K#	K131503	Current Submission	——
Intended Use	The intended use of SE-601 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 only intended to be used on adult patients and is offered to clinicians on an advisory basis only.	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.	Same
WIFI Specifications (Optional)			
Transmitting Frequency	2412-2497MHz	2400-2497MHz	Different
Frequency Band	2412-2497MHz	2400-2497MHz	
Modulation Type	DSSS, CCK	DSSS, CCK,OFDM	
Transmitting Power	18dBm	6-17dBm	
Effective	18dBm	6-17dBm	

Radiated Power			

Table 3: Comparison between predicate device Atria 6100 and the proposed system

Item	Predicate device (Atria 6100)	Proposed device (SE-12, SE-12 Express， SE-1200, and SE-1200 Express)	Comparison Result
K#	K060167	Current Submission	——
Screen Size	640*480	320*240（SE-12，SE-1200） 800*600(SE-12Express， SE-1200Express)	Different
SW Algorithm	Glasgow	Glasgow	Same

Table 2-4: Comparison between predicate device SE-1515 **(**K152427**) and SE-12, SE-12 Express， SE-1200, and SE-1200 Express**

Item	Predicate device (SE-1515)	Proposed device (SE-12, SE-12 Express， SE-1200, and SE-1200 Express)	Comparison Result
K#	K152427	Current Submission	——
Intended Use	SE-1515 PC ECG is intended to acquire, process and store ECG signals from adult and pediatric patients undergoing stress exercise test or resting test. The SE-1515 PC ECG is intended to be used only in hospitals and healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the SE-1515 PC ECG can help users to analyze and diagnose heart diseases. However, the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only. It is mainly used in the ECG Outpatient Department and Physical Examination Department.	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.	different
SW Algorithm	SEMIP	SEMIP	Same

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

demonstrated in the non-clinical testing, the different technological characteristics do not affect the safety and effectiveness of the Edan SE-12 series electrocardiograph.

9. Performance Data:

Non-clinical data:

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

Biocompatibility testing
The biocompatibility evaluation for SE-12 series electrocardiograph 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. 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 series electrocardiograph, 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.

Bench Testing
Bench testing was conducted per IEC 60601-2-25: 2011, and all the results show pass.

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.

Battery Testing
Testing on battery are conducted per UL 2054, UL60950-1:2007 and IEC 61233:2012, and results show pass for all testing items.

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.

10. Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that SE-12 series electrocardiograph device should perform as intended in the specified use conditions, and all the data demonstrate that the subject devices perform comparably to the predicate device that is currently marketed for the same intended use. In other words, the subject SE-12 series electrocardiograph device is substantially equivalent to the predicate devices.