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

June 2, 2017

Edan Instruments, Inc.
Mr. Doug Worth
Sr. Dir. US RA/QA
1200 Crossman Ave, Suite 200
Sunnyvale, California 94086

Re: K170995
Trade/Device Name: SE-18 Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: March 30, 2017
Received: April 3, 2017

Dear Mr. 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,

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: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K170995

Device Name

SE-18 Electrocardiograph

Indications for Use (Describe)

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.

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:

Edan Instruments, Inc
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Contact person: Alice Yang

Preparing date: March 30, 2017

2. Device name and classification:

Device Name: Electrocardiograph
Model: SE-18
Classification Name/ Product code:
870.2340 Electrocardiograph/DPS
Regulatory Class: Class II

3. Predicate Device(s):

1. EDAN Instrument, Inc. Electrocardiograph, models SE-1515, K152427 (Primary)
2. EDAN Instrument, Inc. Electrocardiograph, models SE-12, SE-12 Express, SE-1200, and SE-1200 Express, K160876 (Reference)

4. Reason for Submission

New model

5. Pre-Submission, IDE

Not applicable, there is no prior submission.

6. Device Description:

The SE-18 acquires and displays an 18 leads waveforms, which can also be printed by an integrated thermal printer with effective recording width 216mm.

Digital filtering techniques similar to those incorporated on the SE-1515 and SE-12 have been used in SE-18: including

Anti-baseline drift filter, AC filter (50/60Hz), EMG Filter and Low pass Filter, which can help the user to record a higher quality ECG.

The EDAN Instruments “Smart ECG Measurement and interpretation program” (SEMIP) is included in this machine. The SEMIP program is completely integrated and provides the clinician with a detailed analysis of the ECG signal to aid in the interpretation of the ECGs.

The recorded ECG can be saved in flash memory or sent to a PC by Ethernet or WIFI. During the examination, there are no substances delivered to and/or extracted from the patient.

SE-18’sfunction block diagram is shown as Fig 1.It’s made up of an external ECG Sampling Box, SE-18 Main Control Board with RAM, FLASH, Ethernet module, WIFI module and USB module, a thermal printer module, a power supply module, a keyboard, and 15’ 1024*768 display module.

7. 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.

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 SE-18 and SE-1515

Item	**Proposed device (SE-18)**	**Predicate device (SE-1515)**	**Remark**
510(k) Number	Current Submission	K152427	----

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.	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.	Different
SW Algorithm			
----	SEMIP	SEMIP	Same
Sampling Box			
----	**DE18**	**DE18/DE15/DX12/DP12**	Different
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 60601-2-25:2011	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 60601-2-25:2011	Same
Anti-electric-shock type:	Class I with internal power supply	Class II	Different
Anti-electric-shock degree:	Type CF with defibrillation-proof	Type CF with defibrillation-proof	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
Patient Leakage Current:	NC	<10μA (AC) / <10μA (DC)	<10μA (AC) / <10μA (DC)	Same
	SFC	<50μA (AC) / <50μA (DC)	<50μA (AC) / <50μA (DC)	Same
Patient Auxiliary Current:	NC	<10μA (AC) / <10μA (DC)	<10μA (AC) / <10μA (DC)	Same
	SFC	<50μA (AC) / <50μA (DC)	<50μA (AC) / <50μA (DC)	Same
Environmental Specifications				
Temperature				
Operating		+5ºC (+41ºF) ~ +40ºC (+104ºF)	+5ºC (+41ºF) ~ +40ºC (+104ºF)	Same
Transport/Storage		-20ºC (-4ºF) ~ +55ºC (+131ºF)	-20ºC (-4ºF) ~ +55ºC (+131ºF)	Same
Humidity				
Operating		15%RH~95%RH Non-Condensing	25% RH~80% RH Non-Condensing	Different
Transport/Storage		15%RH~95%RH Non-Condensing	25% RH~93% RH Non-Condensing	
Pressure				
Operating		70 kPa ~106 kPa	86 kPa ~106 kPa	Different
Transport/Storage		70 kPa ~106 kPa	70 kPa ~106 kPa	
Performance Specifications				
HR Recognition				
HR Range:		30 bpm ~300 bpm	30 bpm ~300 bpm	Same
Accuracy:		±1 bpm	±1 bpm	Same
ECG Unit (only DE18 is listed for SE-1515)				
Leads:		18 standard leads	18 standard leads	Same
Acquisition Mode:		18 leads acquisition simultaneously	18 leads acquisition simultaneously	Same
Sampling Frequency		16kHz	16kHz	Same
A/D:		24bits	24 bits	Same

Resolution:		0.1575 μV/LSB	0.1575uV/LSB	Same
Time Constant:		≥3.2s	≥3.2s	Same
Frequency Response:		0.01~300Hz(-3dB)	0.01~300Hz(-3dB)	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:		≥100M Ω (10Hz)	≥100MΩ (10Hz)	Same
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	±600mV	Same
Minimum Amplitude:		20 μVp-p	20 μVp-p	Same
Noise:		≤12.5μVp-p	≤12.5μVp-p	Same
Multichannel crosstalk		≤0.5mm	≤0.5mm	Same
Filter	AC	50Hz/60Hz/Off	50Hz/60Hz/Off	Same
	DFT	0.01Hz/0.05Hz/0.32Hz/0.67Hz	0.01Hz/0.05Hz/0.32Hz/0.67Hz	
	EMG	25Hz/35Hz/45Hz/Off	25Hz/35Hz/45Hz/Off	
	LOWPASS Filter	300Hz/270Hz/150Hz/ 100Hz/75Hz	300Hz/270Hz/150Hz/100Hz/75Hz	
CMRR		≥123dB (AC OFF)	≥123dB (AC OFF)	Same
Pacemaker Detection				
Amplitude		±750μV to ±700mV	±750uV ~ ±700mV	Same
Width		50μs to 2.0ms	50us ~ 2.0ms	Same

Table 2-2: Comparison between SE-18 and SE-12 Series

Item	**Proposed device (SE-18)**	**Predicate device (SE-12 Series)**	**Remark**
510(k) Number	Current Submission	K160876	---
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	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	Same

		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.	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.	
SW Algorithm				
----		SEMIP	SEMIP	Same
Safety Specifications				
Safety Standards		IEC 60601-1:2005/A1:2012 EN 60601-1:2006/A1:2013 IEC 60601-1-2:2007 EN60601-1-2:2007/AC:2010 IEC 60601-2-25:2011	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 with defibrillation-proof	Type CF with defibrillation-proof	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
Patient Leakage Current:	NC	<10μA (AC) / <10μA (DC)	<10μA (AC) / <10μA (DC)	Same
	SFC	<50μA (AC) / <50μA (DC)	<50μA (AC) / <50μA (DC)	Same
Patient Auxiliary Current:	NC	<10μA (AC) / <10μA (DC)	<10μA (AC) / <10μA (DC)	Same
	SFC	<50μA (AC) / <50μA (DC)	<50μA (AC) / <50μA (DC)	Same

Ingress rating	IPX0	IPX0	Same
Environmental Specifications			
Temperature			
Operating	+5ºC (+41ºF) ~ +40ºC (+104ºF)	+5ºC (+41ºF) ~ +40ºC (+104ºF)	Same
Transport/Storage	-20ºC (-4ºF) ~ +55ºC (+131ºF)	-20ºC (-4ºF) ~ +55ºC (+131ºF)	Same
Humidity			
Operating	15%RH~95%RH Non-Condensing	25% to 80% RH Non-condensing	Different
Transport/Storage	15%RH~95%RH Non-Condensing	25% to 93% RH Non-condensing	
Pressure			
Operating	70 kPa ~106 kPa	86 kPa ~106 kPa	Different
Transport/Storage	70 kPa ~106 kPa	70 kPa ~106 kPa	
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 = 0.9 ~ 0.4A	Same
Internal Li-ion Battery Pack:	Rated Voltage = 14.8V	Rated voltage = 14.8V	Different
	Rated Capacity = 5000mAh	SE-12 Express&SE-1200 Express: Rated capacity = 5000mAh SE-12& SE-1200: Rated capacity =2500mAh	
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	Folded thermal paper: 210mm×295mm×100pages Folded thermal paper: 215mm×280mm×100pages	Same

		Folded thermal paper: 210mm×295mm×200pages	(Optional) Rolled thermal paper: 210mm×30m (Optional)	
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				
HR Range:		30 bpm ~300 bpm	30 BPM ~ 300 BPM	Same
Accuracy:		±1 bpm	±1 bpm	Same
ECG Unit				
Leads:		18 standard leads	Standard 12 leads	Different
Acquisition Mode:		18 leads acquisition simultaneously	Simultaneously 12 leads	
Sampling Frequency		16kHz	10k Hz	Different
A/D		24bits	24 bits	Same
Resolution:		0.1575 μV/LSB	2.52uV/LSB	Different
Time Constant:		≥3.2s	≥ 3.2 s	Same
Frequency Response:		0.01~300Hz(-3dB)	0.05 Hz ~ 150 Hz (-3 dB)	Different
Gain:		2.5, 5, 10, 20, 10/5, AGC (mm/mV)	2.5, 5, 10, 20, 10/5, AGC (mm/mV)	Same
Input Impedance:		≥100M Ω (10Hz)	≥50 MΩ(10 Hz)	Different
Input Circuit Current:		≤0.01μA	≤0.01μA	Same
Input Voltage Range		≤±5 mVpp	≤±5 mVpp	Same
Calibration Voltage:		1mV±2%	1 mV±2%	Same
DC Offset Voltage:		±600mV	±600 mV	Same
Noise:		≤12.5μVp-p	≤12.5 μVp-p	Same
Multi-channel Crosstalk		≤0.5mm	≤0.5 mm	Same
Filter	AC	50Hz/60Hz/Off	50Hz/60Hz/Off	Same
	DFT	0.01Hz/0.05Hz/0.32Hz/0.67Hz	0.05Hz / 0.15Hz / 0.25Hz / 0.32Hz / 0.5Hz / 0.67Hz	Different
	EMG	25Hz/35Hz/45Hz/Off	25Hz/35Hz/45Hz/Off	Same
	LOWPASS Filter	300Hz/270Hz/150Hz/ 100Hz/75Hz	150Hz / 100Hz / 75Hz	Different

CMRR	≥140dB (AC On), ≥123dB (AC Off),	≥115dB (AC Off)	Different
Pacemaker Detection			
Amplitude	±750μV to ±700mV	±2 to ±700 mV	Different
Width	50μs to 2.0ms	0.1 to 2.0 ms	Different
Sampling Frequency	16kHz, Rhythm Lead	10,000/sec/channel	Different
External Input/Output			
Input	≥100kΩ; Sensitivity 10mm/V±5%; Single ended	≥100kΩ; Sensitivity 10mm/V±5%; Single ended	Same
Output	≤100Ω; Sensitivity 1V/mV±5%; Single ended	≤100Ω; Sensitivity 1V/mV±5%; Single ended	Same
WIFI Specifications (Optional)			
Transmitting Frequency	2.400-2.500GHz（2.4 GHz ISM band）	2400-2497MHz	Different
Frequency Band	2.400-2.500GHz（2.4 GHz ISM band）	2400-2497MHz	
Modulation Type	DSSS, CCK,OFDM	DSSS, CCK,OFDM	
Transmitting Power	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM	6-17dBm	
Effective Radiated Power	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM	6-17dBm	

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-18 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-18 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-18 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.

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-18 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-18 electrocardiograph device is substantially equivalent to the predicate devices.