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

September 25, 2017

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

Re: K171943
Trade/Device Name: Electrocardiographs: SE-301, SE-300A, SE-300B, SE-3
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: June 19, 2017
Received: June 28, 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 (DICE) 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 (DICE) 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)*
K171943

Device Name
Electrocardiograph, models SE-3, SE-300A, SE-300B and SE-301

Indications for Use *(Describe)*
The intended use of the 3-Channel 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 intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the 3-Channel Electrocardiograph can help users to analyze and diagnose heart disease. However, the 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 #15 Jinhui Road,Jinsha Community, Kengzi Sub-District, Pingshan District, Shenzhen, 518122 P.R.China. 518067 P.R. China Tel: +86(0755) 26858736 Fax: +1 (408) 418-4059
Contact person:	Alice Yang
Preparing date:	June 19, 2017
2. Device name and classification:	**Device Name:** Electrocardiograph **Model:** SE-3, SE-300A, SE-300B and SE-301 **Classification Name/ Product code:** 870.2340 Electrocardiograph/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 Instrument, Inc. SE-3, SE-300A,SE-300B, K091513 2) EDAN Instrument, Inc. SE-601C, K131503 (reference) 3) EDAN Instrument, Inc. SE-12 Series, K160876 (reference)
5. Reason for Submission	The SE-3, SE-300A and SE-300B Electrocardiograph received FDA 510(k) clearance on July 24, 2009(K091513); while SE-301 is a newly designed system which is developed based on SE-3 but with better designed hardware structure, appearance, display, battery adapter together with a Wi-Fi module, and not cleared yet. The changes of SE-3, SE-300A, SE-300B in this submission compared to the last cleared version are mainly in resolution, color of screen, lithium battery pack, DE12 ECG board and assemble of screen.
6. Pre-Submission,	Not applicable, there is no prior submission.

IDE

7. Device Description:

SE-3 Series (including SE-3, SE-300A, SE-300B, and SE-301) 3-channel electrocardiograph gathers ECG signals of 12 leads simultaneously. While all 12 leads are recorded and analyzed, printouts will only have 3 leads on a page, with 4 pages in series to output all 12 leads. It displays the operation menu, ECG parameters as well as electrocardiograms.

8. Intended Use:

The intended use of the 3-Channel 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 intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the 3-Channel Electrocardiograph can help users to analyze and diagnose heart disease. However, the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.

9. 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 predicate device SE-3, SE-300A, SE-300B (K091513) and proposed device SE-3, SE-300A, SE-300B

Item	Predicate device (SE-3，SE-300A,SE-300B)	Proposed device (SE-3, SE-300A, SE-300B)	Comparison Result
K#	K091513	Current Submission	—
Intended Use	The intended use of SE-3 is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare	The intended use of the 3-Channel Electrocardiograph is to acquire ECG signals from adult and pediatric patients (beginning at birth through 21 years of age) through body surface ECG	Same

	facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-3 can help users to analyze and diagnose heart disease. However, the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.	electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the 3-Channel Electrocardiograph can help users to analyze and diagnose heart disease. However, the 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 NSI/AAMI EC-11	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
Environment Specifications			
Temperature			
Transport	-20℃~50℃	-20ºC ~ +55ºC	Different
Storage	-10℃~40℃	-20ºC ~ +55ºC	Different
Working	5 ºC ~40 ºC	+5ºC ~ +40ºC	Same
Relative Humidity:			
Transport & Storage	25% RH ~ 95% RH Non-Condensing	25% RH ~ 93% RH Non-Condensing	Different

Working	25% RH ~ 85% RH Non-Condensing	25% RH ~ 80% RH Non-Condensing	Different
Atmospheric Pressure:			
Transport & Storage	700 hPa ~ 1060 hPa	700 hPa ~ 1060 hPa	Same
Working	800 hPa ~ 1060 hPa	800 hPa ~ 1060 hPa	Same
Power Supply Specifications			
Mains Supply:	Operating voltage =100 V-115 V~/220 V-240 V~	Operating voltage =100 V-115 V~/220 V-240 V~	Same
	Operating frequency = 50 Hz / 60 Hz	Operating frequency = 50 Hz / 60 Hz	Same
	input power = 35 VA	input power = 35 VA	Same
Built-in Lithium Battery Pack:	Rated voltage = 14.4 V	Rated voltage = 14.8 V	Different
	Rated capacity =1600 mAh	Rated capacity = 2500 mAh	
	When the battery is fully charged, SE-3 can work normally 6 hours.	When the battery is fully charged, the 3-channel electrocardiograph can work normally about 6.5 hours. It can continuously record about 3 hours in Manual mode, and record 330 reports at most in the AUTO mode.	
	Cycle life ≥ 300 times	Cycle life ≥ 300 times	Same
Performance Specifications			
Recording			
Recorder:	Thermal dot-matrix recorder	Thermal dot-matrix recorder	Same
Recorder Paper:	Folded thermal paper Rolled thermal paper	Folded thermal paper, Rolled thermal paper,	Same
Effective Width:	72 mm	72 mm	Same
Paper Speed:	5 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s (±3%)	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s (±3%)	Different
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 Resolution:	12 bits	12 bits or 24 bits (optional, with DE12 ECG board)	Different
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
Input Impedance:	≥50 MΩ (10 Hz)	≥50 MΩ (10 Hz)	Same
Input Circuit Current:	≤0.05 μA	≤0.05 μA / ≤0.01 μA (optional, with DE12	Different

		ECG board)	
Input Voltage Range	≤±5 mVpp	≤±5 mVpp	Same
Calibration Voltage:	1 mV±3%	1 mV±3%	Same
DC Offset Voltage:	±500 mV	±500 mV / ±600 mV (optional, with DE12 ECG board)	Different
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 / 0.5Hz	DFT Filter: 0.05Hz / 0.15Hz / 0.25Hz / 0.32Hz / 0.5Hz / 0.67Hz	Different
	EMG Filter: 25Hz / 35Hz / OFF	EMG Filter: 25Hz / 35Hz / 45Hz / OFF	Different
	LOWPASS Filter:150Hz / 100Hz / 75Hz	LOWPASS Filter:150Hz / 100Hz / 75Hz	Same
CMRR	≥110 dB	≥110dB / ≥115dB (optional, with DE12 ECG board)	Different
Sampling Frequency	1000 Hz	1000 Hz	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 predicate device SE-3, SE-300A, SE-300B (K091513) and proposed device SE-301

Item	Predicate device (SE-3，SE-300A,SE-300B)	Proposed device (SE-301)	Comparison Result
K#	K091513	Current Submission	——
Intended Use	The intended use of SE-3 is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-3 can help users to analyze and diagnose heart disease. However, the ECG	The intended use of the 3-Channel 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 intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The	Same

	with measurements and interpretive statements is offered to clinicians on an advisory basis only.	cardiogram recorded by the 3-Channel Electrocardiograph can help users to analyze and diagnose heart disease. However, the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.	
Electronic Safety			
Comply with:	IEC 60601-1:1988+A1+A2, EN 60601-1:1990+A1+A2, IEC/EN 60601-1-2: 2001+A1, IEC/EN60601-2-25 NSI/AAMI EC-11	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	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
Environment Specifications			
Temperature			
Transport	-20℃~ 50℃	-20ºC (-4ºF) ~ +55ºC (+131ºF)	Different
Storage	-10℃~ 40℃	-20ºC (-4ºF) ~ +55ºC (+131ºF)	Different
Working	+5ºC ~ +40ºC	+5ºC (+41ºF) ~ +40ºC (+104ºF)	Same
Relative Humidity:			
Transport & Storage	25% RH ~ 95% RH Non-Condensing	15% RH ~ 95% RH Non-Condensing	Different
Working	25% ~ 85% RH Non-Condensing	15% RH ~ 95% RH Non-Condensing	
Atmospheric Pressure:			
Transport & Storage	70 kPa ~ 106 kPa	70 kPa ~ 106 kPa	Same
Working	80 kPa ~ 106 kPa	70 kPa ~ 106 kPa	Different
Power Supply Specifications			
Mains Supply:	Operating voltage = 100 V-115 V ~ / 220 V-240 V~	Operating voltage = 100 V-240 V~	Different
	Operating frequency = 50 Hz /	Operating frequency = 50 Hz /	Same

	60 Hz	60 Hz	
	input power = 35 VA	Power adapter output voltage: 19 V, 2 A	Different
Built-in Lithium Battery Pack:	Rated voltage = 14.4 V	Rated voltage = 14.8 V	Different
	Rated capacity = 1600 mAh	Rated capacity = 2500m Ah	
	When the battery is fully charged, SE-3 can work normally 6 hours.	When the battery is fully charged, the 3-channel electrocardiograph can work normally about 8.5 hours. It can continuously record about 5 hours in Manual mode, and record at least 500 reports at most in the AUTO mode.	
	Cycle life ≥ 300 times	Cycle life ≥ 300 times	Same
Performance Specifications			
Recording			
Recorder:	Thermal dot-matrix recorder	Thermal dot-matrix recorder	Same
Recorder Paper:	Folded thermal paper, 80 mm × 70 mm × 200 pages Rolled thermal paper, 80 mm × 20 m	Folded thermal paper, 80 mm × 70 mm × 200 pages Rolled thermal paper, 80 mm × 20 m	Same
Effective Width:	72 mm	72 mm	Same
Paper Speed:	5 mm/s,10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s (±3%)	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s (±3%)	Different
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:	12 bits	24 bits	Different
Time Constant:	≥3.2 s	≥3.2 s	Same
Frequency Response:	0.05 Hz ~ 150 Hz (-3 dB)	0.01 Hz ~ 300 Hz (-3 dB)	Different
Input Impedance:	≥50 MΩ (10 Hz)	≥50 MΩ (10 Hz)	Same
Input Circuit Current:	≤0.05 μA	≤0.01 μA	Different
Input Voltage Range	≤±5 mVpp	≤±5 mVpp	Same
Calibration Voltage:	1 mV±3%	1 mV±3%	Same
DC Offset Voltage:	±500 mV	±600 mV	Different
Noise:	≤12.5 μVp-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: 0.05 Hz/0.15 Hz/0.25 Hz/0.32 Hz/0.5 Hz/0.67 Hz	DFT Filter: 0.01 Hz, 0.05 Hz, 0.32 Hz, or 0.67 Hz	Different

	EMG Filter: 25 Hz/35 Hz/OFF	EMG Filter: 25 Hz/35 Hz/45 Hz/OFF	Different
	LOWPASS Filter:150 Hz/100 Hz/75 Hz	LOWPASS Filter:300 Hz/270 Hz/150 Hz/100 Hz/75 Hz	Different
CMRR	≥110 dB	≥140 dB (AC: ON) ≥110 dB (AC: Off)	Different
Sampling Frequency	1000 Hz	16000 Hz	Different
Algorithm	SEMIP	SEMIP	Same

Table 3: Comparison between reference device SE-601C (K131503) with WiFi and SE-301

Item	Predicate device (SE-601C)	Proposed device (SE-301)	Comparison Result
K#	K131503	Current Submission	——
WIFI Specifications (Optional)			
Transmitting Frequency	2.4 GHz	2.4 GHz	Same
Frequency Band	2.400 - 2.500 GHz (2.4 GHz ISM band)	2.400 - 2.500 GHz (2.4 GHz ISM band)	Same
Modulation Type	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS	OFDM with BPSK, QPSK, 16-QAM, and 64-QAM 802.11b with CCK and DSSS	Same
Transmitting Power	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM	17 dBm for 802.11b DSSS 17 dBm for 802.11b CCK 15 dBm for 802.11g/n OFDM	Same

Table 4: Comparison between reference device SE-601C (K131503) and SE-3 with DE12 ECG board

Item	Predicate device (SE-601C)	Proposed device (SE-3)	Comparison Result
K#	K131503	Current Submission	——
Sensitivity:	2.5, 5, 10, 20mm/mV, 10/5 mm/mV, AGC	2.5, 5, 10, 20mm/mV, 10/5 mm/mV, AGC	Same
Pacemaker Detection			
Amplitude	±2 mV ~ ±700 mV	±2 mV ~ ±700 mV	Same
Width	0.1 ms ~ 2.0ms	0.1 ms ~ 2.0 ms	Same
Sampling Frequency	10,000 / sec / channel	10,000 / sec / channel	Same

The version of SEMIP used in SE-301 is V1.8, which is the same as SE-12 Series.(K160876). But the version of SEMIP used in SE-3 series is V1.7, which was upgraded based on V1.6, the SEMIP version used in SE-601C.(K131503). Comparing SEMIP V1.6, the improvements of V1.7 were that the criteria of some diseases are optimized to improve automatic diagnostic accuracy including RVH, MI, T wave abnormal and optimization of some terms and optimize ventricular preexcitation measure method to improve accuracy. The V1.7 algorithms were explicated tested for pediatrics (from starting from birth) and the results were comparable to the V1.8 version of SEMIP.

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-301, SE-300A, SE-300B and SE-3 Electrocardiograph.

10. 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-301, SE-3001A, SE-300B, and SE-3 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. 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-301, SE-300A, SE-300B and SE-3 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.

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.

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. Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that SE-301, SE-300A, SE-300B and SE-3 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-301, SE-300A, SE-300B and SE-3 ELECTROCARDIOGRAPH device is substantially equivalent to the predicate devices.