



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 5, 2016

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

Re: K152427
Trade/Device Name: PC ECG, model SE-1515
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 24, 2015
Received: December 28, 2015

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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152427

Device Name

PC ECG, model SE-1515

Indications for Use (Describe)

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.

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:** Queena Chen
Preparing date: December 24, 2015
- 2. Device name and classification:** **Device Name:** PC ECG
Model: SE-1515
Classification Name/ Product code:
870.2340 Electrocardiograph/DPS
Regulatory Class: Class II
- 3. Predicate Device(s):** 1) EDAN Instrument, Inc. SE-1010, K131819 (Primary)
2) Philips Medical Systems, Philips DXL 12/16-lead ECG Algorithm, K132068 (Reference)
3) Philips Medical Systems, Philips TC70, K113144(Reference)
- 4. Reason for Submission** New product.
- 5. Pre-Submission, IDE** Not applicable, there is no prior submission.
- 6. Device Description:** SE-1515 is a PC-based ECG designed to acquire, process and store ECG signals and analyze and diagnose heart disease. SE-1515 consists of analysis software and sampling boxes, and has four configurations: Wired 18-lead ECG system, Wired 16-lead ECG system, Wired 12-lead ECG system and Wireless 12-lead ECG system.
- Wired 18-lead ECG system consists of analysis software and wired DE18 sampling box.
- Wired 16-lead ECG system consists of analysis software and wired DE15 sampling box. Wired 12-lead ECG system consists of analysis software and wired DP12 sampling box. Wireless

12-lead ECG system contains analysis software, wireless DX12 sampling boxes (DX12 transmitter and DX12 receiver). The communication between DX12 transmitter and DX12 receiver is based on Bluetooth technology.

For stress exercise testing, the user should connect a BP monitor and a treadmill or an ergo meter to the PC.

7. 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.

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-1515 and SE-1010

Item	SE-1515	SE-1010	Remark
510(k) Number	Current Submission	K131819	----
Indications for Use			
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	SE-1010 is a PC-based diagnostic tool intended to acquire, process and store ECG signals from adult and pediatric patients undergoing stress exercise test or resting test. PC ECG is intended to be used only in hospitals and healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by SE-1010 can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinicians on an	Different

	Outpatient Department and Physical Examination Department.	advisory basis only.	
High/Low Pass Filters	DFT Filter: 0.01 Hz/0.05 Hz/0.32 Hz/0.67 Hz AC Filter: 50 Hz/60 Hz/Off EMG Filter: 25 Hz/35 Hz/45 Hz/Off Low Pass Filter: 300 Hz/270 Hz/150 Hz/100 Hz/75 Hz	DFT Filter: weak/strong AC Filter: 50 Hz/60 Hz/Off Low Pass/EMG Filter: 25 Hz/35 Hz/45 Hz/75 Hz/100 Hz/150 Hz	Different
Sampling Box			
----	DE15	DP12	----
Classification			
Anti-electric-shock type	Class II	Class II	Same
Anti-electric-shock degree	Type CF with defibrillation-proof	Type CF with defibrillation-proof	Same
Lead number	16-lead	12-lead	Different
Degree of protection against harmful ingress of water	Sealed equipment without waterproof	Sealed equipment without waterproof	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
Processing			
Sampling Rate	16 kHz /channel	1 kHz /channel	Different
Resolution	0.1575 μ V/LSB @ 1 kHz	2.52 μ V/LSB @ 1 kHz	Different
Time Constant	≥ 3.2 s	≥ 3.2 s	Same
Frequency Response	0.01 Hz ~ 300 Hz	0.05 Hz ~ 150 Hz	Different
Input Impedance	≥ 100 M Ω	> 50 M Ω	Different
Dynamic Range	AC Differential ± 5 mV, DC offset ± 600 mV	AC Differential ± 5 mV, DC offset ± 600 mV	Same
System Noise	≤ 12.5 μ Vp-p	≤ 12.5 μ Vp-p	Same
Common Mode Rejection	≥ 140 dB(AC ON) ≥ 123 dB(AC OFF)	> 110 dB	Different
Pace Detect	± 750 μ V $\sim \pm 700$ mV @ 50 μ s ~ 2.0 ms	± 2 to ± 700 mV @ 0.1 ms to 2.0 ms	Different
ESD Sensitivity	± 6 kV contact	± 6 kV contact	Same

	±8 kV air	±8 kV air	
Heart Rate Meter	30 BPM ~300 BPM, ±1 BPM	30 BPM ~300 BPM, ±1 BPM	Same
	DE18	DP12	
Classification			
Anti-electric-shock type	Class II	Class II	Same
Anti-electric-shock degree	Type CF with defibrillation-proof	Type CF with defibrillation-proof	Same
Lead number	18-lead	12-lead	Different
Degree of protection against harmful ingress of water	Sealed equipment without waterproof	Sealed equipment without waterproof	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
Processing			
Sampling Rate	16 kHz /channel	1 kHz /channel	Different
Resolution	0.1575 μ V/LSB @ 1 kHz	2.52 μ V/LSB @ 1 kHz	Different
Time Constant	≥ 3.2 s	≥ 3.2 s	Same
Frequency Response	0.01 Hz ~ 300 Hz	0.05 Hz ~ 150 Hz	Different
Input Impedance	≥ 100 M Ω	> 50 M Ω	Different
Dynamic Range	AC Differential ± 5 mV, DC offset ± 600 mV	AC Differential ± 5 mV, DC offset ± 600 mV	Same
System Noise	≤ 12.5 μ Vp-p	≤ 12.5 μ Vp-p	Same
Common Mode Rejection	≥ 140 dB (AC ON) ≥ 123 dB (AC OFF)	> 110 dB	Different
Pace Detect	± 750 μ V ~ ± 700 mV @ 50 μ s ~ 2.0 ms	± 2 to ± 700 mV @ 0.1 ms to 2.0 ms	Different
ESD Sensitivity	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Same
Heart Rate Meter	30 BPM ~300 BPM, ± 1 BPM	30 BPM ~300 BPM, ± 1 BPM	Same
DP12 Sampling Box			
Classification			
Anti-electric-shock type	Class II	Class II	Same
Anti-electric-shock degree	Type CF with defibrillation-proof	Type CF with defibrillation-proof	Same
Lead number	12-lead	12-lead	Same
Degree of	Enclosed equipment without	Enclosed equipment without	Same

protection against harmful ingress of water	protection against ingress of water	protection against ingress of water	
Degree of safety of application in the presence of flammable gas	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Same
Working mode	Continuous operation	Continuous operation	Same
Processing			
Sampling Rate	1,000 /sec/channel	1,000 /sec/channel	Same
Resolution	2.52 μ V/LSB @ 1 kHz	2.52 μ V/LSB @ 1 kHz	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
Input Impedance	>50 M Ω @ 10 Hz, defibrillator protected	>50 M Ω @ 10 Hz, defibrillator protected	Same
Dynamic Range	AC Differential ± 5 mV, DC offset ± 600 mV	AC Differential ± 5 mV, DC offset ± 600 mV	Same
System Noise	$\leq 12.5\mu$ Vp-p	$\leq 12.5\mu$ Vp-p	Same
Common Mode Rejection	>110 dB	>110 dB	Same
Pace Detect	± 2 to ± 700 mV@0.1 to 2.0 ms	± 2 to ± 700 mV@0.1 to 2.0 ms	Same
ESD Sensitivity	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Same
Heart Rate Meter	30 BPM ~300 BPM, ± 1 BPM	30 BPM ~300 BPM, ± 1 BPM	Same
DX12 Sampling Box			
Classification			
Anti-electric-shock type	Class II	Class II	Same
Anti-electric-shock degree	Type CF with defibrillation-proof	Type CF with defibrillation-proof	Same
Lead number	12-lead	12-lead	Same
Degree of protection against harmful ingress of water	Enclosed equipment without protection against ingress of water	Enclosed equipment without protection against ingress of water	Same
Degree of safety of application in the presence of flammable gas	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide	Same
Working mode	Continuous operation	Continuous operation	Same

Processing			
Sampling Rate	10,000/sec/channel	10,000/sec/channel	Same
Resolution	2.52 μ V/LSB @ 500 Hz	2.52 μ V/LSB @ 500 Hz	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
Input Impedance	≥ 20 M Ω @ 10 Hz, defibrillator protected	≥ 20 M Ω @ 10 Hz, defibrillator protected	Same
Dynamic Range	AC Differential ± 5 mV, DC offset ± 500 mV	AC Differential ± 5 mV, DC offset ± 500 mV	Same
System Noise	≤ 15 μ Vp-p	≤ 15 μ Vp-p	Same
Common Mode Rejection	≥ 100 dB	≥ 100 dB	Same
Pace Detect	± 2 to ± 500 mV@0.1 to 2.0 ms	± 2 to ± 500 mV@0.1 to 2.0 ms	Same
ESD Sensitivity	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Same
Heart Rate Meter	30 BPM ~300 BPM, ± 1 BPM	30 BPM ~300 BPM, ± 1 BPM	Same
Transmitting Frequency	2402-2480Hz	2402-2480Hz	Same
Frequency Band	2402-2480Hz	2402-2480Hz	Same
Modulation Type	FHSS	FHSS	Same
Transmitting Power	4.65dBm	4.65dBm	Same
Analysis Software			
Operating system	Windows XP SP2/SP3 (32/64 bit), Windows 7 SP1 (32/64 bit) or Windows 8 (32/64 bit)	Windows XP PROFESSIONAL SP2/SP3, Windows Vista (32/64 bit) or Windows 7 (32/64 bit)	Different
Safety requirements	Tested for compliance with IEC 62304	Tested for compliance with IEC 62304	Same
Vector loop	Support the FRANK sampling and Calculating VCG. Can show the FRANK leads X,Y,Z wave and median complexes of the orthogonal FRANK leads X,Y,Z as well as the vector loops in three plans	Support the FRANK sampling and Calculating VCG. Can show the FRANK leads X,Y,Z wave and median complexes of the orthogonal FRANK leads X,Y,Z as well as the vector loops in three plans.	Same
Resting ECG			
Measuring the ECG	Amplitudes(mV),intervals(ms) and slopes(mV/s) can be ensured on all ECG waveforms	Amplitudes(mV),intervals(ms) and slopes(mV/s) can be ensured on all ECG waveforms	Same
Reanalysis	Manually change the	Manually change the	Same

	measurement marks of medians and the interpretation result	measurement marks of medians and the interpretation result	
Interpretation library	Has Interpretation library and can edit	Has Interpretation library and can edit	Same
Exercise Test			
Test Phase	each protocol has three phase: pretest, exercise, recovery	each protocol has three phase: pretest, exercise, recovery	Same
Pretest Phase	Consists of stages configured in each protocol. Commonly used stages are: supine, standing, hyperventilation, warm-up	Consists of stages configured in each protocol. Commonly used stages are: supine, standing, hyperventilation, warm-up	Same
Exercise Phase	The selected protocol will control the treadmill or bicycle ergo-meter	The selected protocol will control the treadmill or bicycle ergo-meter	Same
Recovery phase	The clock begins timing the recovery phase. In recovery, the treadmill speed and grade or the bicycle load will change according to the protocol configuration	The clock begins timing the recovery phase. In recovery, the treadmill speed and grade or the bicycle load will change according to the protocol configuration	Same
Full disclosure ECG	Can save the full disclosure ECG and print either the entire full l disclosure ECG or only a selected segment	Can save the full disclosure ECG and print either the entire full l disclosure ECG or only a selected segment	Same
Final reports	Configured report, tabular summary, graded exercise summary report, selected medians report, sample cardiac cycles, trend report ST/HR Slope, ECG strips	Configured report, tabular summary, graded exercise summary report, selected medians report, sample cardiac cycles, trend report ST/HR Slope, ECG strips	Same
Writer			
Writer Technology	laser printer or jet printer	laser printer or jet printer	Same
Writer Amplitude Accuracy	±5%	±5%	Same
Paper Size	A4, Letter	A4, Letter	Same
Environmental Specifications			
Temperature			
Operating	+5□~+40□	+5□~+40□	Same
Transport/Storage	DP12/DE15 ECG sampling box: -40°C (-8°F) ~ +55°C (+131°F)	DP12 sampling box: -40°C (-8°F) ~ +55°C (+131°F)	Same

	DX12 ECG sampling box: -20°C (-4°F)~+55°C (+131°F)	DX12 ECG sampling box: -20°C (-4°F)~+55°C (+131°F)	
Humidity			
Operating	25% to 80% RH	25% to 80% RH	Same
Transport/Storage	non-condensing 25% to 93% RH non-condensing	non-condensing 25% to 93% RH non-condensing	Same
Pressure			
Operating	860 hPa ~1060 hPa	860 hPa ~1060 hPa	Same
Transport/Storage	700 hPa ~1060 hPa	700 hPa ~1060 hPa	Same

Table 2: Comparison between SE-1515 and DXL 12/16-lead ECG Algorithm

Item	SE-1515	Philips DXL 12/16-lead ECG Algorithm	Remark
510(k) Number	Current Submission	K132068	---
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.	To analyze multi-channel ECG signals from adult and pediatric patients with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user. The interpreted ECG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the ECG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation. Where the clinician decides to evaluate the electrocardiogram of adult and pediatric patients as part of decisions regarding possible diagnosis, potential treatment, effectiveness of treatment or to rule-out causes for symptoms.	Different
Lead Number	12/15/16	12/16	Different

Table 3: Comparison between SE-1515 and Philips TC70

Item	SE-1515	Philips TC70	Remark
510(k) Number	Current Submission	K113144	---
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.	To acquire multi-channel ECU signals from adult and pediatric patients from body surface ECG electrodes and to record, display, analyze and store these ECU signals for review by the user. To be used in healthcare facilities by trained healthcare professionals. Analysis of the ECU signals is accomplished with algorithms that provide measurements, data presentations, graphical presentations and interpretations for review by the user. The interpreted EGG with measurements and interpretive statements is offered to the clinician on an advisory basis only. It is to be used in conjunction with the clinician's knowledge of the patient, the results of the physical examination, the EGG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) the computer generated ECG interpretation.	Different
Lead Number	12/15/16/18	12/16/18	Different

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-1515 PC ECG.

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-1515 PC ECG 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-1515 PC ECG 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.

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.

10. Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that SE-1515 PC ECG 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-1515 PC ECG device is substantially equivalent to the predicate devices.