DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 1, 2016

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

Re: K161302
Trade/Device Name: PC ECG, model PADECG
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: April 28, 2016
Received: May 9, 2016

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,

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)*
K161302

Device Name
PC ECG, model PADECG

Indications for Use *(Describe)*
The intended use of PADECG is to acquire resting ECG signals from adult and pediatric patients through body surface ECG electrodes. It is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by PADECG 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. It is mainly used in ECG inpatient department of hospitals or healthcare facilities.

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 content and format regulatory requirements of 21 CFR Part 807.92

1. Submitter:	Edan Instruments, Inc 3/F - B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, Shekou, Nanshan Shenzhen, 518067 P.R. China Tel: +86(0755) 26858736 Fax: +1 (408) 418-4059
Contact person:	Alice Yang
Preparing date:	June 29, 2016
2. Device name and classification:	**Device Name:** PC ECG, model PADECG **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 Instruments, Inc., SE-1515, K152427
5. Reason for Submission	New Model.
6. Pre-Submission, IDE	Not applicable, there is no Pre-Submission.
7. Device Description:	PADECG is iPad-Based ECG work station. PADECG System primarily composed of DX12(iOS) Transmitter and PADECG Analysis Software, the product is designed to collect and analyzes 12-Lead resting ECG. The DX12(iOS) Transmitter contains lead wires and sends the ECG data to PADECG Analysis Software through Bluetooth. The PADECG Analysis Software will be uploaded to the App Store, so that customers can download it to their own iPad and install it. The PADECG Analysis Software which is installed in the iPad can display the ECG data. The PADECG Analysis Software can analysis the ECG data, and provide an advisory diagnostic result.

8. Indications for Use: The intended use of PADECG is to acquire resting ECG signals from adult and pediatric patients through body surface ECG electrodes. It is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by PADECG 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. It is mainly used in ECG inpatient department of hospitals or healthcare facilities.

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 items, detailed comparison information can be found in the following tables.

Comparison between PADECG and Predicate Device SE-1515

Item	PADECG (Edan Instruments, Inc)	SE-1515 (Edan Instruments, Inc)
510(k) Number	Current Submission	K152427
Intended Use	The intended use of PADECG is to acquire resting ECG signals from adult and pediatric patients through body surface ECG electrodes. It is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by PADECG 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. It is mainly used in ECG inpatient department of hospitals or healthcare facilities.	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.
Lead Number	12	12/15/16/18
Analysis time	10s	10s
Measuring the ECG	Amplitudes(mV),intervals(ms) and slopes(mV/s) can be ensured on all	Amplitudes(mV),intervals(ms) and slopes(mV/s) can be ensured on all

Item	PADECG (Edan Instruments, Inc)	SE-1515 (Edan Instruments, Inc)
	ECG waveforms	ECG waveforms
Reanalysis	Manually change the measurement marks of medians and the interpretation result	Manually change the measurement marks of medians and the interpretation result
Vector loop	Do not support the 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
Interpretation library	Has Interpretation library and can edit	Has Interpretation library and can edit
Algorithm	Algorithm of the Smart ECG Measurement and Interpretation Programs(SEMIP), version 1.8	Algorithm of the Smart ECG Measurement and Interpretation Programs(SEMIP), version 1.8
CPU	Apple A5 or above	Pentium P4, Celeron D 310 or above
System Memory (RAM)	/	1G or above
Capacity/Hard Disk	16GB or above	128GB or above
Printer	/	ink jet printer of more than 300dpi or laser printer Recommend HP2035, HP2010, CANON iP1980
Display	iPad 4:9.7’1536×2048 iPad Air 1: 9.7’1536×2048 iPad Mini 2:7.9’1536×2048 iPad Mini 1:7.9’1024×768	17" TFT (Resolution: 1280*1024, 1366*768), 19" TFT (resolution: 1440×900), 21" TFT(1920*1080)
Operating System	iOS 7,iOS 8, iOS 9	Windows XP SP3 (32 bit), Windows 7 SP1 (32/64 bit) or Windows 8 (32/64 bit), Windows 8.1 (32/64 bit)
Operating	DX12 (iOS) Transmitter: +5□~+40□	DX12 Transmitter: +5□~+40□
Transport/Storage	DX12 (iOS) Transmitter: -20ºC (-4ºF)~+55ºC	DX12 Transmitter: -20ºC (-4ºF)~+55ºC
Operating	DX12 (iOS) Transmitter: 15%~95% Non-Condensing	DX12 Transmitter: 25% to 80% RH
Transport/Storage	DX12 (iOS) Transmitter: 15%~95% Non-Condensing	DX12 Transmitter: 25% to 93% RH non-condensing

Item	PADECG (Edan Instruments, Inc)	SE-1515 (Edan Instruments, Inc)
Safety Standards	IEC60601-1 IEC60601-1-2 IEC60601-2-25 IEC60601-1-6 EN ISO14971	IEC60601-1 IEC60601-1-2 IEC60601-2-25 IEC60601-1-6 EN ISO14971
Data Transmission	Wireless Bluetooth Technology(Version:2.0,Frequency：2402-2480Hz)	USB interface and Wireless Bluetooth Technology(Version:2.0,Frequency：2402-2480Hz)
Anti-electric-shock type	Class II	Class II
Anti-electric-shock degree	Type CF with defibrillation-proof	Type CF with defibrillation-proof
Lead number	12-lead	12-lead
Degree of protection against harmful ingress of water	Enclosed equipment without protection against ingress of water	Enclosed equipment without 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
Working mode	Continuous operation	Continuous operation
Sampling Rate	10,000/sec/channel(sampling)	10,000 /sec/channel (sampling)
Resolution	2.52uV/LSB	2.52uV/LSB
Time Constant	≥3.2 s	≥3.2 s
Frequency Response	0.05 Hz ~ 150 Hz (-3 dB)	0.05 Hz ~ 150 Hz (-3 dB)
Input Impedance	≥20MΩ (10Hz)	≥20MΩ (10Hz)
System Noise	≤15μVp-p	≤15μVp-p

Item	PADECG (Edan Instruments, Inc)	SE-1515 (Edan Instruments, Inc)
Dynamic Range	AC Differential ± 5mV, DC offset ±500mV	AC Differential ± 5mV, DC offset ±500mV
Common Mode Rejection	≥100 dB	≥100 dB
Pace Detect	±2 to ±500 mV@0.1 to 2.0ms	±2 to ±500 mV@0.1 to 2.0ms
ESD Sensitivity	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air
Heart Rate Meter	30 BPM ~300 BPM ， ±1BPM	30 BPM ~300 BPM ， ±1BPM
High/Low Pass Filters	AC Filter: 50 Hz/60 Hz/Off DFT Filter: 0.32Hz/0.67Hz/0.05Hz EMG Filter: 25Hz/35Hz/45Hz/Off Lowpass Filter: 150Hz/100Hz/75Hz/Off	AC Filter: 50 Hz/60 Hz/Off DFT Filter: 0.01 Hz/0.05 Hz/0.32 Hz/0.67 Hz EMG Filter: 25 Hz/35 Hz/45 Hz/Off Low Pass Filter: 300 Hz/270 Hz/150 Hz/100 Hz/75 Hz

All the differences don't affect the safety and effectiveness which is concluded after all the required testing, so no safety and effectiveness issues relating to the system come into conclusion.

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 PADECG 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. And the accessories of PADECG are all cleared.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the PADECG PC ECG device, consisting of all the accessories in the system. The system complies with the IEC 60601-1:2005/A1: 2012 standards for safety and the IEC 60601-1-2: 2007 for EMC.

Bench Testing

Bench testing was conducted on the PADECG PC ECG device, consisting of all the accessories in the system. The system complies with the IEC 60601-2-25: 2011 and IEC

62366: 2007 standards.

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 PADECG 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 PADECG PC ECG device is substantially equivalent to the predicate devices.