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

August 9, 2016

ACME Portable Machines, Inc.
James Cheng
General Manager
1330 Mountain View Circle
Azusa, California 91702

Re: K152135
Trade/Device Name: Quantitative Electrocardiographic Detector (QED 2000)
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: July 7, 2016
Received: July 11, 2016

Dear James Cheng:

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,

Brian D. Pullin -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4 – Indications for Use Statement

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)*
K152135

Device Name
Quantitative Electrocardiographic Detector (QED2000)

Indications for Use *(Describe)*
Intended Use:

The intended use of the QED2000 is to record 12-lead ECG signals from patient's heart activity through body surface ECG electrodes. This device can acquire, display, record, analyze, and store these ECG signals from adult patients for review by the user. Analysis of the ECG signals is accomplished with algorithms that provide data presentations, graphical presentations, and measurements. These are presented for review and interpretation by a trained physician or clinician in determining a diagnosis based upon knowledge of the patient, the result of physical examination, and other clinical findings.
The QED2000 is intended to be used in hospital and general physician's office by trained healthcare professionals.

Indications for Use:

The QED2000 is intended to be used to acquire, display, record, analyze, and store 12-lead ECG waveforms from adult patients through body surface ECG electrodes. Using algorithms to generate data presentations, graphical presentations, and measurements for review and interpretation by a trained physician or clinician in determining a diagnosis based upon knowledge of the patient, the result of physical examination, and other relevant clinical findings.
The QED2000 is intended to be used in hospital and general physician's office by trained healthcare professionals. The QED2000 is not intended to be used as a cardiac monitor.

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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Section 5 – 510(k) Summary

1. **Submitter**
   ACME Portable Machines, Inc.

   1330 Mountain View Circle, Azusa, California 91702
2. **Contact Person**
   Karen Ngai, specialist

   Phone: (626) 610-1888

   Email: karen@acmeportable.com
3. **Date Prepared**
   April 22, 2015
4. **Trade Name**
   Quantitative Electrocardiographic Detector (QED 2000)
5. **Classification**
   Class II

   Electrocardiograph

   21 CFR 870.2340
6. **Product Code**
   DPS
7. **Predicate Device(s)**
   The subject device is equivalent to the following devices:

   K113144: “Pagewriter TC 20, 30, 50, 70”; Philips Medical Systems

   K110266: “MAC 5500 HD, MAC 3500”; GE Medical Systems Information Technologies, Inc.
8. **Device Description**
   The Quantitative Electrocardiographic Detector (QED2000) is a 12-lead resting electrocardiograph. It is a device for acquiring, displaying, analyzing and storing the 12-lead electrocardiogram.

   The device can print the resting ECG report via the external printer including USB printer and network printer. The device has optional removable storage to store resting ECG records. The device also can export the resting ECG record to SD card/shared directory/FTP server as an optional function. An optional USB barcode reader and magnetic card scanner to enter patient information is also available.
9. **Intended Use**
   The intended use of the QED2000 is to record 12-lead ECG signals from patient’s heart activity through body surface ECG electrodes. This device can acquire, display, record, analyze, and store these ECG signals from adult patients for review by the user. Analysis of the ECG signals is accomplished with algorithms that provide data presentations, graphical presentations, and measurements. These are presented for review and interpretation by a trained physician or clinician in determining a diagnosis based upon knowledge of the patient, the result of physical examination, and other clinical findings.
   The QED2000 is intended to be used in hospital and general physician’s office by trained healthcare professionals.
10. **Non-clinical Testing In Support of Substantial Equivalence Determination**
    Non-clinical tests were conducted to verify that the proposed device meets all design specifications as is substantially equivalent to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

    IEC 60601-1:2005 + CORR.1(2006) + CORR.2(2007) +AM1(2012), Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

    EN 60601-1-2:2007+AC:2010, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-2-25:2011, Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.

IEC 60601-2-27:2011, Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance of electrocardiographic monitoring equipment.

Software Verification Test was performed to verify the software functions against its intended use.

The collective results of the non-clinical testing demonstrate that the QED2000 meets the established specifications and complies with the aforementioned standards.

11. **Substantially Equivalent (SE) Conclusion**

Table 1 Comparison with Predicate Devices

Characteristic	ACME QED2000	GE MAC® 5500 HD	Philips PageWriter ®
510(k) Number		K110266	K113144
510(k) Decision Date		04/29/2011	04/03/2012
Manufacturer	Acme Portable Machine, Inc.	GE Medical Systems Information Technologies, Inc.	Philips Medical Systems
Classification	Electrocardiograph	Electrocardiograph	Electrocardiograph
Product Code	DPS	DPS	DPS
Regulation	870.2340	870.2340	870.2340
Indications for Use	The QED2000 is intended to be used to acquire, display, record, analyze, and store 12-lead ECG waveforms from adult patients through body surface ECG electrodes. Using algorithms to generate data presentations, graphical presentations, and measurements for review and interpretation by a trained physician or clinician in determining a diagnosis based upon knowledge of the patient, the result of physical examination, and other relevant clinical findings. The QED2000 is intended to be used in hospital and general physician's office by trained healthcare professionals. The QED2000 is not	MAC 5500 HO: The MAC 5500 HD ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information from adult and pediatric populations. Basic systems deliver 3; 6, 12, or 15 lead ECGs; interpretive analysis, vector loops. and can be upgraded to provide software analysis options such as high resolutions signal averaging of QHS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional. The MAC 5500 HD is intended to be used under the direct supervision, of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.	To acquire multi-channel EGG signals from adult and pediatric patients from body surface electrodes and to record, display, analyze and store these EGG signals for review by the user. To be used in healthcare facilities by trained healthcare professionals. Analysis of the EGG signals is accomplished with algorithms accomplished with algorithms that 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 conjunction with the clinician's knowledge of the patient, the results of

	intended to be used as a cardiac monitor.		the physical examination, the EGG tracings, and other clinical findings. A qualified physician is asked to over read and validate (or change) computer generated ECG interpretation.
Data Acquisition: Sampling Rate	3000 sample/s	4000 sample/s	2000 sample/s
ECG Leads	12 leads	12 leads	12 leads
Data Entry Interface	Touch Display	Keyboard	Keyboard
Gain Settings	5, 10, 20 mm/mV	2.5, 5, 10, 20 mm/mV	2.5, 5, 10, 20 mm/mV
Time base Settings	25, 50 mm/s	5, 25, 50 mm/s	25, 50 mm/s
Filter Frequency	0.067 Hz 40,100,150 Hz	0.04 Hz 40,100,150 Hz	0.05 Hz 40,100,150 Hz
Algorithms	ACME 12-lead ECG measurement algorithm	Marquette 12SL ECG analysis program	Phillips 12-lead ECG algorithm
Display Type	Color TFT	Color TFT	Color TFT
Display Pixel Resolution	1920 x 1080	800 x 480	640 x 480
Electrical Safety	Comply with IEC 60601-1	Same	Same
EMC	Comply with IEC 60601-1-2	Same	Same
Particular requirements	Comply with IEC 60601-2-25	Same	Same

Note:

1. The proposed device provides different sampling rate with those of the predicate devices. This difference will not affect the safety and effectiveness of the proposed devices.
2. The proposed device provides a bandwidth slightly narrower than those of the predicate devices. This difference will not affect the safety and effectiveness of the proposed devices.
3. The proposed device provides different gain and time base with those of the predicate devices. This difference will not affect the safety and effectiveness of the proposed devices.
4. The proposed device provides higher display resolution than those of the predicate devices. This difference will not affect the safety and effectiveness of the proposed devices.

Table 2 Algorithms Comparison with Predicate Devices

Characteristic	ACME QED2000	GE MAC® 5500HD	Philips PageWriter ®
Algorithms Name	ACME 12-lead ECG measurement algorithm	Marquette* 12SL* ECG Analysis Program	Phillips 12-lead Algorithm
Analyze Data Type	12 leads 10 seconds unfiltered ECG data with 1000 sampling rate	12 leads 10 seconds unfiltered ECG data with 500 sampling rate	12 leads 10 seconds unfiltered ECG data with 500 sampling rate
Measurement parameters	All 12 leads P, QRS, T amplitudes and intervals. Global values with Heart rate, P duration, PR interval, QRS duration, QT interval, QTc and P, QRS, T axes.	All 12 leads P, QRS, T amplitudes and intervals. Global values with Heart rate, P duration, PR interval, QRS duration, QT interval, QTc and P, QRS, T axes.	All 12 leads P, QRS, T amplitudes and intervals. Global values with Heart rate, P duration, PR interval, QRS duration, QT interval, QTc and P, QRS, axes.

Table 3 Comparison with Predicate Devices

IEC calibration ECGs								
	IEC 60601-2-25 Standard		ACME QED2000		GE MAC5500		Philips TC30	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
PR-interval (ms)	±10	8	4.5	5.4	-6.8	1.7	-4.9	2.8
QRS-duration (ms)	±6	5	-0.1	2.2	1.4	1.5	2.5	3.0
QT-Interval (ms)	±12	10	-0.8	1.1	-0.2	5.1	2.2	3.2
Biological ECGs: CSE Database								
	Standard		ACME QED2000		GE MAC5500		Philips TC30	
	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation	Mean	Standard Deviation
PR-interval (ms)	±10	10	0.7	7.4	-4.2	4.5	2.9	6.1
QRS-duration (ms)	±10	10	-0.3	8.3	-5.6	5.2	-3.2	3.8
QT-Interval (ms)	±25	30	4.9	11.5	0.5	8.3	0.9	7.9

12. **Conclusion**

Based on the performance testing and comparison with predicate devices, the results of the nonclinical testing, technical and functional characteristics demonstrate that the QED 2000 is substantially equivalent to the predicate devices and as safe as effective as the predicates.