December 15, 2017

Vales & Hills Biomedical Tech. Ltd.
% Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
No. 55 Shizhou Middle Road, Nanshan District
Shenzhen, 518000 CN

Re: K163607
Trade/Device Name: ECG Acquisition Systems
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: November 11, 2017
Received: November 17, 2017

Dear Field Fu:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K163607

Device Name
ECG Acquisition Systems

Indications for Use *(Describe)*

The ECG Acquisition Systems is intended to acquire a resting, diagnostic 12-lead ECG for display and subsequent upload to vhECG Pro, which installed in iPad or iPhone. This enables clinicians, or trained care personnel who are acting on the orders of a licensed physician, to acquire, process, display, store, and print diagnostic 12-lead ECGs.

The ECG Acquisition Systems is for use on adult and pediatric populations, diseased or non-diseased and is not intended for use on neonatal (birth to 28 days) or infants (29 days up to 2 years). The device is not for use as a vital signs physiological monitor.

The subject device is intended to be used for clinical use rather than home use. It can be used in a professional healthcare facility, or a clinical environment such as clinics. It cannot be used in transport environment, such as ambulance.

The ECG Acquisition Systems provides uninterpreted 12-lead ECG data and is not to be a sole means of diagnosis.

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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VOL_005: 001_510(k) Summary

1. Administrative Information

Submission Date	Dec, 12, 2016
Manufacturer information	Submitter's Name: VALES & HILLS BIOMEDICAL TECH. LTD. Address: Bldg. 46-1, No.2 North Street Jingyuan, Beijing Economic-technological Development Aera, 100176 Beijing, China Guangdong, China 518101 Contact person: Melody Huang TEL: +86-10-51665548 FAX: +86-10-67856343 E-Mail: liu@vhmedical.com
Submission Correspondent	Company Name: Shenzhen Joyantech Consulting Co., Ltd. Address: Room 1122, International Mayors Communication Centre, NO. 55 Shizhou Zhong road, Nanshan District, Shenzhen,China. Contact person: Mr. Field Fu E-Mail: cefda13485@163.com
Establishment registration number	Unknown.

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	ECG Acquisition Systems

Model:	iCV200(BLE)
Classification name:	Electrocardiograph
Review Panel:	Cardiovascular
Product Code:	DPS
Device Class:	II
Regulation Number:	870.2340

3. Predicate Device Information

Sponsor:	Spaulding Clinical Research, LLC
Device:	Spaulding Electrocardiograph 2100iQ
510(K) Number:	K150564

4. Device Description

The ECG Acquisition Systems is a hand-held, battery powered, 12-lead resting electrocardiograph system with vhECG Pro software. The ECG Acquisition Systems consists of ECG Acquisition Recorder, Patient Cable and vhECG Pro software. ECG data is transferred via Bluetooth® 4.0 Technology and displayed on mobile screen in real-time before, during and after acquisition. With vhECG Pro, resting ECGs can be recorded, viewed and printed in various formats. Besides, ECGs can also be uploaded to vhCloud (cloud platform) by vhECG Pro, they can be reviewed by other medical staff authorized via its iPhone or iPad in which vhCloud is installed. The device is intended to provide reference for medical diagnosis, not intended for a replacement of diagnosis of clinicians.

5. Intended Use/ Indications for Use

The ECG Acquisition Systems is intended to acquire a resting, diagnostic 12-lead ECG for display and subsequent upload to vhECG Pro, which installed in iPad or iPhone. This enables clinicians, or trained care personnel who are acting on the

orders of a licensed physician, to acquire, process, display, store, and print diagnostic 12 lead ECGs.

The ECG Acquisition Systems is for use on adult and pediatric populations, diseased or non-diseased and is not intended for use on neonatal (birth to 28 days) or infants (29 days up to 2 years). The device is not for use as a vital signs physiological monitor.

The subject device is intended to be used for clinical use rather than home use. It can be used in a professional healthcare facility, or a clinical environment such as clinics. It cannot be used in transport environment, such as ambulance.

The ECG Acquisition Systems provides uninterpreted 12-lead ECG data and is not to be a sole means of diagnosis.

6. Technological characteristics of the subject device compared to the predicate device

Items	Predicate Device (K150564), Spaulding Clinical	Subject Device	Comparison
Intended use/ Indications for use	The Spaulding Electrocardiograph 2100iQ is intended to acquire a resting, diagnostic 12-lead ECG for display and subsequent upload to a Medical Device Data System (MDDS). This enables clinicians, or trained care personnel who are acting on the orders of a licensed physician, to acquire, process, display, store, and print diagnostic 12	The ECG Acquisition Systems is intended to acquire a resting, diagnostic 12-lead ECG for display and subsequent upload to vhECG Pro, which installed in iPad or iPhone. This enables clinicians, or trained care personnel who are acting on the orders of a licensed physician, to acquire, process, display, store, and print diagnostic 12 lead ECGs. The ECG Acquisition Systems is for use on adult and pediatric populations, diseased or non-diseased and is not intended for use	Same

Items	Predicate Device (K150564), Spaulding Clinical	Subject Device	Comparison
	lead ECGs. The Spaulding Electrocardiograph is for use on adult and pediatric populations, diseased or non-diseased and is not intended for use on neonatal (birth to 28 days) or infants (29 days up to 2 years). The device is not for use in highly invasive environments, or as a vital signs physiological monitor. The Spaulding Electrocardiograph provides uninterpreted 12-lead ECG data and is not to be a sole means of diagnosis.	on neonatal (birth to 28 days) or infants (29 days up to 2 years). The device is not for use as a vital signs physiological monitor. The subject device is intended to be used for clinical use rather than home use. It can be used in a professional healthcare facility, or a clinical environment such as clinics. It cannot be used in transport environment, such as ambulance. The ECG Acquisition Systems provides uninterpreted 12-lead ECG data and is not to be a sole means of diagnosis.	
Patient Cable	Proprietary 12-Lead Patient Cable	iCV200(BLE) 12-Lead Patient Cable	Different (**Note01**)
Leads	12-Lead	12-Lead	Same
Power source	An internal polymer lithium ion 3.7V rechargeable battery	Two internal AA LR06 batteries each at 1.5V non-rechargeable batteries	SE
ECG Data Transfer	Data transfer via Bluetooth® Technology	Data transfer via Bluetooth® Technology	Same
Bluetooth Version	Bluetooth 2.0+	Bluetooth 4.0	SE
Software	Spaulding Client Application	vhECG Pro Software	Different

Items	Predicate Device (K150564), Spaulding Clinical	Subject Device	Comparison
Component	Software		(**Note02**)
Client Software platform	Mobile device	Mobile device (iPhone, iPad)	SE
ECG Interpretation	No	No	Same
ECG Display	ECG data is displayed on mobile screen in real-time before, during, and after acquisition. Acquired ECG displayed before and after upload.	ECG data is displayed on mobile screen in real-time before, during, and after acquisition. Acquired ECG displayed before and after upload.	Same
Filter	High pass filter to remove baseline wander ; Adaptive band-reject filter for power line noise	Highpass filter, Lowpass filter, AC notch filter, Baseline wander erase and EMG filter	SE
Internet access	Internet access is required for ECG data upload and retrieval.	Internet access is required for ECG data upload and retrieval.	Same
Materials	Device enclosure: ABS Polycarbonate.	Device enclosure: ABS Polycarbonate.	SE
Gain	2.5, 5, 10, 20, 40 mm/mV	5, 10, 20 mm/mV	SE
Sampling Rate	500 s/sec/channel (Hz)	500 Hz	SE
Chart Speed	5, 10, 12.5, 25, 50 mm/s	12.5mm/s, 25mm/s, 50mm/s	SE
Frequency Response	0.05 to 250 Hz	0.05 to 150 Hz	Different (**Note03**)
ECG display	User Selectable	User Selectable	SE

Items	Predicate Device (K150564), Spaulding Clinical	Subject Device	Comparison
formats	12-Lead, 12×1, 6×1, 4×1, 3×1, 2×1, 1×1, 6×2, 4×2, 3×2, 2×2, 1×2	3×4, 6×2, 12×1	
Performance	IEC 60601-2-25:2011 Particular requirements for the basic safety and essential performance of electrocardiographs	IEC 60601-2-25:2011 Particular requirements for the basic safety and essential performance of electrocardiographs	SE
Biocompatibility Safety	ISO 10993 Part 1, Part 5, Part 10	ISO 10993 Part 1	Different (**Note04**)
Electric and EMC Safety	IEC 60601-1 3rd edition: 2005, IEC 60601-1-2: 2007, IEC 60601-2-25:2013	IEC 60601-1 3rd edition: 2005, IEC 60601-1-2: 2007, IEC 60601-2-25:2013	SE
Water ingress and particulate matter rating	IP22	IPX0	Different (**Note05**)
Applied Part Classification	TYPE CF	TYPE CF	Same
Patient Cable Safety	AAMI/ANSI EC53:2013 ECG Trunk Cables and Patient Leadwires	AAMI/ANSI EC53:2013 ECG Trunk Cables and Patient Leadwires	SE
Cleaning/ disinfection	The ECG device, the 12-lead ECG Patient Cable, and leadwires are cleaned by a mild detergent and warm water solution.	The ECG device (Recorder), the 12-lead ECG Patient Cable, and leadwires are cleaned and disinfected by 70%	Different (**Note06)**

Items	Predicate Device (K150564), Spaulding Clinical	Subject Device	Comparison
		alcohol.	

Note01: The iCV200(BLE) 12-Lead Patient Cable had passed the safety test according to AAMI/ANSI EC53:2013.

Note02: The vhECG Pro Software has been validated and the hazards and risks have been indentified and controlled in relevant software information documents. The differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note03: The bandwidth 0.05 to 150 Hz is the common frequency range, such as the products marketed in US through clearance K160840, K160876 and K102830 (cited in K160876 summary) .

Note04: A biocompatibility test evaluation report has been provided to explain the reason for exempting the biocompatibility tests.

Note05: The subject device provides no degrees of protection against water, thus it is not suitable for use in the environment with water.

Note06: The Cleaning method has been described in the instruction for use.

The subject device and the predicate device have the same intended use and similar technological characteristics. They both use Bluetooth® Technology to transfer ECG data. They are compact, small and light-weight. Though they are different in Biocompatibility Safety, Water ingress and particulate matter rating and Cleaning/ disinfection, these differences do not raise any new questions.

Thus, the subject device is substantially equivalent to the predicate devices.

7. Brief discussion of the nonclinical tests

The nonclinical tests of the ECG Acquisition Systems are listed as below table:

Tests Item	Test Standards/ Guidance	Results
Electric Safety	IEC 60601-1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Pass
EMC	1) IEC 60601-1-2: 2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests; 2) 47 CFR PART 15 Subpart C, Radio Frequency Devices Subpart C – Intentional Radiators 3) ESTI EN 301 489-1 V1.9.2 (2011), Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; 4) ESTI EN 301 489-17 V2.2.1 (2012), Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems; 5) ESTI EN 300328 V1.8.1 (2012), Electromagnetic compatibility and Radio	Pass

Tests Item	Test Standards/ Guidance	Results
	spectrum Matters(ERM); Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R & TTE Directive.	
QoS testing	Guidance for Industry and Food and Drug Administration Staff: Radio Frequency Wireless Technology in Medical Devices	Pass
Wireless coexistence	47 CFR PART 15 Subpart C, Radio Frequency Devices Subpart C – Intentional Radiators; EN 300328 V1.8.1, Electromagnetic compatibility and Radio spectrum Matters(ERM); Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive	Pass
ECG performance	IEC 60601-2-25, Medical electrical equipment – Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	Pass
Patient cable performance	AAMI ANSI EC53, Ecg trunk cables And patient leadwires	Pass
Software Verification and Validation Testing	Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	Pass

8. Clinical test conclusion

Clinical data is not applicable for this submission.

9. Conclusions

Based on the above information, we conclude the subject device, iCV200(BLE) ECG Acquisition Systems, is substantially equivalent to the predicate device.