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

January 22, 2015

Shenzhen Biocare Bio-Medical Equipment Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CH

Re: K133985
Trade/Device Name: Digital Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 3, 2014
Received: December 5, 2014

Dear Diana Hong,

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,

Melissa A. Torres -S

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

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)*
K133985

Device Name
Digital Electrocardiograph ECG-2000

Indications for Use *(Describe)*
Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Tab #3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K133985

1. Date of Submission: 01/07/2015

2. Sponsor Identification

Shenzhen Biocare Bio-Medical Equipment Co., Ltd
Room A735, Floor 7, Tower A, Shenzhen Famous Industrial Products Procurement & Exhibition Center,
No. 168 Baoyuan Road, Baoan, Shenzhen, 518102, P.R. China

Establishment Registration Number: 3008457078

Contact Person: Mr. Hongbo Zhong
Position: Director
Tel: +86-755-36615333-8856
Fax: +86-755-27960643
Email: hb-zhong@tom.com

3. Submission Correspondent

Ms. Diana Hong & Mr. Lee Fu
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120, China
Tel: +86-21-22815850
Fax: 240-238-7587
Email: info@mid-link.net

4. Proposed Device Identification

Proposed Device Name: Digital Electrocardiograph
Model: ECG-2000
Proposed Device Common Name: Electrocardiograph

Regulatory Information:
Classification Name: Electrocardiograph
Classification: II;
Product Code: DPS;
Regulation Number: 21 CFR part 870.2340;
Review Panel: Cardiovascular;

Intended Use Statement:
Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

5. Predicate Device Identification

Predicate Device 1
510(k) Number:K092010
Product Name: PC ECG
Manufacturer: Edan Instruments, Inc.

Predicate device 2
510(k) Number: K123816
Product Name: Digital Electrocardiographs iE 12A
Manufacturer: Shenzhen Biocare Electronics Co., Ltd

6. Device Description

Digital Electrocardiograph, ECG-2000, is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease.

It consists of the acquisition box, optional accessories, installation CD, and USB dongle. The acquisition box is connected with ECG electrodes, and intends to acquire ECG signals from patient. The acquired ECG signal is filtered and amplified, then transferred to the working station. The acquisition box is

powered by the working station via a USB line. The working station is a Personal Computer installed with ECG-2000 Software, it intends to receive the processed ECG signal from the acquisition box, and further display and record the signals. Optional accessories include lead wires, limb electrodes and chest electrodes, and general-purpose printer (with USB interface, support PCL language, such as HP1010, P2035, and P2055d series). The CD contains Digital Electrocardiograph installer and dongle installation program module.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) 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.
Software Verification Test was performed to verify the software functions against its intended use.

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, technological characteristics and principles of operation, etc.

Table 3-1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device1	Predicate Device 2
Product Code	DPS	Same	Same
Regulation Number	21 CFR 870. 2340	Same	Same
Class	Class II	Same	Same
Intended Use	Digital Electrocardiograph is intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiograph	Similar	Similar

	shall be used in healthcare facilities by doctors and/or trained healthcare professionals.		
Configuration	Chest Electrode and Limb Electrode	Same	Same
ECG Lead	Standard 12-lead	Same	Same
ECG Gain	1.25, 2.5, 5, 10, 20, 10-5, 20-10 (mm/mV)	Similar	Same
Sampling rate	1000Hz	Same	Same
Input circuit current	≤0.1 μA	Similar	Same
Noise level	<15μ Vp-p	Similar	Same
Electrical Safety	Comply with IEC 60601-1	Same	Same
EMC	Comply with IEC 60601-1-2	Same	Same
Patient-contact Material	Chest Electrode: Metal Limb Electrode: ABS	Same	Same

SE Discussion

The proposed device provides more options for gains than those of the predicate device 1, therefore, this difference will not affect the safety and effectiveness;

The proposed device provides a wider range of bandwidth than that of the predicate device 1. Therefore, the difference will not affect the safety and effectiveness of the proposed device.

The noise level and input circuit current of the proposed and predicate device 1 are different, however both the specifications comply with IEC 60601-1.

SE Conclusion

The proposed device, Digital Electrocardiograph EG-2000, is determined to be Substantially Equivalent (SE) to the predicate devices, PC ECG (K092010) and Digital Electrocardiographs iE 12A (K123816), in respect of safety and effectiveness.