January 11, 2018

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

Re: K171517
Trade/Device Name: Digital Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 12, 2017
Received: December 14, 2017

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.

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)*

K171517

Device Name
Digital Electrocardiograph

Indications for Use *(Describe)*

The intended use of electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

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 #7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation: 04/12/2017

2. Sponsor Identification

Shenzhen Biocare Bio-Medical Equipment Co.,Ltd.
#16-1, Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan New District, 518102 Shenzhen, China

Establishment Registration Number: 3008457078

Contact Person: Mr. Hongbo Zhong
Position: R&D Director
Tel: +86-0755-36615333
Fax: +86-0755-27960643
Email: hb-zhong@tom.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Jing Cheng (Alternative Contact Person)

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. Identification of Proposed Device

Trade Name: Digital Electrocardiograph;
Common Name: Electrocardiograph;
Models: iE 10

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

Intended Use Statement:
The intended use of electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

Device Description:
The proposed device can acquire ECG signal via twelve leads simultaneously, display or print waveform of ECG signal. The ECG electrical signals from patient body surface are acquired by disposable ECG electrodes; after been amplified, filtered and transferred, the ECG signal waveforms are displayed on the LCD and recorded on the paper via an external printer.

The proposed device is a modification to the predicate device, Digital Electrocardiograph, cleared under K141946.

5. Identification of Predicate Device

510(k) Number: K141946
Product Name: Digital Electrocardiograph;
Manufacturer: Shenzhen Biocare Bio-Medical Equipment Co., Ltd.

6. 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.

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

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 teats.

7. Substantially Equivalent

Table 1 Substantially Equivalent Comparison

ITEM	**Proposed Device, Digital Electrocardiograph**	**Predicate Device, Digital Electrocardiograph, K141946**
Model	iE 10	iE 12
Product Code	DPS	DPS
Regulation No.	21 CFR 870.2340	21 CFR 870.2340
Class	II	II

Intended Use	The intended use of electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.	The intended use of electrocardiograph is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.
Patient Population	Adult and pediatric patients	Adult and pediatric patients
Intended Environment	Hospital or Healthcare facilities	Hospital or Healthcare facilities
Portable	Yes	No
Size	194 mm×117 mm×25 mm	345mm×260mm×80mm
Weight	About 0.5 kg	About 4.6 kg
Configuration	ECG unit, patient cable, power adaptor	ECG unit, patient cable, power adaptor, built-in printer and reusable electrodes
Contraindication	Not specified	Not specified
Automated analysis	Yes	Yes
Lead	Standard 12-lead	Standard 12-lead
Acquisition mode	Simultaneous 12-lead acquisition	Simultaneous 12-lead acquisition
Recording format	Automatic / Manual / Rhythm	Automatic / Manual / Rhythm
Key mode	Touch screen	Keyboard
CMRR	>110dB	>60dB, >100 with AC filter
Time reference	6.25 mm/s, 12.5mm/s, 25 mm/s, 50 mm/s	6.25 mm/s, 12.5mm/s, 25 mm/s, 50 mm/s
Input CIR current	≤ 0.1μA	≤ 0.1μA
Patient leak current	<10μA	<10μA
Frequency response	0.01～250Hz	0.05～150Hz
Noise level	<15μVp-p	<15μVp-p
AC Power supply	100 V～240 V, 50 Hz/60 Hz	100 V～240 V, 50 Hz/60 Hz
DC Power supply (battery)	Rechargeable lithium battery, 3.7 V/ 5800mAh	Sealed maintenance-free rechargeable battery, 14.8V-2200mAh

Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
Particular Safety	Comply with IEC 60601-2-25	Comply with IEC 60601-2-25
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2

The main differences between proposed device and predicate device include product portability, size, weight, configuration, touch screen type, CMRR and battery specification. The proposed device and predicate device has the same indications for use, target population, using environment and functional modes including automated analysis. Both proposed device and predicate device comply with the same standards and the relevant tests demonstrate the safety and effectiveness.

The proposed device, Digital Electrocardiograph iE 10, is determined to be Substantially Equivalent (SE) to the predicate device, Digital Electrocardiograph iE 12, (K141946), in respect of safety and effectiveness.