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

February 12, 2016

Shenzhen Biocare Bio-medical Equipment Co., Ltd.
Ms. Diana Hong
General Manager
P.O. Box 120-119
Shanghai, 200120 CN

Re: K160092
Trade/Device Name: Digital Electrocardiograph, iE101 and iE300
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 29, 2015
Received: January 15, 2016

Dear Ms. 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.

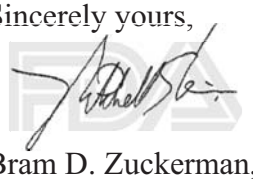
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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)*
K160092

Device Name
Digital Electrocardiograph, iE101 and iE300

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. The proposed device has analysis feature, 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.

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K160092

510(k) Summary

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

The assigned 510(k) Number: K160092

1. Date of Preparation: 01/21/2016

2. Sponsor Identification

Shenzhen Biocare Bio-Medical Equipment Co.,Ltd
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3. Designated Submission Correspondent

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

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Digital Electrocardiograph;
Common Name: Electrocardiograph
Models: iE 101 and iE300

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. The proposed device has analysis feature, however the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.

Device Description

The proposed digital electrocardiograph, iE 101 and iE 300, are designed based on the cleared digital electrocardiographs K141946 (iE 3). The proposed device has same intended use, functional modules design, working modes, analysis function and accessories. the proposed devices are different than the predicate device in that they has new printing channel (one channel for iE 101); new layout of user-machine interface; three different physical specification, such as screen size, device dimension, device weight; three different specification, such as battery capacity, noise level and CMRR; and a modified software which is modified to applicable to the proposed devices.

The proposed electrocardiographs, iE 101 and iE 300, follow the same design principle, main components, accessories and software; they acquire ECG electrical signals from patient body surface by ECG electrodes. After been amplified, filtered and transferred, the ECG signal waveforms are displayed on the LCD and recorded on the paper through thermal printer.

They consist of four modules, which are power supply module, signal collection module, amplification

module, and control module.

They can acquire ECG signal via twelve leads simultaneously, display or print waveform of ECG signal via one channel (iE 101) or three channel (iE 300).

5. Identification of Predicate Device

510(k) Number: K141946
Product Name: Digital Electrocardiograph
Model: iE 3

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 + A 1：2012, Medical electrical equipment, Part 1: General requirements for safety.
- 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.
- IEC 60601-2-25:2011, Medical electrical equipment, Part 2-25: Particular requirements for the safety of electrocardiographs.

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	**Proposed Devices**	**Predicate Device K141946**
Model	**iE 101/ iE 300**	**iE 3**
Product Code	DPS	DPS
Regulation Number	870.2340	870.2340
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. The proposed device has analysis feature, however the ECG with measurements and interpretive statements is offered to clinician on an advisory basis only.	SAME
Intended Population	Adult and pediatric patients	SAME
Intended Environment	Hospital, clinics	SAME
Configuration	ECG main unit	SAME
	Chest electrodes and Limb electrode	SAME
Lead	Standard 12-lead	SAME
Acquisition mode	Simultaneous 12-lead acquisition	SAME
Recording format	Automatic / Manual / Rhythm	SAME
Analysis mode	Yes	SAME
Screen size	5.0″ (iE 101) 5.0″ (iE 300)	6.0″
Channel	1 channel (iE 101) 3 channel (iE 101)	3 channel
Biocompatibility	Comply with ISO 10993	SAME
Electrical Safety	Comply with IEC 60601-1	SAME
EMC	Comply with IEC 60601-1-2	SAME
Particular requirements	Comply with IEC 60601-2-25	SAME

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate device.