**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 13, 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: K141946
Trade/Device Name: Digital electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 5, 2015
Received: January 15, 2015

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

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)*
K141946

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# Section 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: K141946

1. Date of Submission: July 04, 2014

2. Sponsor Identification

   Shenzhen Biocare Bio-Medical Equipment Co.,Ltd.
   #A735, Shenzhen Mingyou Industrial Product Exhibition & Procurement Center, Bao'an, Shenzhen, Guangdong, 518102, China

   Establishment Registration Number: 3008457078

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3. Submission Correspondent

   Ms. Diana Hong & Mr. Lee Fu
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4. Proposed Device Identification

Proposed Device Name: Digital Electrocardiograph;
Models: iE 3, iE 6, iE 12, iE 12A, iE 15, ECG-12l0, ECG-3010 and ECG-6010;
Proposed Device Common Name: Electrocardiograph;

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.

5. Predicate Device Identification

510(k) Number: K091513
Product Name: Smart ECG (SE) Series Electrocardiograph, SE-12
Model: SE-12
Manufacturer: Edan Instruments, Inc

510(k) Number: K050858
Product Name: Ascentia HeartStation™ ECG Management System
Manufacturer: Heartlab, Inc.

6. Device Description

Digital Electrocardiograph, iE 3/ iE 6/ iE 12/ iE 12A/ iE 15/ ECG-1210/ ECG-3010/ ECG-6010, are intended 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.

All the proposed models, iE 3/ iE 6/ iE 12/ iE 12A/ iE 15/ ECG1210/ ECG3010/ ECG6010, 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 three channel, six channel, twelve channel or fifteen channel.

The CardioPro analysis program is the analysis program used in this proposed device.

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 60601-1:1990+ A1:1993+ A11:1993+ A12:1993+ A2:1995+ A13:1996, Medical electrical equipment, Part 1: General requirements for safety.

IEC 60601-2-25:1993+A1:1999, Medical electrical equipment, Part 2-25: Particular requirements for the safety 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.

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 Device K091513 | Predicate Device K050858 |
|---|---|---|---|
| Model | iE 3/ iE 6/ iE 12/ iE 12A/ iE 15/ ECG-1210/ ECG-3010/ ECG-6010 | SE-12 | N.A. |
| Product Code | DPS | Same | Same |
| Regulation Number | 21CFR 870.2340 | Same | Same |
| 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. | The Heartlab HeartStation™ ECG Management System is a comprehensive data management solution which automates the processing, storage and display of electrocardiograms (ECGs) throughout a healthcare enterprise. HeartStation™ accepts standard 12-lead ECGs, which originate from any one of a variety of manufacturers' cardiographs and patient monitors, and normalizes them to a common format. ECGs are then measured, interpreted, compared to previous ECGs (“serial comparison”), optionally printed and stored with a preliminary diagnosis. A graphical user interface allows a physician to review these computer-generated reports, modify them or add comments as appropriate, electronically apply his or her signature and trigger the automatic distribution of final, confirmed diagnostic reports to other care providers. |
| Lead | Standard 12-lead or 15 lead | Standard 12-lead | N.A. |
| Acquisition mode | Simultaneous 12-lead acquisition or 15 lead acquisition | Simultaneous 12-lead acquisition | N.A. |
| Recording | Automatic / Manual / Rhythm | Same | Unknown |

| | | | |
|---|---|---|---|
| format | | | |
| Analysis mode | Yes | Yes | Yes |
| CMRR | >60dB<br>>100 with AC filter | Similar | Unknown |
| Paper Speed | 4 levels as 6.25, 12.5, 25, 50mm/s, OR<br>6 levels as: 5, 6.25, 10, 12.5, 25 and 50mm/s | Similar | Unknown |
| Input CIR current | ≤0.1μA | Similar | Unknown |
| Input impedance | >50MΩ | Same | Unknown |
| Patient leak current | <10μA | Same | Unknown |
| Frequency response | 0.05～150Hz | Same | Unknown |
| Noise level | <15$\mu V_{p-p}$ | Similar | Unknown |
| 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 | Unknown |
| Biocompatibility | Comply with ISO 10993 | Same | N.A. |

The proposed device, Digital Electrocardiograph, is determined to be Substantially Equivalent (SE) to the predicate device, Smart ECG (SE) Series Electrocardiograph, SE-12 (K091513) and Ascentia HeartStation™ ECG Management System (K050858) in respect of safety and effectiveness.