Exhibit #1 510(k) Summary

MAR - 1 2010

This 510(k) Summary is prepared per the request of 21 CFR 807.92.

Date	19 JAN 2011
Sponsor	**Shenzhen Biocare Electronics Co., Ltd** 5/F, Taohuayuan High-Tech Innovation Park, Baoan Shenzhen, Guangdong, 518102, China
Correspondent	Ms. Diana Hong / Mr. Lee Fu Shanghai Mid-Link Business Consulting Co., Ltd Suite 5D, No.19, Lane 999, Zhongshan Road (S-2), Shanghai, 200030, China
Proposed Device	**Digital Electrocardiographs, ECG-1210 / ECG-1230 / ECG-3010 / ECG-6010**
Classification	Electrocardiograph; DPS; 21CFR870.2340; Class II
Intended Use	Digital Electrocardiographs, ECG-1210 / ECG-1230 / ECG-3010 / ECG-6010, are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.
Device Description	Digital Electrocardiographs, ECG-1210 / ECG-1230 / ECG-3010 / ECG-6010, are designed to acquire, display and record ECG signals from patient body surface by ECG electrodes. After been amplified, filtered, the ECG signals waveforms are displayed in the LCD and recorded in the paper through thermal printer. ECG data and patient information could be stored in the memory of the device. All the models, ECG-1210 / ECG-1230 / ECG-3010 / ECG-6010, of the proposed device, Digital Electrocardiographs, follow the same design principle and same technical specifications: They consist of four modules, which are power supply module, signal collection module, amplification module, and control module.
Testing	Performance testing was conducted to validate and verify that the proposed devices met all design specifications and was substantially equivalent to the predicate device.
Predicate Device	Smart ECG (SE) Series Electrocardiograph, SE-12, K091513
SE Conclusion	The proposed devices, Digital Electrocardiograph ECG-1210 / ECG-1230 / ECG-3010 / ECG-6010, are claimed to be Substantially Equivalent (SE) to the predicate device, Smart ECG (SE) Series Electrocardiograph, SE-12, in safety and effectiveness concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Shenzhen Biocare Electronics Co., Ltd
c/o Ms. Diana Hong
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Suite 5D, No. 19, Lane 999, Zhongshan Road (S-2)
Shanghai, 200030
CHINA

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Re: K101876
Trade Name: Digital Electrocardiograph, Models ECG-1210, ECG-1230, ECG-3010, ECG-6010
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS
Dated: February 20, 2011
Received: February 23, 2011

Dear Ms. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit #2 Indications for Use Statement

510(k) Number: K101876
Device Name: Digital Electrocardiographs
Models: ECG-1210 / ECG-1230 / ECG-3010 / ECG-6010

Indications for Use:

Digital Electrocardiographs, ECG-1210 / ECG-1230 / ECG-3010 / ECG-6010, are intended to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

☒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 ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101876