Section V 510(k) Summary

OCT 25 2012

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

The assigned 510(k) Number: _____

1. Date of Submission: August 17, 2012 .

2. Sponsor

   Shenzhen Biocare Electronics Co., Ltd
   5/F, Taohuayuan High-Tech Innovation Park, Baoan,
   Shenzhen, Guangdong, 518102, China

   Establishment Registration Number: 3008457078

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   Position: Director
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Digital Electrocardiographs
   Proposed Device Model: ECG-8080/ iE 3S/ iE 6S/ iE 12/ iE 12P
   Classification: Class II
   Product Code: DPS
   Regulation Number: 21 CFR 870.2340
   Review Panel: Cardiovascular

Intended Use Statement:

Digital Electrocardiographs, ECG-8080/ iE 3S/ iE 6S/ iE 12/ iE 12P, 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.

5. Predicate Device Identification

510(k) Number: K101876
Product Name: Digital Electrocardiograph
Model: ECG-3010/ECG-6010
Manufacturer: Shenzhen Biocare Electronics Co., Ltd

510(k) Number: K112431
Product Name: Digital Electrocardiograph
Model: ECG-1216/ECG-1215
Manufacturer: Shenzhen Biocare Electronics Co., Ltd

6. Device Description

Digital Electrocardiographs, ECG-8080/ iE 3S/ iE 6S/ iE 12/ iE 12P, are designed to acquire, display and record ECG signals from patient body surface by ECG electrodes. After been amplified and filtered, the ECG signals waveforms are displayed in the LCD and recorded in the paperthrough thermal printer. ECG data result and patient information could be stored in the memory of the device.

All the models, ECG-8080/ iE 3S/ iE 6S/ iE 12/ iE 12P, of the proposed device, Digital Electrocardiographs, follow the same design principle and similar technical specifications.

7. Non-Clinical Test Conclusion

Bench 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: Particular requirements for the safety of electrocardiographs.
IEC 60601-1-2:2007, Medical electrical equipment– Part 1-2: General requirements for safety– Collateral standard: Electromagnetic compatibility– Requirements and teats.
IEC 60601-2-25:1995 +A1:1999 Clause 36, Medical electrical equipment – Part 2 Clause 36: Particular requirements for the safety of electrocardiographs – Electromagnetic compatibility.

8. Substantially Equivalent Conclusion

The proposed device, Digital Electrocardiograph, is determined to be Substantially Equivalent (SE) to the predicate device, Digital Electrocardiograph (K101876 and K112431), in respect of safety and effectiveness.

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

OCT 25 2012

Shenzhen Biocare Electronics Co., LTD
c/o Ms. Diana Hong
Mid-Link Consulting Co., LTD
P.O. Box 237-023
Shanghai, China 200237

Re: K122712
Trade/Device Name: Digital Electrocardiography models ECG-8080, iE 3S, iE 12, and iE 12P
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiography
Regulatory Class: Class II
Product Code: DPS
Dated: September 24, 2012
Received: October 1, 2012

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

Enclosure

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Section II Indications for Use

510(k) Number:
Device Name:Digital Electrocardiographs

Indications for Use:

Digital Electrocardiographs, ECG-8080/ iE 3S/ iE 6S/ iE 12/ iE 12P, 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 K122712