K131262

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: K131262

1. Date of Submission: Apr 22, 2013

NOV 14 2013

2. Sponsor Identification

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3. Submission Correspondent

Ms. Diana Hong & Mr. Tarzan Wang
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Proposed Device Identification

Proposed Device Trade Name: Digital Electrocardiograph;
Proposed Device Common Name: Electrocardiograph;
Proposed Device Model: IE3/ IE6/ IE12/ IE12P/ IE15

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

Intended Use Statement:
Digital Electrocardiographs, IE3/ IE6/ IE12/ IE12P/ IE15, 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.

4. Predicate Device Identification

510(k) Number: K122712
Product Name: Digital Electrocardiographs
Product Model: iE 3S, iE 6S, iE 12 and iE 12P
Manufacturer: Shenzhen Biocare Electronics Co., Ltd

510(k) Number: K123816
Product Name: Digital Electrocardiographs
Product Model: iE 15S
Manufacturer: Shenzhen Biocare Electronics Co., Ltd

5. Device Description

Digital Electrocardiographs, IE3/ IE6/ IE12/ IE12P/ IE15, are designed to acquire, analyze, display and record ECG signals from patient body surface by ECG electrodes. After been amplified, filtered and analyzed, the ECG signals waveforms and analysis results are displayed in the LCD and recorded in the paper through thermal printer. ECG data, analysis result and patient information could be stored in the memory of the device.

The device consists of three modules, which are power supply module, amplification module, and control module.

The device has three recording mode, AUTO mode, MAN mode and RHY mode.

They are standard twelve leads, including bipolar limb leads, augmented unipolar limb leads and unipolar chest leads.

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 60601-1:1990+ 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.

7. Substantially Equivalent (SE) Conclusion

The following table compares the Digital Electrocardiographs to the predicate devices with respect to intended use and technological characteristics, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	Proposed Device	Predicate Device K122712	Predicate Device K123816
Model	IE3/IE6/IE12/IE12P/IE15	iE 3S/iE 6S/iE 12/iE 12P	iE 15S
Product Code	DPS	Same	Same
Regulation Number	21CFR 870.2340	Same	Same
Intended Use	Digital Electrocardiographs, IE3/ IE6/ IE12/ IE12P/ IE15, 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.	Similar	Similar
Main Unit Specification			
Lead	Standard 12-lead	Same	Same
Acquisition mode	Simultaneous 12-lead acquisition	Same	Same
Recording format	Automatic / Manual / Rhythm	Same	Same
Analysis mode	No	No	No
CMRR	>60dB >100 with AC filter	Same	Same
Paper Speed	4 levels as 6.25, 12.5, 25, 50mm/s, OR 6 levels as: 5, 6.25, 10, 12.5, 25 and 50mm/s	Same	Same
Input CIR current	≤0.1μA	Same	Same
Input impedance	>50M Ω	Same	Same
Patient leak current	<10μA	Same	Same
Frequency response	0.05～150Hz	Same	Same
Noise level	<15μV_{p-p}	Same	Same
Specification of external input and external output			
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	Same
Biocompatibility	Comply with ISO 10993	Same	Same

The proposed devices, Digital Electrocardiographs, IE3/ IE6/ IE12/ IE12P/ IE15, are determined to be Substantially Equivalent (SE) to the predicate devices, K122712 and K123816, in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

November 14, 2013

Sonoscape Company Limited
c/o Ms. Diana Hong
General Manager
P.o. Box 120-119
Shanghai, 237-023 CH

Re: K131262
Trade/Device Name: Digital Electrocardiographs
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: September 28, 2013
Received: October 15, 2013

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 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. 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 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,

Owen P. Faris -S

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

Enclosure

K131262

Indications for Use

510(k) Number: K131262
Device Name: Digital Electrocardiograph

Indications for Use:

Digital Electrocardiographs, IE3/ IE6/ IE12/ IE12P/ IE15, 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)

OR

☐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)

Digitally signed by
Owen P. Faris -S
Date: 2013.11.14
10:26:47 -05'00'