DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 22, 2016

Contec Medical Systems Co., Ltd
% Diana Hong
General Manager
Mid-link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 CHINA

Re: K152863
Trade/Device Name: Portable ECG Monitor
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: May 20, 2016
Received: May 23, 2016

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,

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)*
K152863

Device Name
Portable ECG Monitor

Indications for Use *(Describe)*
The Portable ECG Monitor PM10 is intended to record and store Lead I ECG signals, and display heart rate for home health care use. The intended users are adults above 20 years old. This device is not intended to substitute for a hospital diagnostic ECG device. Users with implanted pacemaker are not recommended to use this device. The Portable ECG Monitor PM10 has simple user interface without ECG trace viewing function.

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.

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.

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Tab #7 510(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: _____

1. Date of Preparation: 05/21/2016

2. Sponsor Identification

Contec Medical Systems Co., Ltd
No.112 Qinhuang West Street, Economic & Technical Development Zone,
Qinhuangdao, Hebei, 066004, China.

Establishment Registration Number: 3006979678

Contact Person: Xueyong Li
Position: Quality Manager
Tel: 86 355 8015489
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Lee Fu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 240-238-7587
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Portable ECG Monitor
Common Name: Electrocardiograph
Model: PM10

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

Intended Use Statement:
The Portable ECG Monitor PM10 is intended to record and store Lead I ECG signals, and display heart rate for home health care use. The intended users are adults above 20 years old. This device is not intended to substitute for a hospital diagnostic ECG device. Users with implanted pacemaker are not recommended to use this device. The Portable ECG Monitor PM10 has simple user interface without ECG trace viewing function.

Device Description

The Portable ECG Monitor is intended to record and store Lead I ECG signals, and display heart rate for home health care use. It is composed of host and USB cable, powered by Built-in large capability rechargeable lithium battery.

The device can be connected with PC via USB, with mobile phone via Bluetooth protocol. The function of software PC and mobile phone includes sample mode and time setting, upload case, case review, measurement etc.

5. Identification of Predicate Device

510(k) Number: K112622
Product Name: Handheld ECG Monitor
Model Name: MD100A1-F

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 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012, Medical electrical equipment -

Part 1: General requirements for basic safety and essential performance.
IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests.
ISO 60601-2-47:2012, Medical Electrical Equipment -- Part 2-47: Particular Requirements For The Basic Safety And Essential Performance Of Ambulatory Electrocardiographic Systems.
IEC 60601-1-11: 2010, MEDICAL ELECTRICAL EQUIPMENT – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
ISO 10993-10:2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

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 Device(s)	Predicate Device(s)
Product Code	DPS	Same
Regulation Number	870.2340	Same
Intended Use	The Portable ECG Monitor PM10 is intended to record and store Lead I ECG signals, and display heart rate for home health care use. The intended users are adults above 20 years old. This device is not intended to substitute for a hospital diagnostic ECG device. Users with implanted pacemaker are not recommended to use this device. The Portable ECG Monitor PM10 has simple user interface without ECG trace viewing function.	Similar
Lead	Lead I	Same
Recording mode	automatic	Same
Measurement parameters	Heart rate	Similar
Display	LCD	Same
HR measurement range	30bpm～300bpm	Similar
HR measurement accuracy	±1bpm or 1%	Similar

Power supply	Battery	Same
Electrical safety	The proposed device was tested to demonstrated to comply with IEC 60601-1	Same
EMC	The proposed device was tested to demonstrated to comply with IEC 60601-1-2	Same
Patient Contact Material	Metal electrode	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 devices.