January 22, 2018

Contec Medical Systems Co., Ltd.
% Ray Wang
General Manager
Beijing Believe Technology Service Co., Ltd.
5-402, Building #27, YangGuangYiShang, No.56, LiangXiang East Rd.
FangShan District, Beijing, 102401 China

Re: K171360
Trade/Device Name: CONTEC™ Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 20, 2017
Received: December 22, 2017

Dear Ray Wang:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K171360

Device Name

CONTECTM Electrocardiograph

Indications for Use *(Describe)*

CONTECTM Electrocardiograph, ECG90A, is intended to acquire ECG signals from adult or children patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. The proposed devices also have measurements and diagnostic interpretation functions, which are offered to clinician on an advisory basis. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

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 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: _____

1. Date of Preparation: 05/05/2017

2. Sponsor Identification

Contec Medical System Co., Ltd.
No.112 Qinhuang West Street, Economic & Technical Development Zone,
Qinhuangdao, Hebei, 066004, China.
Establishment Registration Number: 3006979678

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3. Designated Submission Correspondent

Mr. Ray Wang

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510(k) Summary

4. Identification of Proposed Device

Trade Name: CONTEC^{TM} Electrocardiograph
Common Name: Electrocardiograph
Model(s): ECG90A

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

Intended Use Statement:

CONTEC^{TM} Electrocardiograph, ECG90A, is intended to acquire ECG signals from adult or children patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. The proposed devices also have measurements and diagnostic interpretation functions, which are offered to clinician on an advisory basis. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.

Device Description

This product is an electrocardiograph collecting 12-lead ECG signal simultaneously and printing ECG waveform with thermal printing system, which features in, recording and displaying ECG waveform with manual or auto mode, measuring and diagnosing ECG waveform parameters automatically, prompting for “Lead off” and “Lack of paper”, optional interface languages(Chinese/ English), case database management.

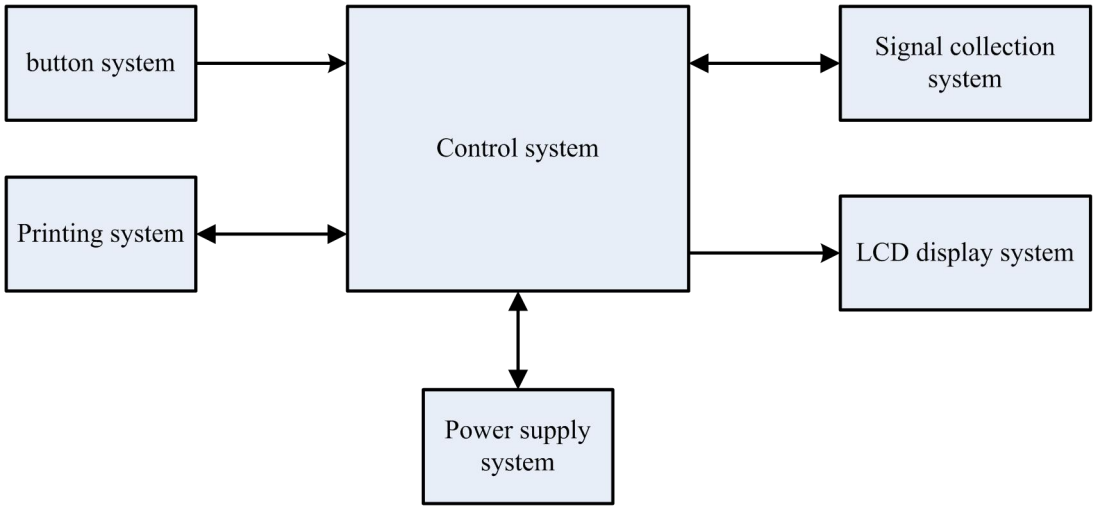
This product is used to assist doctors to analyze and print the ECG waveform of children and adults, which can be applied to ECG room, ward, hospital, etc.

The ECG machine provides medical department human ECG wave group for pattern and rhythm analysis that applied in clinical diagnosis and research.

Essential Performance:Sync collection and display of 12-lead ECG,Display of HR,Print ECG wave with different format,Filter settings,and Auto-measurement of ECG data.

Fig 7-1 Working Frame of ECG90A

510(k) Summary



ECG90A is divided into button system, printing system, power supply system, LCD display system, signal collection system, control system

Button system: to collect the user's key operation input, send the signal to the control system to process;

Printing system: print the print data sent by the control system, heat the printer head to record the waveform on the thermal printing paper, and feedback whether the lack of paper;

Power system: provide power supply for each system module;
The proposed device adopts two kinds of power supply modes: build-in lithium battery DC power supply and AC-DC adapter power supply.

AC-DC adapter power supply: after the external power adapter connecting with the proposed device, the AC voltage is reduced to 12V via the AC-DC power adapter. The 12V voltage is used to charge the lithium battery via the charging management chip;meanwhile the 12V voltage is reduced to 8.6V via a voltage converter, which is used to power the following circuit and printer. Then the 8.6V voltage is reduced again to 5.0V voltage via the voltage converter, and the 5.0V voltage pass through power isolation and is used to power the signal collection and processing module; meanwhile the 5V voltage will be reduces to 3.3Vvoltage, which is used to power the control module.
Build-in lithium battery DC power supply: when the proposed device is connected with AC-DC adapter power supply, the build-in lithium battery will be charged automatically. The charged battery will power the whole system as DC power supply when the proposed device is not connected with the external AC-DC adapter power supply

LCD display system: display various of settings of waveform information to the user for viewing ;

Signal collection system: collect the waveform data,submit the final data to the control system to process; the signal acquisition and process module adopts floating and optical isolation to reduce the external disturbance to signal. After filtering and amplification, the A/C conversion of acquired ECG signal is completed on MCU (Micro Controller Unit); and then the data is transmitted to control system,

after processing the data will be displayed on the LCD screen and the waveform will be printed on the thermal paper. MCU can identify and response the key operation through connecting line, and MCU can connect and communicate with the SD card and USB through the signal line.

Control system: the MCU is used to control the whole system operation. The device parameters setting, the processing of acquired signal, the printing, screen display and charging are all controlled by this module.

5. Identification of Predicate Device(s)

Predicate Device ：

510(k) Number: K131900
Product Name: CONTEC™ Electrocardiograph
Model Name: ECG300G
Manufacturer:
Contec Medical System Co., Ltd.

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:

a. IEC 60601-1:2005+A1:2012, Medical Electrical Equipment- Part 1: General requirements for basic safety and essential performance
b. 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 Tests
c. IEC 60601-2-25:2011 Medical Electrical Equipment - Part 2-25: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographs. (Cardiovascular)
d. ISO 10993-5:2009, Biological Evaluation of Medical Device, Part 5-Tests for Vitro cytotoxicity.
e. ISO 10993-10:2010 Standard, Biological Evaluation of Medical Device, Part 10-Test for irritation and delay-type hypersensitivity

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 7-1 Comparison of Technology Characteristics

Item	Proposed Device(s)	Predicate Device(s)
Device name	ECG90A CONTEC^{TM} Electrocardiograph	ECG300G CONTEC^{TM} Electrocardiograph
Classification Name	Electrocardiograph	Electrocardiograph
Product Code	DPS	DPS
Regulation Number	CFR 870.2340	CFR 870.2340
Comparison Statement	**The proposed device has same classification information as the predicate device.**	
Intended Use	CONTEC^{TM} Electrocardiographs, ECG90A, are intended to acquire ECG signals from adult or children patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. The proposed devices also have measurements and diagnostic interpretation functions, which are offered to clinician on an advisory basis. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.	CONTEC^{TM} Electrocardiographs, ECG300G, are intended to acquire ECG signals from adult patients through body surface ECG electrodes. The obtained ECG records can help users to analyze and diagnose heart disease. The proposed devices also have measurements and diagnostic interpretation functions, which are offered to clinician on an advisory basis. Digital Electrocardiographs shall be used in healthcare facilities by doctors and/or trained healthcare professionals.
Comparison Statement	**The proposed device has similar intended use as the predicate device.**	
Main Unit Technical Specifications		
Channel	3 channel	3 channel
collection mode	Simultaneous 12-lead collection	Simultaneous 12-lead collection
Recording mode	Automatic /Manual/rhythm	Automatic /Manual/rhythm
Patient leak current	<10 μA	<10μA
Frequency response	0.5 Hz~150 Hz (-3 dB~0.4 dB)	0.5 Hz~150 Hz (-3 dB~0.4 dB)
Noise level	≤15 μVp-p	≤15 μVp-p

CMRR		＞60 dB, ＞100 dB(filter)	＞60 dB, ＞100 dB(filter)
Input way		Floating and defibrillation protection	Floating and defibrillation protection
Measurement Function		Have measurement function	Have measurement function
Input CIR current		≤50nA	≤50nA
Input impedance		≥50 MΩ	≥50 MΩ
Paper speed	Auto record	6.25 mm/s、12.5 mm/s、25 mm/s、50 mm/s, error: ±5 %	25mm/s, 50mm/s, error: ±5%
	Manual record	6.25 mm/s、12.5 mm/s、25 mm/s、50 mm/s, error: ±5 %	5mm/s,6.25mm/s,10mm/s,12.5mm/s,25mm/s,50mm/s,error:±5%
	Rhythm record	6.25 mm/s、12.5 mm/s、25 mm/s、50 mm/s, error: ±5 %	25mm/s, 50mm/s, error: ±5%
EMG interference filter		25 Hz or 35 Hz (-3 dB)	25Hz/35Hz (-3dB)
Recording way		Thermal printing system	Thermal printing system
Specification of recording paper		50 mm (W)×20 m(L) high-speed thermal paper	80mm (W)*20m (L) High-speed thermal paper
Sensitivity selections		5/10/20 mm/mV, error: ±5 %, Standard sensitivity is 10 mm/mV±0.2 mm/mV	2.5/5/10/20/40mm/mV,error:±5%.Standard sensitivity is 10mm/mV±0.2mm/mV
Net weight		0.5 Kg	1.7kg
Power supply		12 V adapter/7.4 V, 2000 mAh rechargeable lithium battery	AC: 100-240V, 50/60Hz/DC: 7.4V, 3700 mAh lithium rechargeable battery
Dimensions(mm)		207 mm(L)×96 mm(W)×62 mm(H)	315mm (L)*215mm (W)*77mm (H)
Skin Contacted Material		Chest Suction ball (silicone, nickel plated copper)	Chest Suction Electrode (Tin Alloy)
		Limb Clamp Electrode (ABS, PMO +10%fiberglass, nickel plated brass)	Limb Clamp Electrode(Tin Alloy and ABS)
		ECG lead cable (TPU)	ECG lead cable (TPU)
Operation Environment		Temperature: +5℃~ +40℃ Relative humidity: ≤80 % Atmosphere pressure: 700 hPa ~ 1060 hPa	Temperature: +5℃~ +40℃ Relative humidity: ≤80 % Atmosphere pressure: 700 hPa ~ 1060 hPa

Storage environment	Temperature: -40℃~+55℃, Relative Humidity: ≤95%, no condensation Atmosphere pressure: 500 hPa ~ 1060 hPa,	Temperature: -40℃~+55℃, Relative Humidity: ≤95%, no condensation Atmosphere pressure: 500 hPa ~ 1060 hPa,
Sterile	No	No
Single Use	No	No
Comparison Statement:	**The proposed device has the similar main unit specifications with the predicate device.**	
Applied Standards:		
Biocompatibility	ISO10993-5&ISO10993-10	ISO10993-5&ISO10993-10
Electrical Safety	IEC60601-1	IEC60601-1
EMC	IEC60601-1-2	IEC60601-1-2
Performance	IEC 60601-2-25	IEC 60601-2-25
Comparison Statement	**The proposed probe has same applied Standards with the predicate device.**	

9. Substantially Equivalent (SE) Conclusion

SE Analysis :

The subject device has same classification information, same intended use, same indication for use, similar product design, similar specification, same safety elements, similar applied Standards as predicate device.

The differences are included as followings:

Analyse 1：The device and predicate device have difference in Paper speed, paper speed is a manifestation of ECG reporting on paper, per IEC 60601-2-25:2011 Section 201.12.4.108.3 ECG reporting on paper, it stated that the device shall provide at least two recording speeds,: 25mm/s and 50mm/s. the proposed device has passed the IEC60601-2-25 test , therefore the paper speed of the proposed device meet the requirements of the standard. we believe these differences will not affect the effectiveness and safety compared with the predicate device.

Analyse 2： Although the Power supply specifications of ECG90A is different from the predicate device,but both the predicate device and the proposed device has passed the IEC60601-1 safety test, we believe these differences will not affect the effectiveness and safety compared with the predicate device.

Analyse 3：Although the skin Contacted Material of ECG90A is different from the predicate device, but both the predicate device and the proposed device has passed the ISO10993 series test, we believe these differences will not affect the effectiveness and safety compared with the predicate device.

Conclusion: The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.