April 28, 2020

Contec Medical Systems Co., Ltd.
℅ Ray Wang
General Manager
Beijing Believe-Med Technology Service Co., Ltd.
Rm.912, Building #15, XiYueHui, No.5, YiHe North Rd.,
FangShan District,
Beijing, Beijing 102401
China

Re: K202757
Trade/Device Name: Electronic Sphygmomanometer, Automatic Blood Pressure Monitor
CONTEC08A/CONTEC08C/ABPM50
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: March 24, 2021
Received: March 29, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202757

Device Name

Trade Name: Electronic Sphygmomanometer; Automatic Blood Pressure Monitor
Model: CONTEC08A/CONTEC08C/ABPM50

Indications for Use *(Describe)*

The Electronic Sphygmomanometer and Automatic Blood Pressure Monitor are intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.

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.

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Tab #4 510(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: K202757

1. Date of Preparation

   03/19/2021

2. Sponsor

Contec Medical Systems Co., Ltd.

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3. Submission Correspondent

Mr. Ray Wang

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4. Identification of Proposed Device

Trade Name: Electronic Sphygmomanometer; Automatic Blood Pressure Monitor
Common Name: system, measurement, blood-pressure, non-invasive
Model(s): CONTEC08A/CONTEC08C/ABPM50

Regulatory Information:
Classification Name: Noninvasive Blood Pressure Measurement System;

Classification: II;
Product Code: DXN;
Regulation Number: 21 CFR 870.1130;
Review Panel: Cardiovascular ;

Indication For Use Statement:

The Electronic Sphygmomanometer and Automatic Blood Pressure Monitor are intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.

5. Device Description

The proposed devices, ABPM50 Automaitc Blood Pressure Monitor, CONTEC08A and CONTEC08C Electronic Sphygmomanometers are battery driven automatic non-invasive Blood Pressure Monitor. They can automatically complete the inflation, deflation and BP measurement, which can measure systolic, and diastolic blood pressure as well as the pulse rate at upper arm within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or kPa. ABPM50 and CONTEC08A and CONTEC08C can be only used on adult individuals.
The devices have the data storage function for data review including measurement time, systolic blood pressure, diastolic blood pressure and pulse rate.

ABPM50 and CONTEC08A have physiological over-limit prompt function which can be turned on or off by users. When the measurement results exceed the over-limit prompt limit, the physiological over-limit prompt function will be triggered. The over-limit prompt limit can be set by users, and the low limit must be lower than the corresponding high limit.
In addition, all of the three proposed devices have technical over-limit prompt function, which will be triggered when the battery voltage is low, and this technical over-limit prompt function can not be cancelled unless being closed or the power replaced.
The main differences among the three (CONTEC08A / CONTEC08C / ABPM50) are as follows:

model	CONTEC08A	CONTEC08C	ABPM50
Trade Name	Electronic Sphygmomanometer	Electronic Sphygmomanometer	Automatic Blood Pressure Monitor
Over limit prompt	yes	no	yes
display	TFT LCD display	Segment code screen display	TFT LCD display
Storage function	Three users, each user stores 100 groups of data	Three users, each user stores 99 groups of data	General single blood pressure measurement storage 300 groups of data , automatic blood pressure measurement (350 groups of data)
Power Supply	four alkaline batteries or 5V power adapter	four alkaline batteries or 5V power adapter	two alkaline batteries

6. Identification of Predicate Device

Predicate Device:

510(k) Number: K191180

Product Name: Electronic Blood Pressure Monitor: Models AOJ-30A and AOJ-30B

Manufacturer: Shenzhen AOJ Medical Technology Co., Ltd.

7. 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 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 Edition 2.0 2015-01 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

- IEC 80601-2-30 Edition 1.1 2013-07，Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 81060-2 Third edition 2018-11 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type [including: Amendment 1 (2020)]
- ISO 10993-5 Third Edition 2009-06-01, Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)
- ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)

8. Clinical Test Conclusion

Controlled human clinical studies were conducted on proposed device with predicates in accordance with ISO 81060-2, mean deviation, standard deviation has been evaluated per clinical validation. The clinical trial results verify that the clinical accuracy of the proposed device is not inferior to that of predicate device.

Total 85 subjects are included in each clinical study, the results of proposed device meet the performance parameters claimed in user manual, and the proposed device complies with ISO 81060-2.

9. Substantially Equivalent (SE) Comparison

Table 7-1 General Comparison

Item	Proposed Device CONTEC08A/CONTEC08C/ABPM50		Predicate Device AOJ-30A and AOJ-30B K191180	Remark
Manufacture	Contec Medical Systems Co., Ltd.		Shenzhen AOJ Medical Technology Co., Ltd.	--
Product Code	DXN		DXN	SE
Regulation Number	21 CFR 870.1130		21 CFR 870.1130	SE
Indication for Use	The Electronic Sphygmomanometer and Automatic Blood Pressure Monitor are intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.		The Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique at medical facilities or at home.	SE
Clinical Use	Medical Facilities and Home Use		Medical Facilities and Home Use	SE
Patient Population	Adult		Adult	SE
Measurement Type	Upper arm		Upper arm	SE
Measurement Principle	Oscillometric		Oscillometric	SE
Components	LCD / Key / Cuff / MCU / Pump / Batteries		LCD / Key / Cuff / MCU / Pump / Batteries	SE
Power Source	CONTEC08A/CONTEC08C	4x1.5V(4 "AA" alkaline batteries); 5V adapter, optional	4x1.5V	Analysis 1
	ABPM50	2x1.5V(2 "AA" alkaline batteries)		
Physical Dimensions	CONTEC08A/CONTEC08C	130(L)*110(W)*80(H) mm	Approx: 138 mm(Length)x120 mm(Width)x59 mm(Height)	Analysis 1
	ABPM50	128(L)*69(W)*36 mm(H)		

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Weight	CONTEC08A/CONTEC08C	300 gram(without batteries)	Approx: 483.8 g, excluding battery		Analysis 1
	ABPM50	240 gram(without batteries)			
Measurement Range	Blood Pressure	10 ~ 270 mmHg	Blood Pressure	30 ~ 255 mmHg	Analysis 2
	Pulse Rate	40~240BPM	Pulse Rate	40-199 bpm	
Accuracy	Static Pressure	±3 mmHg	Static Pressure	±3 mmHg	SE
	Pulse	±5 %	Pulse	±5%	
Arm Circumference	22-32 cm and 32-43cm		22 cm~36 cm		Analysis 2
Patient Contact Material	PVC+ Nylon+Ployester		Cuff –Terylene		Analysis 3
Electrical safety	IEC 60601-1 IEC 60601-1-11		IEC 60601-1 IEC 60601-1-11		SE
EMC	IEC 60601-1-2		IEC 60601-1-2		SE
Performance test	IEC80601-2-30		IEC80601-2-30		SE
Clinical data	ISO81060-2		ISO81060-2		SE
Biocompatibility test	Cytotoxicity Skin Sensitization Skin Irritation		Cytotoxicity Skin Sensitization Skin Irritation		SE
Operation Environments	+5 ºC~40 ºC 15 %RH~85 %RH (Non-condensing) 700 hPa~1060 hPa		+ 5℃~ + 40℃, 15%RH~90%RH 70 kPa~106 kPa		Analysis 1
Storage Environments	-20 ºC~+55 ºC; Relative humidity: ≤95 %; No corrosive gas and drafty. 700 hPa~1060 hPa		- 20℃~ + 55℃, 10%RH~93%RH 70 kPa~106 kPa		Analysis 1

Analysis 1

The proposed device is different in Power Source, Physical Dimensions, Weight, Operation Environments and Storage Environments from the predicate device. The differences is small, and the proposed device has passed the IEC60601-1-2 , IEC60601-1 and IEC60601-1-11 test, the safety and performance of the proposed device can be guaranteed. By complying with non-clinical test conducted, the proposed device is determined to be substantially equivalency with predicate device.

Analysis 2

The proposed device is different in Measurement Range and Arm Circumference from the predicate device. But the proposed device has passed the IEC80601-2-30 and ISO81060-2 test, the performance of the proposed device can be guaranteed. By complying with non-clinical test conducted, the proposed device is determined to be substantially equivalency with predicate device.

Analysis 3

The proposed device is different in Patient Contact Material from the predicate device. but the proposed device has passed the Biocompatibility test (including Cytotoxicity , Skin Sensitization ,Skin Irritation), we believe these differences will not affect the effectiveness and safety compared with the predicate device., the proposed device is determined to be substantially equivalency with predicate device.

10. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed device is determined to be Substantially Equivalent (SE) to the predicate device.