November 15, 2021

Beijing Choice Electronic Technology Co., Ltd.
Haiying Zhao
Quality Director
No.9 Shuangyuan road, Badachu Hi-tech Zone,
Shijingshan District
Beijing, 100041
China

Re: K211754
Trade/Device Name: Vital Signs Monitor
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: October 14, 2021
Received: October 18, 2021

Dear Haiying Zhao:

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,

for LCDR 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)*
K211754

Device Name
Vital Signs Monitor

Indications for Use *(Describe)*
Vital Signs Monitor MD2000C is a portable device indicated for measuring physiological parameters, such as NIBP, SpO2, PR, and Pulse waveform of adult and three years old and older pediatric patients in hospitals, community hospitals and medical facilities.
Vital Signs Monitor is intended for spot-checking and/or continuous monitoring of patients.

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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510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

3.1 Submitter Information

- **Manufacturer Name:**
  Establishment Registration Number: 3005569927
  Beijing Choice Electronic Technology Co., Ltd.
  2nd Floor, 3rd Floor and Room 410-412 4th Floor, No. 2 Building, No. 9 Shuangyuan Road , Shijingshan District BEIJING, 100041, P.R.China
- **Contact Person:**
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  Email: cc@choicemmed.com
- **Date prepared：October 14, 2021**

3.2 Proposed Device Information

Device Common Name: Vital Signs Monitor

Device Trade/Proprietary Name: Vital Signs Monitor

Model: MD2000C

Classification Name: Monitor, Physiological, Patient (Without Arrhythmia Detection Or Alarms)

Regulation Number: 870.2300

Product Code: MWI

Class: Ⅱ

Premarket Notification 510(k) Submission—Section II 510(k) Summary

Panel: Cardiovascular

3.3 Predicate Device

510(k) Number: K100740

Common Name: Vital Signs Monitor

Device Trade/Proprietary Name: Vital Signs Monitor

Model: MD2000B

Classification Name: Monitor, physiological, patient(Without Arrhythmia Detection Or Alarms)

Product Code: MWI

Regulation Number: 870.2300

Device Class: Ⅱ

Panel: Cardiovascular

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.

Intended Use: The vital signs monitor is a portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate(PR), Non-invasive measurement of blood pressure(NIBP) of adult and pediatric patients in hospitals, medical facilities, and sub-acute environments. The vital signs monitor is intended for spot-checking and/or continuous monitoring of patients.

3.4 Device Description

The proposed device Vital Signs Monitor MD2000C is a device powered by internal electrical power source and external electrical power source. The MD2000C is used in hospital,community hospitals and medical facilities. It can measure and record functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Non-invasive measurement of blood pressure (NIBP) of adult and pediatric patients.

Its accessories include SpO2 probe, NIBP cuff for adult, NIBP cuff for pediatric, and power adapter. It has data storage,display,alarm.

Measurement Principle:

Blood Pressure measurement principle:

The monitor uses the oscillometric method for measuring the non-invasive blood pressure (NIBP).NIBP measurement is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall. The device uses a blood pressure cuff to sense

Premarket Notification 510(k) Submission—Section II 510(k) Summary

these oscillations, which appear as tiny pulsations in cuff pressure. The device measures the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery.As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum(which approximates to the mean pressure), and then diminish. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

Pulse Oxygen Saturation measurement principle:

The pulse oxygen saturation is measured by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photo detector. The one wavelength of light source is 660 nm, which is red light; the other is 905 nm, which is ultra-red light. Skin, bone, tissue and venous vessels normally absorb a constant amount of light over time. The photo detector in finger sensor collects and converts the light into electronic signal which is proportional to the light intensity. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement. This measurement is referred to as SpO2.

The device is for prescription.

The device does not contain drug or biological products.

The device is software-driven.

3.5 Comparison list of the technological characteristics

Table 2-1 Performance Specification Comparison Table between the Proposed Device (MD2000C) and Predicate Device

Comparison Elements	**Subject Device**	**Predicate Device**
Product Name	Vital Signs Monitor	Vital Signs Monitor
Model	MD2000C	MD2000B
Regulation No.	21 CFR 870.2300	21 CFR 870.2300
Classification	Ⅱ	Ⅱ
Classification Name	Monitor, physiological, patient(Without Arrhythmia Detection Or Alarms)	Monitor, physiological, patient(Without Arrhythmia Detection Or Alarms)
Product Code	MWI	MWI
Indications for Use	Vital Signs Monitor MD2000C is a portable device indicated for measuring physiological parameters, such as NIBP, SpO2, PR, and Pulse waveform of adult and three years old and older pediatric patients in hospitals, community hospitals and medical facilities. Vital Signs Monitor is intended for spot-checking and/or continuous monitoring of patients.	The vital signs monitor is a portable device indicated for use in non-invasively measuring and displaying functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), Non-invasive measurement of blood pressure (NIBP) of adult and pediatric patients in hospitals, medical facilities, and sub-acute environments. The vital signs monitor is intended for spot-checking and/or continuous monitoring of patients.
Comparison Statement	**The proposed device and the predicate device have the same classification and same intended use.**	

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Performance Specification	Measurement Wavelengths	660 nanometers 905 nanometers	660 nanometers 940 nanometers
	Display unit specification	TFT	LED & LCD
	Display data	SpO2%, PR,PAI,SYS, DIA	SpO2%, PR, SYS,MAP,DIA
	SpO2 measuring range	70%-100%	70%-100%
	SpO2 resolution	1%	1%
	SpO2 Accuracy	±2%	80-100%: ±2%; 70-79%: ±3%;
	SpO2 Alarm range	85%-100%	85%-100%
	PR measuring range	30~250 bpm	30~235 bpm
	PR resolution	1 bpm	1 bpm
	PR Accuracy	±2bpm or ±2% (choose larger)	30-100, ±2bpm; 101-235,±2%
	Pulse Amptitude Index measurment range	0.1%-20%	/
	PAI resolution	0.1%	/
	NIBP Measurement Method:	Oscillometric method	Oscillometric method

Premarket Notification 510(k) Submission—Section III 510(k) Summary

	NIBP Measurement Range:	Adult: SYS :60mmHg~255mmHg DIA:30mmHg~195mmHg Padiatric: SYS :60mmHg~215mmHg DIA:30mmHg~195mmHg	Adult: SYS :30mmHg~255mmHg MAP:20mmHg~235mmHg DIA:15mmHg~220mmHg Padiatric: SYS :30mmHg~135mmHg MAP:20mmHg~125mmHg DIA:15mmHg~110mmHg
	Static pressure measurement range	20~280mmHg	0~270mmHg
	Maximum static pressure error	±3mmHg	±3mmHg
	Alarm method	3 levels audible and visual alarm	3 levels audible and visual alarm
Comparison Statement		The proposed device has similar product specification as predicate device.The differences are Measurement Wavelengths,the measurement range and accuracy of PR and NIBP, the measurement range of PAI,and we can verify that which will not effect the basic safety and essential performance of the proposed device.	
Contacting Material	Fingertip Cushion	Silicone Gel	Silicone Gel
	Blood Pressure Cuff	Nylon	Nylon
Comparison Statement		**The contacting materials of the proposed device are same to those of the predicate device.**	

Premarket Notification 510(k) Submission—Section III 510(k) Summary

Performance Testing	Laboratory Testing	The laboratory tests include SpO2 , PR Accuracy Test, Device Response Time of SpO2/PR , SpO2/PR output time and finger out time , PAI measurement range , Static pressure Accuracy, High and Low Temperature and Humidity Test, Performance Test After Cleaning , ISO 80601-2-61, ISO 80601-2-30	The laboratory tests include SpO2 , PR Accuracy Test, Device Response Time of SpO2/PR , SpO2/PR output time and finger out time , Static pressure Accuracy, High and Low Temperature and Humidity Test, Performance Test After Cleaning , ISO 9919, ISO 80601-2-30
EMC and Electrical Safe	Electrical Safety	Conformed to IEC60601-1,IEC 60601-1-8,IEC 60601-2-49	Conformed to IEC60601-1,IEC 60601-1-8,IEC 60601-2-49
	Electromagnetic Compatibility	Conformed to IEC60601-1-2	Conformed to IEC60601-1-2
Software		Major level of concern	Moderate level of concern
		Compliance with FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices.	Compliance with FDA Guidance for the content of Premarket Submissions for Software Contained in Medical Devices.
		Risk Management in Compliance with ISO14971	Risk Management in Compliance with ISO14971

Premarket Notification 510(k) Submission—Section III 510(k) Summary

Label and Labeling	Conform to 21 CFR 801	Conform to 21 CFR 801
Comparison Statement	**The proposed device is in comformity with the current latest standard.**	

3.6 Indications for Use

Vital Signs Monitor MD2000C is a portable device indicated for measuring physiological parameters, such as NIBP, SpO2, PR, and Pulse waveform of adult and three years old and older pediatric patients in hospitals, community hospitals and medical facilities.
Vital Signs Monitor is intended for spot-checking and/or continuous monitoring of patients.

3.7 Testing

Biocompatibility Testing

The patient contacted materials fingertip cushion used in the proposed device MD2000C are the same as the materials used in the predicate device MD300M which has been cleared by FDA on April 18, 2016 as K152563. The blood pressure cuff used in the proposed device MD2000C is same as the material in the predicate device CBP111,which has been cleared by FDA on February 10,2017 as K162089.

Electrical safety and electromagnetic compatibility (EMC)

The proposed device Vital Signs Monitor MD2000C is tested in accordance with IEC 60601-1, IEC 60601-1-2,IEC 60601-1-8,IEC 60601-2-49 to evaluate the electrical safety and EMC.

Performance Test-Bench

We have conducted safety and performance test for the proposed device MD2000C in accordance with ISO 80601-2-61, Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment, and accordance with IEC 80601-2-30:2013 Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers. We have also conducted other performance tests including SpO_2, PR Accuracy Test, Device Response Time of SpO2/PR, SpO2/PR output time and finger out time, PAI measurement range, Static pressure Accuracy, Cleaning Test, High and Low Temperature & Humidity Test, Shelf-life Test.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was

provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Major" level of concern, since a failure or latent flaw could indirectly result in death or serious injury of the patient or operator through incorrect or delayed information or through the action of a care provider.

Clinical Testing

The SpO2 module and sensor of the proposed device are identical same as whose of MD300M manufactured by Beijing Choice Electronic Technology Co., Ltd. MD300M has been cleared by FDA on April 18,2016 as K152563, so the clinical study for SpO2 was not repeated. The Clinical Test of MD300M was conducted in Yue Bei people's Hospital. 12 healthy adult volunteer subjects (6 females and 6 males ages 21-43yr, 47-82kg, 155-185cm, with representative range of pigmentation) were included in the study conducted September 20-22, 2014 to evaluate the SpO2 accuracy performance of the MD300M Pulse Oximeter. The SpO2 accuracy performance results showed the MD300M Pulse Oximeter and its supporting Oximeter probe have an ARMS of 1.75 during steady state conditions over the range of 70-100%.

The blood pressure module and cuff of Vital Signs Monitor MD2000C are identical as whose of Multi-parameters health Examination System manufactured by Beijing Choice Electronic Technology Co., Ltd, so the clinical study for blood pressure was not repeated. The clinical Test of Multi-parameters health Examination System was conducted in PLA Rocket Force Characteristic Medical Center. 85 subjects (35 child subjects aged between 3y and 12 y old and 50 adults subjects) were included in the study conducted from September 16, 2018 to September 20, 2019. The blood pressure accuracy performance results showed that the mean error is within ±5mmHg and the standard deviation is within 8mmHg.

3.8 Determination of substantial equivalence

The proposed device of the vital signs monitor MD2000C has the same classification information, same intended use, same design principle, similar product design and specifications as the predicate device. The main difference is that the proposed device has the function of PAI measurement, and we can verify that will not affect the basic safety and the essential performance of the proposed device. Therefore, the proposed device is Substantially Equivalent (SE) to the predicate device which is a US legally marketed device.