January 30, 2025

Shenzhen Zhongkemingwang Telecommunications Software Corp.
Queena Chen
Regulatory Manager
Room 1701,T2, CRC Qianhai Center,55, Guiwan 4th Road Nanshan
Sub-district, Qianhai Shenzhen-Hong Kong Cooperation Zone
Shenzhen, Guangdong 518066
China

Re: K242568
Trade/Device Name: Wrist Blood Pressure Monitor (OHMS11, OHMS12)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 31, 2024
Received: December 31, 2024

Dear Queena Chen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert T. Kazmierski -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242568

Device Name

Wrist Blood Pressure Monitor (OHMS11, OHMS12)

Indications for Use *(Describe)*

The device is intended for use in measuring blood pressure in adult patient population with wrist circumference ranging from 13.0 cm to 21.0 cm.

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.

510(k) Summary

Prepared on: 2025-01-29

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen Zhongkemingwang Telecommunications Software Corp., Ltd.
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Applicant Contact Telephone	+86 13433943993
Applicant Contact	Ms. Queena Chen
Applicant Contact Email	chenqin1@oppo.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Wrist Blood Pressure Monitor (OHMS11, OHMS12)
Common Name	Noninvasive blood pressure measurement system
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number	870.1130
Product Code(s)	DXN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K182481	HEM-6410T-ZM Wrist Blood Pressure Monitor	DXN

Device Description Summary

21 CFR 807.92(a)(4)

The Wrist Blood Pressure Monitor is a reusable, active, non-sterile, non-invasive and non-implantable device for use in measuring blood pressure in adult patient population with wrist circumference ranging from 13.0 cm to 21.0 cm. It is a home-use device prohibited from use in MRI (magnetic resonance imaging) environment. This device has the systolic and diastolic display features. The device is of the watch type and powered by a rechargeable lithium-polymer battery. An AC adapter is used for charging the device, but the device cannot be operated while charging. The device wrist cuff inflates using an integral pump, and deflates via an electric valve. During inflation, the wrist cuff pressure is monitored and pulse waveform data is extracted. The extracted pulse waveform data is then analyzed by software which determines systolic and diastolic blood pressure. The systolic and diastolic blood pressures are measured using the oscillometric method. The cuff can measure pressure range from 0 to 300mmHg.
Product includes device (preinstalled with a strap and large-sized cuff: 16.6-21.0cm), strap with a medium-sized cuff: 13.0-16.5cm, wrist measuring tape, charging base (with the power cable).
The product functional configurations of OHMS11 and OHMS12 are completely identical, and the difference between the two is reflected in the color (OHMS11 is the dark gray color, OHMS12 is the champagne color).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The device is intended for use in measuring blood pressure in adult patient population with wrist circumference ranging from 13.0 cm to 21.0 cm.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Although “Intended Use / Indications for Use” of the subject device are a little different from the predicate devices, but the different circumference range of subject device similar as other similar device K211288 (13.5~21.5 cm), and complied with the laboratory accuracy IEC 80601-2-30 and clinical accuracy ISO 81060-2. Besides, the intended use of the predicate device includes the functionality of the subject device, without any novel features. So these differences will not raise any safety or effectiveness issue.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device and predicate device (K182481) have the same measurement range, accuracy, pressure sensor, intended use population, environment of use, measurement method/principle of operation, inflation method and deflation method. Although “Intended Use / Indications for Use” and “Cuff range(cm)” of the subject device are a little different from the predicate devices, but the different circumference range of subject device similar as other similar device K211288 (13.5~21.5 cm), and complied with the laboratory accuracy IEC 80601-2-30 and clinical accuracy ISO 81060-2, so these differences do not raise issues regarding substantial equivalence. Although the “Display” of the subject device is different from the predicate devices, the display screen material is different but the display effect is similar or better, so this difference will not raise issues regarding substantial equivalence.
Although the “Power supply”, “Operating conditions”, “Storage conditions”, “Dimensions (mm)” and “Weight” of the subject device are a different from the predicate devices, all these factors are not the essential parameters of the device which will not affect the effectiveness, and all of them complied with the safety standards IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30, which show the safety of subject device, so these parameters’ differences do not raise issues regarding substantial equivalence.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Wrist Blood Pressure Monitor has been evaluated the safety and performance by lab bench testing as following:
Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the proposed device. The system was shown to comply with IEC 60601-1-2:2020 for electromagnetic compatibility, IEC 60601- 1:2020 and IEC 80601-2-30 for electrical safety.

Performance testing
Performance tests were conducted on the proposed device in accordance with product design specifications. Data generated from the test met the predetermined acceptance criteria.

Software Verification and Validation
The Software verification and validation is in compliance with FDA Guidance-Guidance for the
Content of Premarket Submissions for Software Contained in Medical Devices.

Cybersecurity
The subject device verification and validation is in compliance with FDA guidance “Content of Premarket Submissions for Management of Cybersecurity in Medical Devices”.

Biocompatibility
The biocompatibility evaluation for the device was conducted in accordance with the FDAGuidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO10993-1, “Biological evaluation of medical devices - Part 1: Evaluation and testing within a riskmanagement process”. The biocompatibility testing includes the following tests: Cytotoxicity, Sensitization, Irritation
The subject device has all features of the predicate device. The few differences do not affect the substantial equivalence of the subject device. Thus, the subject device is substantially equivalent to the predicate device.

Clinical testing
ISO 81060-2:2019 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type;In this clinical investigation, Wrist Blood Pressure Monitor had 85 patients (49 males and 36 females) participated in the clinical study. Same arm sequential method was adopted during the clinical testing. The manual Mercury Sphygmomanometer was used as a reference device. All the subjects volunteered to take part in the clinical study, all the subjects completed the clinical study without any adverse events or side-effect. The results showed the accuracy of the blood pressure monitor is within acceptable scope specified in ISO 81060-2.

The subject device has all features of the predicate device. The few differences do not affect the substantial equivalence of the subject device. Thus, the subject device is substantially equivalent to the predicate device.

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