March 26, 2024

Shenzhen Hingmed Medical Instrument Co., Ltd.
Huang Yongban, RA Manager
4th Floor, Zhonghangfeixiang Building, NO. 371, Guangshen
Road, Baoan District
Shenzhen, GuangDong 518102
China

Re: K231984
Trade/Device Name: Clinical Automatic Blood Pressure Monitor (DBP-01P,DBP-01HP)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: February 20, 2024
Received: February 20, 2024

Dear Huang Yongban:

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.

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,

Stephen C. Browning -S

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)*
K231984

Device Name
Clinical Automatic Blood Pressure Monitor (DBP-01P, DBP-01HP)

Indications for Use *(Describe)*
This device is a digital monitor intended for use in measuring blood pressure(SYS and DIA) and pulse rate ,and the physician reference the result to diagnose.
Environments of use: Hospital and other medical establishment.
Patient population: Adult (exclude pregnant women).

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) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

510(k) Owner's Name: Shenzhen Hingmed Medical Instrument Co., Ltd

Establishment Registration Number: Applying

Address: 4th Floor, Zhonghangfeixiang Building, NO. 371, Guangshen Road, Baoan District, Shenzhen,,GuangDong , People's Republic of China

Tel: +86-0755-232069446

Contact Person (including title): Yongban Huang (Manger Representative)

E-mail: hyb@hingmed.com

2. Subject Device Information

Type of 510(k): Traditional

Common Name:Noninvasive blood pressure measurement system

Classification Name: System, Measurement, Blood-Pressure, Non-Invasive

Trade Name: Clinical Automatic Blood Pressure Monitor

Model Name: DBP-01P,DBP-01HP

Review Panel: Cardiovascular

Product Code: DXN

Regulation Number: 21 CFR 870.1130

Regulatory Class: Class II

3. Predicate Device Information

Sponsor	A&D Company, Ltd
Device Name	UA-1200BLE Ultraconnect Digital Blood Pressure
Model or type Name	**UA-1200BLE**
510(k) Number	K163683
Product code	DXN

Regulation Number	21 CFR 870.1130
Regulation class	Class II

4. Indications for Use

This device is a digital monitor intended for use in measuring blood pressure(SYS and DIA) and pulse rate ,and the physician reference the result to diagnose.
Environments of use: Hospital and other medical establishment
Patient population: Adult (exclude pregnant women)

5. Device Description

Clinical Automatic blood pressure monitor have two models that are DBP-01HP and DBP-01P,The Clinical Automatic blood pressure monitor is used to measure the blood pressure of adult in hospital or other medical establishment. It's contain of main body、power wire.it can show the time and measure result, print the measure result .There is a difference between DBP-01HP with DBP -01P. DBP-01HP show the measure result and time by the LCD screen,DBP-01P show the measure result and time by the LED screen.

Photos of DBP-01HP &DBP-01P:

Photo of DBP-01HP	Photo of DBP-01P

6. Substantial Equivalence table

Device	Subject Device	Predicate Device	Remarks
Manufacture	Shenzhen Hingmed Medical Instrument Co., Ltd	A&D Company, Ltd	NA
Model	DBP-01P,DBP-01HP	**UA-1200BLE**	NA

classification	II	II	Same
Product code	DXN	DXN	Same
Regulation No.	870.1130	870.1130	Same
510(K) number	N/A	K163683	NA
Intended use/ Indicate for use	This device is a digital monitor intended for use in measuring blood pressure(SYS and DIA) and pulse rate ,and the physician reference the result to diagnose	Measure blood pressure (systolic and diastolic) and pulse rate	Same
Environmental of use	Hospital and other medical establishment	Home or clinical use	Difference
Patient population	Adult (exclude pregnant women)	Adult	Same
Measurement site	Upper Arm	Upper Arm	Same
Measurement method	Oscillometric method	Oscillometric method	Same
Measurement range	Pressure:0 to 289 Pulse rate:40 to 200bpm	Pressure:0 to 299mmHg Pulse rate:40 to 180beats per minute	similar
Measuring accuracy	Pressure:within ±3mmHg Pulse Rate: whichever is grater(±3bpm or±3%)	Pressure:within ±3mmHg Pulse Rate:±5%	similar
Cuff	17-42cm	22-42cm	similar
Inflation	Automatic internal pump	Automatic internal pump	Same
Deflation	Automatic rapid deflation	Solenoid valve for rapid exhaust	Same
Power source	mains	3.7V Li-ion batteries or AC adaptor as an option	Difference
Protection against electrical shock	Class I, Type B	Class I, Type B	same
Display	LCD display or LED display	OLED Display	Difference
Operation Environment condition	5℃-40℃; RH: 10%-95%; non-condensing,atmospheric pressure(70KPa-106Kpa)	50℉(10℃) to 104℉(40℃) 15%RH to 85%RH	Difference
Storage Environment Condition	-20℃- 55℃, RH≤90% (non-condensing) 70KPa-106Kpa	-4℉(-20℃) to 140℉(60℃) 10%RH to 95%RH	Difference
Memory	NA	Last 60 measurements for each of the four	Difference

		user	
Weight	About 6Kg	205g without batteries	Difference
Dimension(L* D*H)	About W:310×L:478×H:300mm	40(W)x126(H)x26(D) mm	Difference
Patient contact materials	Surface contact Skin Limited duration of use<24 hours	Surface contact Skin Limited duration of use<24 hours	Same
Blood Pressure Reading Classification Criteria	WHO Classification Criteria	USA JNC Ⅶ	Difference

5. non-clinical Test Summary

Clinical Automatic blood pressure monitor has been evaluated the safety and performance by lab bench testing,as following:
Electrical safety test according to IEC 60601-1 and IEC 80601-2-30 standards
Electromagnetic compatibility test according to IEC 60601-1-2 standard
Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards

6.Brief discussions of clinical tests

ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type;
In this clinical investigation, The DBP-01P was tested in 85 subjects from the general population (mean age, 69.9 years; 43 men) using a wide-range cuff for arm circumferences from 17 to 42 cm. The mean device–observer difference was 1.32±3.18 mmHg for SBP and 0.78±3.15 mmHg for DBP. These data were in agreement with criterion 1 of the protocol standard requirements (≤5±8 mmHg).
Also, criterion 2 was satisfied with the SDs of the 85 participants being well below the maximum values required by the protocol (6.80 and 6.89 mmHg for SBP and DBP pressure, respectively). The results showed the accuracy of the blood pressure monitor is within acceptable scope specified in ISO 81060-2

7.Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of clinical automatic blood pressure monitor is substantially equivalent to the predicate devices quoted above.
The differences between the subject device and predicate devices do not rise new issues of safety or effectiveness.

8.Conclusion

Non-clinical performance was conducted on the subject device and all tests met specified criteria. Based on the information provided in this submission, the Clinical Automatic blood pressure monitor is substantially equivalent to the predicate device, UA-1200BLE UltraConnect Digital Blood Pressure.