November 22, 2022

Globalcare Medical Technology Co., Ltd.
% Roger Gray
VP Quality and Regulatory
Donawa Lifescience Consluting Srl
Piazza Albania 10
Rome, 00153
Italy

Re: K222160
Trade/Device Name: GUS610 Blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 20, 2022
Received: October 27, 2022

Dear Roger Gray:

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,

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)*
K222160

Device Name
GUS610 Automatic Blood Pressure Monitor

Indications for Use *(Describe)*
The Globalcare GUS610 Automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm. The cuff circumference is limited to 22 to 42 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.

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510(k) Summary

Device Name:	GUS610 Blood Pressure Monitor
Type of 510(k) submission:	Traditional
Date of submission:	21 November 2022
Manufacturer:	Globalcare Medical Technology Co., Ltd No.7 Factory, European Industrial Park No. 39 Mid Industrial Main Road Xiaolan Town, Zhongshan City Guangdong, CHINA 528415
Phone:	+86-760-22589901
FDA Establishment Reg. Number:	3010880718
510(k) Owner and Submitter:	Globalcare Medical Technology Co., Ltd No.7 Factory, European Industrial Park No. 39 Mid Industrial Main Road Xiaolan Town, Zhongshan City Guangdong, CHINA 528415
Owner/Operator Reg. Number:	10046812
510(k) Contact:	Mr Roger Gray VP Quality and Regulatory Donawa Lifescience Consulting Piazza Albania 10 00153 Rome Italy
Phone: **Fax:** **Email:**	+39 06 578 2665 +39 06 574 3786 rgray@donawa.com
FDA Product Code:	DXN
FDA Regulation Number:	21 CFR 870.1130
FDA Classification Name:	Noninvasive blood pressure measurement system
Classification Panel:	Cardiovascular
Common Name:	Upper arm blood pressure monitor
FDA Classification:	Class II
Submission Type:	510(k)
Indications for Use:	The Globalcare GUS610 automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm. The cuff circumference is limited to 22 to 42 cm.

Device Description:
The Globalcare GUS610 Blood Pressure Monitor is an automatic upper arm blood pressure monitor intended for non-invasive measurement or monitoring of adults' arterial blood pressure and pulse rate.

The device is powered by batteries or by a mains-connected power supply.

The Globalcare GUS610 Blood Pressure Monitor comprises the following parts:

- Blood pressure monitor main device x1
- Upper arm cuff x1
- 1.5 V LR03 AAA batteries x4
- Storage bag x1
- Instructions for use x1
- 100-240Vac 50/60Hz power supply (optional) with USB cable x1

None of the parts included with the device are supplied in a sterile condition.

The Globalcare GUS610 Blood Pressure Monitor main unit is an electronic unit incorporating a screen that displays results and other information relevant to device operation. The device is powered by batteries or by a mains-connected power adapter and is designed for home ('OTC') use**.**

The clinical outputs from the GUS610 Blood Pressure Monitor are:

- Systolic pressure (mm Hg)
- Diastolic pressure (mm Hg)
- Pulse rate (1/min)
- Cardiac arrhythmia (Irregular heartbeat (IHB)) symbol
- Risk indicator (WHO color scale)
- Hemodynamic Rest Condition (HSD) indication

The device operates on the oscillometric method**:** pressure sensors on the cuff are used to capture pulse waves during constricted blood flow and the device then computes the results for display by means of an algorithm which analyses the pressures transmitted during arterial oscillations that occur during cuff inflation.

Irregular heartbeat (IHB) is detected by measuring the interval time between each heartbeat and comparing these values with the average heartbeat interval (heartbeat per minutes shown on the display). If the difference between any heartbeat interval and the average is higher or lower than 25 %, the device shows the irregular heartbeat (IHB) symbol on the display.

The pulse rate is determined by calculating the frequency of the oscillations in the cuff, which are cardiac synchronous.

The GUS610 is controlled by software which calculates the blood pressure (diastolic and systolic) and pulse rate by the oscillometric method. To do this, it also controls the pneumatic components to inflate the cuff (with a pump), holds the cuff pressure, and then deflates the cuff (by means of a solenoid valve). The software collects the relevant data from the pressure sensor during inflation.

The software also drives the LCD display, from which the user can read the result of the blood pressure and pulse rate measurements and undertakes the Hemodynamic Rest Condition (HSD) detection calculations, and reports whether any irregular heartbeat is occurring.

Performance data:
The GUS610 has been tested and found to be in compliance with the following standards:

Safety and EMC:

- IEC 60601-1:2005/AMD1:2012 + AMD2:2020
- IEC 60601-1-11:2015/AMD1:2020
- IEC 60601-1-2:2014/A1:2020
- IEC 80601-2-30:2018

Clinical performance:

- ISO 81060-2:2018/AMD1:2020

Cuff biocompatibility:

- ISO 10993-5:2009
- ISO 10993-10:2010

Bench tests:

- Internal tests to verify performance
  - Mains and Battery comparison
  - After 500 hour Life Test has been completed
  - After 12 months storage
  - After drop test

The results of the above testing assist in the demonstration of substantial equivalence of the subject device with the predicate device.

Clinical performance

A clinical investigation was performed to validate the clinical accuracy of the subject device, using the arm sequential method described in subclause 5.2.4.1 of ISO 81060-2:2018+A1:2020 to collect 255 blood pressure datasets from 85 adult subjects.

A clinical investigation was carried out to validate device clinical accuracy. The investigation was performed on Globalcare model GCE610 blood pressure monitor, a device that is technologically identical to the subject device, but which is cleared for marketing in a non-US regulatory jurisdiction. The clinical validation was performed using the same arm sequential method described in subclause 5.2.4.1 of ISO 81060-2:2018+A1:2020 to collect 255 blood pressure datasets from 85 adult subjects.

According to the requirements of ISO 81060-2:2018+A1:2020, a legally available in the US auscultatory reference sphygmomanometer was used for comparison purposes.

The clinical results indicated that the subject device meets the requirements of ISO 81060-2:2018+A1: 2020, and that there were no adverse events during the investigation. Baseline demographic information regarding participants in the study is provided in Table 1.

Table 1: Baseline demographic information

Distribution	Category	Requirement		Actual distribution		Comment
		Minimum proportion	Minimum number	Number	Proportion	
Gender	Male	30%	26	56	65.9%	P
	Female	30%	20	29	34.1%	P
Limb size range (cm)	22-27	20%	17	26	30.6%	P
	27-32	20%	17	20	23.5%	P
	32-37	20%	17	18	21.2%	P
	37-42	10%	17	21	24.7%	P
	22-24.5	10%	9	10	11.8%	P
	39.5-42	10%	9	11	12.9%	P
Blood pressure (mmHg)	SBP ≤100	5%	4	12	14.1%	P
	SBP ≥140	20%	17	19	22.4%	P
	SBP ≥160	5%	4	15	17.6%	P
	DBP ≤60	5%	4	10	11.8%	P
	DBP ≥85	20%	17	28	32.9%	P
	DBP ≥100	5%	4	12	14.1%	P

Analysis of data from the investigation is based on subclause 5.2.4.1.2 of ISO 81060-2:2018+A1:2020 with the following conclusions:

Effectiveness: The results of the investigation show that the subject device is capable of accurately measuring the blood pressure values in all the subgroups foreseen by standard ISO 81060-2:2018+A1: 2020.

Safety: The study reported no adverse events for the subject device.

Summary: Based on the clinical performance as documented in the clinical study report, the subject device was found to have a safety and effectiveness profile that is substantially equivalent to the predicate device.

Substantial equivalence
The predicate device selected for comparison with the GUS610 Blood Pressure Monitor is:

Predicate Device:	Blood Pressure Monitor Model GUS622
Sponsor:	Globalcare, China
510(k) Number:	K192609
Clearance Date:	21 April 2020
FDA Product Code:	DXN
Classification Name:	Noninvasive blood pressure measurement system
Regulation No:	21 CFR 870.1130
Class:	II

Predicate device comparison table:
The following Table 2 provides evidence of substantial equivalence of the subject device with the selected predicate device.

Table 2: Predicate device comparison table

Feature	Subject device	Predicate device	Similarity
Device name	GUS610	GUS622	N/A
Device Manufacturer	Globalcare, China	Globalcare, China	N/A
510(k) Reference	This submission	K192609	N/A
FDA Product Code	DXN	DXN	Same
FDA Classification Name	Noninvasive blood pressure measurement system	Noninvasive blood pressure measurement system	Same
FDA Regulation Number	21 CFR 870.1130	21 CFR 870.1130	Same
Device description	Automatic upper arm blood pressure monitor intended for non-invasive measurement or monitoring of adults' arterial blood pressure and pulse rate via an upper arm cuff.	Automatic upper arm blood pressure monitor intended for non-invasive measurement or monitoring of adults' arterial blood pressure and pulse rate via an upper arm cuff.	Same
Indications for use	The Globalcare GUS610 automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm. The cuff circumference is limited to 22 to 42 cm.	The Globalcare GUS622 automatic Blood Pressure Monitor is indicated for home use for the non-invasive measurement of diastolic and systolic blood pressures and pulse rate of adults by means of an inflatable cuff which is wrapped around the upper arm. The cuff circumference is limited to 22 to 42 cm.	Same

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Table 2: Predicate device comparison table			
Feature	**Subject device**	**Predicate device**	**Similarity**
Use environment	Indoor use, home environment	Indoor use, home environment	Same
Measuring method	Oscillometric method, automatic inflation and measurement during inflation	Oscillometric method, automatic inflation and measurement during deflation	Different
Device measurements (output parameters)	Diastolic and systolic blood pressure Pulse rate	Diastolic and systolic blood pressure Pulse rate	Same
Additional output indications	Irregular heart beat Hemodynamic instability	Irregular heart beat Hemodynamic instability	Same
Output result calculation	Software algorithm	Software algorithm	Same
Measurement range	Cuff pressure: 0-300 mmHg Systolic: 50-280 mmHg Diastolic: 30-200 mmHg Pulse: 40-200 beats/min	Cuff pressure: 0-300 mmHg Systolic: 50-280 mmHg Diastolic: 30-200 mmHg Pulse: 40-199 beats/min	Same
Accuracy	Pressure: ±3 mmHg Pulse rate: ±5 %	Pressure: ±3 mmHg Pulse rate: ±5 %	Same
External Power Supply	Input 100-240 VAC 50/60 Hz 0.5 A max; Output 6 VDC (+/-5%) / 600mA (optional)	Input 100-240 VAC 50/60 Hz 0.5 A max; Output 6 VDC (+/-5%) / 600mA (optional)	Same
Unit voltage	6V dc	6V dc	Same
Batteries	4 x AAA alkaline 1.5 VDC	4 x AAA alkaline 1.5 VDC	Same
Battery life	Approx 500 cycles	Approx 500 cycles	Same
Standards compliance	IEC 60601-1:2005/AMD1:2012 + AMD2:2020 IEC 60601-1-11:2015/ AMD1:2020 IEC 60601-1-11:2015/ AMD1:2020 IEC 60601-1-11:2015/AMD1:2020	ANSI/AAMI ES60601-1:2005 / A2:2010 IEC 60601-1-11:2015 IEC 60601-1-2:2014 IEC 80601-2-30:2009/ AMD1:2013 ISO 81060-2:2013 EN 1060-3:1997+A2:2009	Subject device complies with more recent standards
Device Protection	IEC 60601-1: Class 2	IEC 60601-1: Class 2	Same
Applied Part	IEC 60601-1: Type BF	IEC 60601-1: Type BF	Same
Memory	90 x 1 user	60 x 2 user	Difference has no effect on safety or effectiveness
Dimensions	L 85 mm x W 170 mm x H 48 mm	L 98 mm x W 140 mm x H 53 mm	Differences have no effect on safety or effectiveness
Weight	275 g device without cuff and batteries	207 g device without cuff and batteries	Difference has no effect on safety or effectiveness

The subject device and the predicate device have many identical or similar properties or features. The differences that exist and are identified in the above table include:

- Blood pressure and pulse rate calculation take place during inflation in the subject device, but during deflation in the predicate device. This method produces a faster measurement result display and a lower cuff compression on the patient's arm.
- The subject device complies with more recent standards than the predicate device.
- The memory function holds different numbers of readings.
- Weight and size are different.

None of the identified differences introduce new aspects of safety or effectiveness.

Conclusion

The subject and predicate devices have very similar intended uses and fundamental technological characteristics. Any differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device performs in a similar manner to the predicate device. The clinical data demonstrate that the subject device performs comparably to the predicate device which is legally available in the US for the same intended use. The performance and clinical data together demonstrate that the subject device is substantially equivalent to the predicate device