April 8, 2025

Globalcare Medical Technology Co., Ltd
Valentina Sassi
Quality and Regulatory Affairs Manager
No.7 Factory, European Industrial Park,
No. 39 Mid Industrial Main Road Xiaolan Town, Zhongshan City
Guangdong, 528415
China

Re: K250136
Trade/Device Name: Globalcare Blood Pressure Monitor (GUS610)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: January 17, 2025
Received: March 11, 2025

Dear Valentina Sassi:

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
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics, and
Monitoring Devices
OHT2: 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)*

K250136

Device Name

Globalcare Blood Pressure Monitor (GUS610)

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 52 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K250136

510(k) Summary

Prepared on: 2025-03-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Globalcare Medical Technology Co., Ltd
Applicant Address	No.7 Factory, European Industrial Park, No. 39 Mid Industrial Main Road Xiaolan Town, Zhongshan City Guangdong 528415 China
Applicant Contact Telephone	+39 02 83451194
Applicant Contact	Ms. Valentina Sassi
Applicant Contact Email	valentina.sassi@globalcare.com.hk

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Globalcare Blood Pressure Monitor (GUS610)
Common Name	Noninvasive blood pressure measurement system
Classification Name	System, Measurement, Blood-Pressure, Non-Invasive
Regulation Number	870.1130
Product Code(s)	DXN, DXQ (CLASS 2) - BLOOD PRESSURE CUFF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222160	Globacare GUS610 Blood Pressure Monitor	DXN

Device Description Summary

21 CFR 807.92(a)(4)

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 adapter and is designed for home use.
The Globalcare GUS610 Blood Pressure Monitor is supplied complete with the following components:
Blood pressure monitor main device - 1
Upper arm cuff 22-42 cm - 1
1.5 V LR03 AAA batteries - 4
Storage bag - 1
Instructions for use - 1
100-240 VAC 50/60 Hz power supply (optional) - 1

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
• Level of risk
• Hemodynamic Rest Condition (HSD) indication

The GUS610 Upper Arm Cuff, with a circumference range of 22 cm to 42 cm, is manufactured by Globalcare China. The cuff is manufactured from gray color Polyester 200D (CAS n. 80595-68-2), supplied by Anhui Wuyixing Fabric and Weaving. This is identical to the cuff provided with the predicate device cited in K222160.

The purpose of this Special 510(k) is to add to the availability of an accessory for the GUS610, this being an optional Upper Arm Cuff with an increased circumference range of 42 to 52 cm. The testing undertaken for the predicate device in accordance with ISO 81060-2:2018, 'Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type', has been repeated with the new larger cuff, with 88 subjects having upper arm circumferences between 42 and 52 cm screened, from which 259 effective analysis datasets were obtained from 87 subjects. Gender distribution met the requirements of the standard (M: 55.2 % / F 44.8 %), arm size distribution met the requirements of the standard, and blood pressure measurements met the requirements of the standard clause 5.2.4.1.2 for Criterion 1 'mean difference' and 'standard deviation' for SBP and DBP, and also for Criterion 2 for SBP and DBP 'standard. deviation'. The accuracy of the BP and pulse rate measurements also met the manufacturer's specifications for accuracy.

There were no adverse incidents during the investigation and no failed measurements. There were no protocol deviations or violations.

A third party test house (TUV SUD China) has assessed the continued compliance of the GUS610 subject device when used together with the new optional XL cuff in accordance with IEC 80601-2-30 and found that the combination continues to meet the requirements of this standard.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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 52 cm.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications statement for the subject device differs from the predicate device only with regard to the labeled upper arm cuff maximum circumference. The intended use is unchanged.

Technological Comparison 21 CFR 807.92(a)(6)

The only difference between the subject device and the predicate device is the availability of an optional upper arm cuff with a 52 cm maximum circumference, which is 10 cm larger than that cleared with the predicate device.

The larger circumference upper arm cuff is manufactured from the same material as that provided with the predicate device.

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

The testing undertaken for the predicate device in accordance with ISO 81060-2:2018, 'Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type', has been repeated with the new larger cuff, with 88 subjects having upper arm circumferences between 42 and 52 cm screened, from which 259 effective analysis datasets were obtained from 87 subjects. Gender distribution met the requirements of the standard (M: 55.2 % / F 44.8 %), arm size distribution met the requirements of the standard, and blood pressure measurements met the requirements of the standard clause 5.2.4.1.2 for Criterion 1 'mean difference' and 'standard deviation' for SBP and DBP, and also for Criterion 2 for SBP and DBP 'standard. deviation'. The accuracy of the BP and pulse rate measurements also met the manufacturer's specifications for accuracy. There were no adverse incidents during the investigation and no failed measurements. There were no protocol deviations or violations.