February 14, 2019

GMC Inc.
Yolanda Li
Director of Quality Management Div.
No. 686, Su Chu Rd.
Chuzhou, 239000
CHINA

Re: K181930
Trade/Device Name: GMC Wrist Automatic Blood Pressure Monitor, Model BQ705
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 11, 2019
Received: January 11, 2019

Dear Yolanda Li:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S5

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181930

Device Name
GMC Wrist Automatic Blood Pressure Monitor, Model BQ705

Indications for Use *(Describe)*
The GMC Wrist Automatic Blood Pressure Monitor, Model BQ705, is a non-invasive blood pressure measurement device that is used for measuring systolic and diastolic blood pressure and pulse rate using the oscillometric method for adults at home.

The device has an irregular heartbeat (IHB) indicator. The device detects the appearance of an irregular heartbeat during measurement, and displays an IHB symbol on the LCD with the reading once the irregular heartbeat is detected.

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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GMC Inc.
No. 686, Su Chu Rd., Chuzhou,
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510(k) Summary

510(k) owner's information:	GMC Inc. No. 686, Su Chu Rd., Chuzhou, Anhui, China Tel: +86-550-2172888 Fax: +86-550-2172889
Official Contact:	Yolanda Lin Bus. Phone: 86-550-2172888 Fax: 86-550-2172889 E-mail: linyolanda23@gmail.com
Proprietary or Trade Name:	GMC Wrist Automatic Blood Pressure Monitor, Model BQ705
Common/Usual Name:	Non-Invasive Blood Pressure Monitor
Classification Name:	System, Measurement, Blood-Pressure, Non-Invasive
Regulation	CFR 870.1130
Product Code	DXN
Device Class:	II
Predicate Device:	Omron BP652N (K142917)
Date Summary Prepared:	07/16/2018

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Device Description:

The GMC Wrist Automatic Blood Pressure Monitor, Model BQ705, measures systolic and diastolic blood pressure and pulse rate of an adult individual. The method used to define blood pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The device utilizes the oscillometric method whereby the electronic pressure sensor converts variation in cuff pressure to electrical signals. The electrical signals are analyzed and used to define the systolic and diastolic measurements and determine the pulse rate. An irregular heart beat (IHB) indicator is displayed when there is more than a 25% deviation from the averaged pulse rate measurements.

Intended Use:

The GMC Wrist Automatic Blood Pressure Monitor, Model BQ705, is a non-invasive blood pressure measurement device that is used for measuring systolic and diastolic blood pressure and pulse rate using the oscillometric method for adults at home.

The device has an irregular heartbeat (IHB) indicator. The device detects the appearance of an irregular heartbeat during measurement, and displays an IHB symbol on the LCD with the reading once the irregular heartbeat is detected.

Substantially Equivalent (SE) Comparison

The GMC Wrist Automatic Blood Pressure Monitor, Model BQ705 is substantially equivalent to the Omron BP652N (K142917).

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Model name	Predicate Device Omron BP652N (K142917)	Subject Device GMC BQ705	Comparison
510(k) submitter/holder	Omron Healthcare, Inc.	GMC Inc.	
Intended use and Indications for Use	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5 1/4 inches to 8 1/2 inches (13.5cm to 21.5 cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	The device is a non-invasive blood pressure measurement device that is used for measuring systolic and diastolic blood pressure and pulse rate using the oscillometric method for adults at home. The device has an irregular heartbeat (IHB) indicator. The device detects the appearance of an irregular heartbeat during measurement, and displays an IHB symbol on the LCD with the reading once the irregular heartbeat is detected.	**Similar** No difference of intended purpose. The proposed indication for use is the same as the cleared indication for use of the predicate device. The wrist circumference is slightly different between the two devices, but this difference does not affect safety or effectiveness.
Use Environment	Home use	Home use	**Identical**
Patient Population	Adult	Adult	**Identical**

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Specifications / Features

Model name		Predicate Device Omron BP652N (K142917)	Subject Device GMC BQ705	Comparison
Measurement method		Oscillometric methods	Oscillometric methods	**Identical**
Cuff fits wrist circumference		13.5 to 21.5cm	13.5~22cm(5.3”~8.7”)	**Similar** This minor difference does not impact safety and effectiveness of the device.
Measurement range	Pressure	0~299 mmHg	30~260 mmHg	**Similar** This minor difference does not impact safety and effectiveness of the device.
	Pulse	40~180 beats/min	40~199 beats/min	**Similar** This minor difference does not impact safety and effectiveness of the device.
Accuracy	Pressure	±3 mmHg or 2 % of reading	±3 mmHg	**Similar** There is no difference in the accuracy range based on mmHg scale
	Pulse	±5% of reading	±5% of reading	**Identical**

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Model name	Predicate Device Omron BP652N (K142917)	Subject Device GMC BQ705	Comparison
Reusable	Yes	Yes	**Identical**
Display Type	LCD	LCD	**Identical**
Display Parameter	Current cuff pressure, Systolic blood pressure, Diastolic blood pressure, Pulse rate, Error message, measurement results in the memory	Systolic pressure, Diastolic pressure, Pulse rate, Memory sequence number, Date/Time, memory zone icons, pulse mark, weak battery mark, AVG, Hypertension Classification Indicator, IHB, Movement indicator	**Similar** The different display parameters do not impact safety and effectiveness of the device.
Inflation	Pump driven	Pump driven	**Identical**
Deflation	Automatic Air Release Valve	Automatic Air Release Valve	**Identical**
Pressure Sensor	Semi-conductor	Semi-conductor	**Identical**
Irregular Heart Beat detection	Yes	Yes	**Identical**
Body movement detection	Yes	Yes	**Identical**
Hypertension indicator	Yes	Yes	**Identical**
Advanced positioning sensor	Yes	No	**Different** This feature does not impact safety

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Model name	Predicate Device Omron BP652N (K142917)	Subject Device GMC BQ705	Comparison
			and effectiveness of the device
Average of latest three measurements	Yes	Yes	**Identical**
Memory	100 readings	120 reading(60memories*2 zones)	**Similar** This feature does not impact safety and effectiveness of the device
Multiple Users	No	Yes(2)	**Different** This feature does not impact safety and effectiveness of the device
Power Source	AAA Battery*2 pcs	AAA Battery*2 pcs	**Identical**
Dimension	89 mm × 61 mm × 13 mm (L x W x H)	67×75.7×30mm (L x W x H)	**Similar** Size is not a factor in function of the device
Weight	Approx. 80g (2 7/8 oz) (without batteries)	81g (without batteries)	**Similar** Weight is not a factor in function of the device

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Model name		Predicate Device Omron BP652N (K142917)	Subject Device GMC BQ705	Comparison
Operating Environment	Temperature	10~40℃ (50-104℉)	10~40℃ (50-104℉)	**Identical**
	Humidity	15%~85% RH	15%~85% RH	**Identical**
	Ambient pressure	N/A	700-1060 hPa	**Different** This feature does not impact safety and effectiveness of the device
Storage Environment	Temperature	-20~60℃ (14-140℉)	-10~60 ℃(14-140℉)	**Identical**
	Humidity	10%~95% RH	10%~90% RH	**Similar** This minor difference does not impact safety and effectiveness of the device.
	Ambient pressure	700-1060 hpa	700-1060 hPa	**Identical**

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Model name	Predicate Device Omron BP652N (K142917)	Subject Device GMC BQ705	Comparison
Compliance Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 AAMI SP10 ANSI/AAMI/ISO81060-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30 ISO 81060-2 ISO 10993-1	**Similar** BQ705 complied with the latest Recognized Consensus Standards

The subject device is viewed as substantially equivalent to the predicate devices Omron BP652N because they have same intended use and use the well known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

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Performance Testing:

Bench testing was conducted to demonstrate that the device meets its requirements and specification.

The following performance tests were completed:

- ANSI AAMI ES60601-1
- IEC 60601-1-2
- IEC 60601-1-11
- IEC 80601-2-30

The GMC Wrist Automatic Blood Pressure Monitor, Model BQ705 meets all applicable requirements.

Biocompatibility

The materials of construction are widely used in the same or similar applications; therefore, demonstrating the material's use in other medical devices and supporting existing biocompatibility.

Clinical testing

Testing to insure clinical accuracy of the device in accordance with ISO 81060-2 as documented in Clinical Investigation Report. 85 patients (38 males and 47 females) were invited for the study. Standard auscultation method was used as the reference blood pressure monitor measuring in the left arm. Blood pressure measurements were repeated alternatively with the device and auscultation in the same arm according to the sequence in ISO 81060-2.

Conclusion

Based on the evaluations completed, there are no new safety or effectiveness issues introduced with this new medical device. Therefore, the GMC Wrist Automatic Blood Pressure Monitor, Model BQ705, is substantially equivalent to the predicate devices Omron BP652N (K142917)