GMC Inc.
No. 686, Su Chu Rd., Chuzhou,
Anhui, China

510(k) Summary

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Proprietary or Trade Name:	GMC Upper Arm Automatic Blood Pressure Monitor, Model X3
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 HEM-7311 (K133379)
Date Summary Prepared:	07/16/2018

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Device Description:

The GMC Upper Arm Automatic Blood Pressure Monitor, Model X3, 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 Upper Arm Automatic Blood Pressure Monitor, Model X3, 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 Upper Arm Automatic Blood Pressure Monitor, Model X3 is substantially equivalent to the Omron HEM-7311 (K133379).

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Model name	Predicate Device Omron HEM-7311 (K133379)	Subject Device GMC X3	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. 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.	**Identical**
Use Environment	Home use	Home use	**Identical**
Patient Population	Adult	Adult	**Identical**

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Specifications / Features

Model name		Predicate Device Omron HEM-7311 (K133379)	Subject Device GMC X3	Comparison
Measurement method		Oscillometric methods	Oscillometric methods	**Identical**
Cuff fits arm circumference		17-22cm/ 22-32cm/ 22-42cm	24-40 cm (9.4”~15.7”)	**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 HEM-7311 (K133379)	Subject Device GMC X3	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**
Average of latest three measurements	Yes	Yes	**Identical**

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Model name		Predicate Device Omron HEM-7311 (K133379)	Subject Device GMC X3	Comparison
Multiple Users		Yes(2)	Yes(2)	**Identical**
Power Source		Battery as well as AC adaptor	Battery as well as AC adaptor	**Identical**
Dimension		183 X 230 X 99mm (L x W x H)	96 X 139.7 X 63.2mm (L x W x H)	**Similar** Size is not a factor in function of the device
Weight		Approx. 640g (1 lbs6 5/8 oz) (without batteries)	246g (without batteries)	**Similar** Weight is not a factor in function of the device
Operating Environment	Temperature	10~40℃ (50-104℉)	10~40℃ (50-104℉)	**Identical**
	Humidity	15%~90% RH	15%~85% RH	**Similar** This minor difference does not impact safety and effectiveness of the device.
	Ambient pressure	N/A	700-1060 hpa	**Different** This feature does not impact safety and effectiveness of the device

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Model name		Predicate Device Omron HEM-7311 (K133379)	Subject Device GMC X3	Comparison
Storage Environment	Temperature	-20~60℃ (-4 -140°F)	-10~60 ℃(14-140°F)	**Similar** This minor difference does not impact safety and effectiveness of the device.
	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**
Compliance Standards		ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30 ISO81060-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30 ISO81060-2 ISO 10993-1	**Identical**

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The subject device is viewed as substantially equivalent to the predicate devices Omron HEM-7311 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

Performance Testing:

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

The following performance tests were completed:

- #19-4
  ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- #19-8
  IEC 60601-1-2 Edition 4.0 2014-02
  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- #19-14
  IEC 60601-1-11 Edition 2.0 2015-01
  Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- #3-123
  IEC 80601-2-30 Edition 1.1 2013-07
  Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

The GMC Upper Arm Automatic Blood Pressure Monitor, Model X3 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.

It is evaluated according to #2-220 ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Clinical testing

Testing to insure clinical accuracy of the device in accordance with ISO 81060-2 as documented in Clinical Investigation Report. 85 patients (39 males and 46 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 #3-122 ISO 81060-2 Second edition 2013-05-01 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.

Conclusion

Based on the evaluations completed, there are no new safety or effectiveness issues introduced with this new medical device. Therefore, the GMC Upper Arm Automatic Blood Pressure Monitor, Model X3, is substantially equivalent to the predicate devices Omron HEM-7311 (K133379).