



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 22, 2016

Shenzhen Urion Technology Co., Ltd.
Ms. Autumn Liu
Sales Manager
4th Building, Hi-tech Industrial Zone,
Heping Community, Fuyong Street, Baoan
Shenzhen, 518103 CN

Re: K160019
Trade/Device Name: Upper Arm Electronic Blood Pressure Monitor U80 Series,
including: U80A, U80AH, U80B, U80BH
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 28, 2015
Received: January 15, 2016

Dear Ms. Autumn Liu,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a faint, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160019

Device Name

Upper Arm Electronic Blood Pressure Monitor U80 Series, including: U80A, U80AH, U80B, U80BH

Indications for Use (Describe)

The U80 Series Upper Arm Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-36cm. Suitable for adults who over the age of 12.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section III 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: Dec 28, 2015
2. Sponsor

Shenzhen Urion Technology Co., Ltd
4th building, Hi-tech Industrial Zone,
Heping Community, Fuyong street,
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China 518103

Establishment Registration Number: not yet;

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3. Submission Correspondent
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4. Proposed Device Identification

Proposed Device Name: Electronic Blood Pressure Monitor;

Proposed Device Model: U80 Series, including: U80A, U80AH, U80B, U80BH

Classification Name: System, measurement, blood-pressure, non-invasive;

Common Name: Electronic Blood Pressure Monitor;

Classification: 2

Product Code: DXN;

Regulation Number: 21 CFR 870.1130;

Review Panel: Cardiovascular;

Intended Use Statement:

The U80 Series Upper Arm Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-36 cm. Suitable for persons who over the age of 12.

5. Predicate Device Identification

510(k) Number: K001670

Product Name: Electronic Blood Pressure Monitor, HEM-757

Manufacturer: Omron Healthcare, Inc

6. Device Description

The proposed device, U80 Series Electronic Blood Pressure Monitor, is a battery driven automatic on-invasive blood pressure monitor. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult person at upper arm within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or kPa.

All the models included in this submission follow the same software, same measurement principle and same specifications. The main differences are appearance, data storage and time display. These three differences will not affect the safety and effectiveness of the device.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance.

IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

ANSI/AAMI/IEC 80601-2-30:2009 Medical electrical equipment Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

ANSI/AAMI/ISO 81060-2:2009 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.

8. Substantially Equivalent

Table III-1 Substantially Equivalent Comparison

ITEM	U80 Series Electronic Blood Pressure Monitor	Electronic Blood Pressure Monitor HEM-757, K001670	Comparison
Product Code	DXN	DXN	Same
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Same
Class	II	II	Same
Intended Use	U80 Series Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-36 cm.	Measure the systolic and diastolic blood pressure and pulse rate in adult patients with arm circumference between 7 inches to 15 inches.	SE Analysis 1
Measurement Type	Upper arm	Upper arm	Same
Patient Population	Adults Person over 12	Adult	Same
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	Same
Principle	Oscillometric	Oscillometric	Same
BP Range	0 ~ 299 mmHg	0 ~ 280mmHg	SE Analysis 2
BP Accuracy	±3 mmHg	±3 mmHg or 2% of reading	SE Analysis 3
PR Range	40-199 bpm	40-180 bpm	SE Analysis 4

Cuff Size	63 cm (length) x 14.4 cm (width)	48 cm (length) x 14 cm (width)	SE Analysis 1
Power Supply	Four AA batteries or AC adapter	Four AA batteries or AC adapter	Same
Software Level Concern	Moderate	Moderate	Same

SE Analysis 1

The intended arm circumferences (22-36 cm VS **about** 17.8-38 cm) and cuff size (63 X 14.4cm VS 48 X 14 cm) of the proposed and predicate device are different. This difference are very slight, and the cuff size is appropriate to the claimed intended arm circumference per ANSI/AAMI/IEC 80601-2-30. Therefore, this point is considered as substantially equivalent.

SE Analysis 2

The blood pressure measurement range of the proposed is a little larger than that of the predicate device. (0-299 mmHg VS 0-280 mmHg). But the difference parts of the range 280-299 mmHg are happened very rare and abnormal, and the range is clearly stated on the label of the container and instructions manual, the operator can select whether to use this product per the actual conditions. Therefore, this difference is considered to be not affect the substantially equivalent conclusion.

SE Analysis 3

The blood pressure measurement accuracy of the proposed is a little different compared with that of the predicate device. (± 3 mmHg VS ± 3 mmHg or 2% of reading). For the predicate device's measurement accuracy with ± 3 mmHg or 2% of reading, the larger shall be taken, that is, for the actual measurement range 0-300mmHg, the accuracy is more than ± 3 mmHg. Therefore, this point is considered as substantially equivalent.

SE Analysis 4

The pulse rate measurement range of the proposed is a little different compared with that of the predicate device. (40 – 199 bpm VS 40 – 180 bpm). The difference parts, 180-199 bpm, is very rare and abnormal, and the the range is clearly stated on the label of the container and instructions manual, the operator can select whether to use this product per the actual conditions. Therefore, this difference is considered to be not affect the substantially equivalent conclusion.

The proposed device, U80 Series Upper Arm Electronic Blood Pressure Monitor, is determined to be Substantially Equivalent (SE) to the predicate device, Electronic Blood Pressure Monitor HEM-757 (k001670), in respect of safety and effectiveness.