eBELTER

Section 5 510(K) Summary

JUL 2 5 2014

K134029

Date: December 12, 2013

Submitter Information

Name: Shenzhen Belter Health Measurement and Analysis Technology Co.,ltd
Address: 702,704, block C ,Tsinghua Unis science park,No.13 Langshan Rd,Hi-Tech Industrial park(north),Nanshan District,518057 shenzhen,People's Republic of China
Tel: 0755-61869839
Fax: 0755-61869122
Contact person: pang ming
E-mail: pangm@ebelter.com

Name of device

Trade name: Belter Blood pressure meter ,Model: ePA-46B
Common name: Belter Blood pressure meter
Classification name: System, Measurement, Blood Pressure, Noninvasive
Production regulation: 21CFR 870.1130
Product code: DXN

Predicate Device

HEM-7200-Z (BP742)(Omron Healthcare Inc.,DXN,K121932)

Description

The Belter Blood pressure meter 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 with arm circumference ranging from 22 cm to 36cm by the oscillometric technique. User can select the blood pressure unit mmHg or KPa.

The device consists of the microprocessor, pressure sensor, operation keys, pump, deflation control valve and LCD. The subject device is powered by four AA alkaline batteries.

The device has a memory function that automatically stores up to 60 sets of the latest measurements. It can also display the latest measurement result.

The subject device embeds a Bluetooth that allows it to transport the measurement data to nearby receiving end.

The device also detects the appearance of irregular heartbeats during measurement. and gives a warning signal with readings.

Intended use

Belter Blood pressure meter is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person. It can be used at medical facilities or at home.

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Substantially Equivalent

The Belter Blood pressure meter (ePA-46B) has the similar essential performance and the same Operation Principle as the predicated devices.

Table 1

Compared item	**Belter** ePA-46B	**Omron** HEM-7200-Z (BP742) (K121932)	**Comment**
Indications for Use	Belter Blood pressure meter is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person. It can be used at medical facilities or at home. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	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.	Similar
Intended patient	Adult	Adult	Same
Environment of use	medical facilities or home	Home	Similar
Operation Principle	Oscillometric	Oscillometric	Same
Measurement Range	Pressure: 0-280mmHg Pulse Rate: 40-200 bpm	Pressure: 0-299mmHg Pulse Rate: 40 -180bpm	Similar
Accuracy	Pressure :±3mmHg (±0.4kPa) Pulse Rate: ±5%	Pressure:±3mmHg (±0.4kPa) or 2% of reading Pulse Rate: ±5%	Similar
Display screen	LCD	LCD	Same
Scale Selection	mmHg/Pka	mmHg/Pka	Same
Cuff	22-36 cm	22-46cm	Similar

Memory	60sets	30sets	Similar
Power supply	4 AA batteries	4 AA batteries or AC Adaptor (AC 100-240 V)	Similar
Operating Environment	Temperature : +10℃ ~ +40℃ ; Humidity : 30 ~ 85%RH	Temperature : +10℃ ~ +40℃ ; Humidity : 30 to 85%RH	Similar
Storage Environment	Temperature : -20 ℃ ~ +50℃; Humidity: 20%~95%	Temperature : -25 ℃ ~ +60℃; Humidity: 10%~95%	Similar
Weight	196g	340g(Not Including batteries)	Similar
Size	74mm×152mm×33mm	141mm×123mm×85mm	Similar
Conformance standard	IEC 60601-1, IEC 60601-1-2, ANSI/AAMI SP10, ISO 10993-5,-10	IEC 60601-1, IEC 60601-1-2, ANSI/AAMI SP10, ISO 10993-5,-10	Same

Performance Data

The following practices were followed and monitored for development of the Belter Blood pressure meter:

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety -Collateral Standard: Electromagnetic Compatibility-Requirements and Tests, 2007
- ANSI/AAMISP10 Manual, electronic, or automated sphygmomanometers, 2002/A1:2003
- IEC60601-1-11 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,2010
- ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing, 2009
- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity, 2010
- EN1060-1:A1:1995+A2:2009 Non-invasive sphygmomanometers —Part 1: General requirements,2010
- EN1060-3 ,Non-invasive sphygmomanometers –Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems,2005
- EN1060-4 Non-invasive sphygmomanometers - Part 4:Test procedures to determine the overall system accuracy of automated Non-invasive

sphygmomanometers,2004

Conclusion

The Belter Blood pressure meter (ePA-46B) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

July 25, 2014

ShenZhen Belter Health Measurement and Analysis Technology Co., Ltd
Mr. Pang Ming, RA Manager
702,704, block C, Tsinghua Unis Science Park,
No.13 Langshan Rd, Hi-tech industrial park (north), Nanshan District,
Shenzhen, Guangdong 518057
People's Republic of China

Re: K134029
Trade/Device Names: Belter Blood Pressure Meter, Model ePA-46B
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: June 17, 2014
Received: June 20, 2014

Dear Mr. Pang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use

510(k) Number: __K134029_____

Device Name: Belter Blood pressure meter

Model: ePA-46B

Indications for Use

Belter Blood pressure meter is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person. It can be used at medical facilities or at home.

The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.

Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Sub part D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FDA
Ken Skodacek for

Bram Zuckerman