



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2015

Xuzhou Maicuff Technology Co.,ltd.
c/o Mr. Ray Wang
Official Correspondent
Beijing Believe Tech. Service Co., Ltd.
1-202, Build 3, Beijing New World, No.5 Chaoyang Rd.,
Chaoyang District
Beijing, 100024 CN

Re: K151290

Trade/Device Name: Disposable Blood Pressure Cuff, Reusable Blood Pressure Cuff -
Models: M5541-1#, M5541-2#, M5541-3#,
M5514-4#, M5542, M5543, M5544, M5545, M5546; M5301,
M5302, M5303, M5304, M5305; M5641-1#, M5641-2#,
M5641-3#, M5614-4#, M5642, M5643, M5644, M5645, M5646;
and M5401, M5402, M5403, M5404, M5405

Regulation Number: 21 CFR 870.1120

Regulation Name: Blood-Pressure Cuff

Regulatory Class: Class II

Product Code: DXQ

Dated: April 29, 2015

Received: May 15, 2015

Dear Mr. Ray Wang,

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

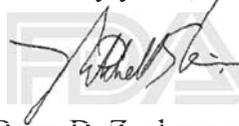
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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, large 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)

K151290

Device Name

Disposable/Reusable Blood Pressure Cuff, Models -

M5541-1#,M5541-2#,M5541-3#,M5514-4#,M5542,M5543,M5544,M5545,M5546; M5301,M5302,M5303,M5304,M5305

M5641-1#,M5641-2#,M5641-3#,M5614-4#,M5642,M5643,M5644,M5645,M5646; and M5401,M5402,M5403,M5404,M5405

Indications for Use (Describe)

The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes.

The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in infant, pediatric and adult sizes.

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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K151290

Page 1 of 6

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 Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation:2015/5/5
2. Sponsor Identification

XUZHOU MAICUFF TECHNOLOGY CO., LTD.

8#-2-1106 Jinxiujiayuan, Jianguo West Road, Xuzhou City, Jiangsu Province, China

Establishment Registration Number: Pending

Contact Person: Li Zhaoqian

Position: General Manager

Tel: +86-516-85908810

Fax:+86-516-85908830

Email: info@maicuff.com

3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe Tech. Service Co., Ltd

Tel: +86-21-50313932,

Fax: +86-21-68093116

Email: Ray.Wang@believe-med.com

4. Identification of Proposed Device

Trade Name: Disposable/Reusable Blood Pressure Cuff

Common Name: Blood Pressure Cuff

Model(s):

M5541-1#,M5541-2#,M5541-3#,M5514-4#,M5542,M5543,M5544,M5545,M5546;

M5641-1#,M5641-2#,M5641-3#,M5614-4#,M5642,M5643,M5644,M5645,M5646;

M5301,M5302,M5303,M5304,M5305;

M5401,M5402,M5403,M5404,M5405;

Regulatory Information

Classification Name: Blood Pressure Cuff

Classification: 2

Product Code: DXQ

Regulation Number: 870.1120

Review Panel: Cardiovascular

Indication For Use Statement:

The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes.

The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in infant, pediatric and adult sizes.

Device Description

The proposed device is an accessory used in conjunction with noninvasive blood pressure measurement systems. It is available in neonatal, infant, pediatric and adult sizes.

The proposed device includes disposable blood pressure cuff and reusable blood pressure, both disposable and reusable blood pressure cuff has same structure, which contains Cuff with bladder and Air Hose. Air hose has single tube and double tube.

The disposable blood pressure cuff is single use device, and which is made of non-woven fabrics & PVC (Cuff) and PVC (Air Hose), thereinto, the non-woven fabrics & PVC (Cuff) is the material used to contacting with the patient.

The disposable blood pressure cuff has 18 models with different size for different population with different arm size, and the 9 models of 18 are use single tube of air hose and other 9 models are use double tube of air hose, which is used for different noninvasive blood pressure measurement system.

The reusable blood pressure cuff is reusable device, and which is made of 210D Nylon TPU (Cuff)

and PVC (Air Hose), thereinto, the 210D Nylon TPU (Cuff) is the material used to contacting with the patient.

The reusable blood pressure cuff has 10 models with different size for different population with different arm size, and the 5 models of 10 are use single tube of air hose and other 5 models are use double tube of air hose, which is used for different noninvasive blood pressure measurement system.

Both disposable and reusable blood pressure cuff are provided as non-sterile.

5. Identification of Predicate Device(s)

Predicate Device

510(k) Number: K112544 and K120364

6. Non-Clinical Test Conclusion

Non clinical 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:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
- ISO 81060-1:2012 Non-Invasive Sphygmomanometers - Part 1: Requirements And Test Methods For Non-Automated Measurement Type

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison (Disposable BP Cuff)

ITEM	Proposed Device (Disposable Blood Pressure Cuff)	Predicate Device (K120364)	Remark
Intended Use	The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes.	The Unimed Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes. The cuff is no designed, sold, or intended for use except as indicated.	SE
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	
Tube Configuration	One or two tube	One or two tube	
Size	Conform to AHA bladder sizes recommendations Neonatal 1 (3-5.5 cm) Neonatal 2 (4-8 cm) Neonatal 3 (6-11 cm) Neonatal 4 (7-13 cm) Infant (9-14.5 cm) Pediatric (13-21.5 cm) Small Adult (21-27 cm) Adult (26-35.5 cm) Large Adult(35-45 cm)	Conform to AHA bladder sizes recommendations Neonatal 1 (3-6 cm) Neonatal 2 (4-8 cm) Neonatal 3 (6-11 cm) Neonatal 4 (7-13 cm) Neonatal 5 (8-15 cm) Infant (9-14.8 cm) Child (13.8-21.5 cm) Small Adult (20.5-28.5 cm) Adult (27.5-36.5 cm) Adult Long (27.5-36.5 cm) Large Adult(35.5-46 cm) Large Adult Long(35.5-46 cm) Thigh (45-56 cm)	SE
Single Use	Y	Y	
Sterile	No	No	
Pressure Limits	0-300 mmHg	0-300 mmHg	

Table 2 General Comparison (Reusable BP Cuff)

ITEM	Proposed Device (Reusable Blood Pressure Cuff)	Predicate Device (K112544)	Remark
Intended Use	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in infant, pediatric and adult sizes.	The Unimed Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is no designed, sold, or intended for use except as indicated.	SE
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	SE
Tube Configuration	One or two tube	One or two tube	SE
Size	Conform to AHA bladder sizes recommendations Infant (9-14.5 cm) Pediatric (13-21.5 cm) Small Adult (21-27 cm) Adult (26-35.5 cm) Large Adult (35-45 cm)	Conform to AHA bladder sizes recommendations Neonatal (6-11 cm) Infant (10-19 cm) Pediatric (18-26 cm) Small Adult (20-28 cm) Adult (25-35 cm) Adult Long(25-35 cm) Large Adult (33-47 cm) Large Adult Long(33-47 cm) Adult Thigh (46-66 cm)	SE
Single Use	No	No	SE
Sterile	No	No	SE
Pressure Limits	0-300 mmHg	0-300 mmHg	SE

Table 3 Biocompatibility Comparison

ITEM	Proposed Device	Predicate Device	Remark
Cytotoxicity	Under the conditions of the study, not cyteotoxicity effect	Comply with ISO 10993-5	SE
Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SE
Sensitization	Under conditions of the study, not a sensitizer.		SE

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.