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

November 28, 2016

Shenzhen Med-link Electronics Tech Co., Ltd.
Mina Cheng
Regulatory Affairs Specialist
4th Fl, Bldg A, Yingtailong Industrial Prk,
Dalang South Road, Longhua District
Shenzhen, 518109 CN

Re: K160530
Trade/Device Name: Med-link Disposable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: December 22, 2015
Received: February 25, 2016

Dear Mina Cheng:

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.

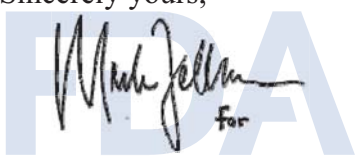
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160530

Device Name
Med-link Disposable Blood Pressure Cuff

Indications for Use *(Describe)*
Med-link 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 cuff is not designed, sold, or intended for use except as indicated.

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
PRAStaff@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."

Shenzhen Med-link Electronics Tech Co., Ltd.

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR§807.92.

Type of submission: Traditional

The assigned 510(k) number is:K160530

1. Submitter information

Manufacturer Name: Shenzhen Med-link Electronics Tech Co., Ltd.

Address: 4th Fl, Bldg A, Yingtailong Industrial Park, Dalang South Road, Longhua District, Shenzhen, Guangdong, CHINA, 518109

Tel: 0086-755-61120299

Fax: 0086-755-61120055

Establishment Registration Number: 3006636961

2. Contact Person

Mina Cheng (Regulatory Affairs Specialist)

E-mail: user22@med-linket.com

3. Date of preparation

Nov. 19, 2016

4. Identification of the Device

Trade Name: Med-link Disposable Blood Pressure Cuff

Models as listed below:

Table 1 Device Model

Device Name/Type	Device Model
Disposable Blood Pressure Cuff	Y000DSN1-1#, Y000DSN2-1#, Y000DSN1-2#, Y000DSN2-2#, Y000DSN1-3#, Y000DSN2-3#, Y000DSN1-4#, Y000DSN2-4#, Y000DSN1-5#, Y000DSN2-5#, Y000DC1, Y000DC2, Y000DSA1, Y000DSA2, Y000DA1, Y000DA2, Y000DAL1, Y000DAL2, Y000DLA1, Y000DLA2, Y000DT1, Y000DT2

Common Name: Non-invasive Blood Pressure Cuff

Classification Name: Blood Pressure Cuff

Device Classification: II

Classification Regulation: 21 CFR 870.1120

K160530

Product Code: DXQ

5. Identification of the Predicate Device

Table 2 Predicate Devices Information

No.	Device Name	Common Name	Manufacture	Classification and Code	Classificiation regulation	510(k) number
Primary Predicate	Disposable/Reusable Blood Pressure Cuff	Non-invasive Blood pressure cuff	XUZHOU MAICUFF TECHNOLOGY CO.,LTD.	Class II, DXQ	21 CRF 870.1120	K151290
Secondary Predicate	Unimed Disposable Blood Pressure Cuff	Non-invasive Blood pressure cuff	Unimed Medical supplies Inc.	Class II, DXQ	21 CRF 870.1120	K120364

6. Intended Use and Indications for Use of the Subject device

Med-link 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 cuff is not designed, sold, or intended for use except as indicated.

7. Device Description

The proposed device, Med-link Disposable Blood Pressure Cuff is rectangle soft inelastic sleeve. There is a single-tube or twin-tube connected to a sealed gas chamber. It is wrapped around the patient's limb/thigh and secured by hook and loop closure. The device tubing is connected to a non-invasive blood pressure measurement system. It is available in various sizes for different limb range. It is provided non-sterile.

Table 3 Intended Limb Range for Each Model

No.	Model	Intended Limb Range (Unit: cm)
1	Y000DSN1-1#	3 - 6
2	Y000DSN2-1#	3 - 6
3	Y000DSN1-2#	4 - 8
4	Y000DSN2-2#	4 - 8
5	Y000DSN1-3#	6 - 11

No.	Model	Intended Limb Range (Unit: cm)
6	Y000DSN2-3#	6 - 11
7	Y000DSN1-4#	7 - 14
8	Y000DSN2-4#	7 - 14
9	Y000DSN1-5#	8 - 15
10	Y000DSN2-5#	8 - 15
11	Y000DC1	15 - 22
12	Y000DC2	15 - 22
13	Y000DSA1	17 - 25
14	Y000DSA2	17 - 25
15	Y000DA1	24 - 32
16	Y000DA2	24 - 32
17	Y000DAL1	28 - 37
18	Y000DAL2	28 - 37
19	Y000DLA1	32 - 42
20	Y000DLA2	32 - 42
21	Y000DT1	42 – 50
22	Y000DT2	42 - 50

Table 4 Contact Components and Relevant Materials

Device Type	Contact Components	Contact Materials
Med-link Disposable Blood Pressure Cuff	Inner face of hose	Nonwoven Polyester with a PVC laminate Backing

8. Non-clinical Testing

A series of safety, essential performance and in vitro biocompatibility tests were performed to assess the safety and effectiveness of Med-link Disposable Blood Pressure Cuff.

The tests listed below were conducted in accordance with

ISO 10993-1 Biological evaluation of medical devices-Part 1: Evaluation and testing

ISO 10993-5 Biological Evaluation of medical devices-Part 5: Test for in vitro cytotoxicity

ISO 10993-10 Biological evaluation of medical devices- Part 10: Tests for Irritation And Skin Sensitization

ISO 81060-1:2007/ AAMI/ANSI/ISO81060-1:2007/(R)2013 Non-Invasive Sphygmomanometers - Part 1: Requirements And Test Methods For Non-Automated Measurement Type

- Cytotoxicity Test
- Skin irritation Test
- Skin Sensitization Test（the Guinea Pig maximization test）

9. Technological Comparison with Predicate Device

Table 4 Comparison to Primary Predicate Device

Item	Proposed Device	Primary Predicate	Secondary Predicate
Trade name	Med-link Disposable Blood Pressure Cuff	Disposable Blood Pressure Cuff	Unimed Disposable Blood Pressure Cuff
510(K) Submitter	Shenzhen Med-link Electronics Tech Co., Ltd.	XUZHOU MAICUFF TECHNOLOGY CO.,LTD.	Unimed Medical supplies Inc.
510(K) Number	—	K151290	K120364
Classification Regulation	21CRF 870.1120	21CRF 870.1120	21CRF 870.1120
Classification and Code	Class II, DXQ	Class II, DXQ	Class II, DXQ
Common name	Non-invasive Blood Pressure Cuff	Non-invasive Blood Pressure Cuff	Non-invasive Blood Pressure Cuff
Intended use	Med-link 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 cuff is not designed, sold, or intended for use except as indicated.	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 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 cuff is not designed, sold, or intended for use except as indicated.
Patient populations	Adults/Pediatrics	Adults/Pediatrics	Adults/Pediatrics
Tube configuration	One or two tube	One or two tube	One or two tube
Size	Conform to AHA bladder	Conform to AHA bladder	Conform to AHA bladder

Item	Proposed Device	Primary Predicate	Secondary Predicate
	sizes recommendations Neonatal 1# (3-6cm) Neonatal 2# (4-8cm) Neonatal 3# (6-11cm) Neonatal 4# (7-14cm) Infant (8-15cm) Pediatric (15-22 cm) Small Adult (17-25 cm) Adult (24-32cm) Adult long(28-37cm) Large Adult (32-42cm) Thigh (42-50cm)	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)	sizes recommendations Neonate 1 (3-6 cm) Neonate 2 (4-8 cm) Neonate 3 (6-11 cm) Neonate 4 (7-13 cm) Neonate 5 (8-15 cm) Infant (9-14.8 cm) Child (13.8-21 cm) Small Adult (20.5-28.5 cm) Adult (27.5-36.5 cm) Large Adult (35.5-46 cm) Large Adult Long (35.5-46cm) Thigh (45-56cm)
Pressure limit	0-300mmHg	0-300mmHg	0-300mmHg
Sterility	Non-sterile	Non-sterile	Non-sterile
Non-clinical Requirement	AAMI/ANSI/ISO81060-1:2007/(R)2013 Comply with ISO 10993 biocompatibility evaluation	Comply with ISO 10993 biocompatibility evaluation	Comply with ISO 10993 biocompatibility evaluation

Med-link Disposable Blood Pressure Cuff has the same intended use, basic construction and technology specification as the predicate device. They are wrapped around the patient's arm or thigh and secured by a hook and loop fastener commonly called Velcro.

We extend the size to satisfy some special patients such as different neonatal size. Based on the performance testing in this submission, the slight difference on the range of these blood pressure cuffs does not raise any safety or effectiveness issue.

10. Comparison of Performance with Predicate Device

Performance testing was performed on the subject device and results were compared with predicate device. Tests were conducted following applicable procedures outlined in the FDA recognized consensus standard of AAMI/ANSI/ISO81060-1:2007/(R)2013, and results met all relevant requirements in the test standard.

11. Conclusion

After analyzing safety, essential performance and biocompatibility testing data, it can be concluded that: Med-link Disposable Blood Pressure Cuff are safe and effective as the predicate device.