August 2, 2018

Shenzhen Med-link Electronics Tech Co., Ltd.
Baihan Feng
Regulatory Affairs Specialist
4th Floor, Building A
Yingtailong Industrial Park
Dalang South Road, Longhua District
Shenzhen, China 518109

Re: K173869
Trade/Device Name: Med-link Reusable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: June 25, 2018
Received: June 25, 2018

Dear Baihan Feng:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173869

Device Name
Med-link Reusable Blood Pressure Cuff

Indications for Use *(Describe)*
Med-link 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 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.

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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:_____

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

Baihan Feng (Regulatory Affairs Specialist)

E-mail: mdl001@medlinket.com

3. Data of Submission

15th, Dec. 2017

4. Identification of the Device

Trade Name: Med-link Reusable Blood Pressure Cuff

Table 1 Device Model

Device Name/Type	Device Model
Reusable Blood Pressure Cuff	Y000N1, Y000N2, Y000I1, Y000I2, Y000C1, Y000C2, Y000S1, Y000S2, Y000A1, Y000A2, Y000L1, Y000L2, Y000T1, Y000T2, Y000RC1, Y000RC2, Y000RSA1, Y000RSA2, Y000RA1, Y000RA2, Y000RAL1, Y000RAL2, Y000RLA1, Y000RLA2, Y000RT1, Y000RT2

Common Name: Non-invasive Blood Pressure Cuff

Classification Name: Blood Pressure Cuff

Classification Regulation: 21 CFR 870.1120

Product Code: DXQ

5. Identification of the Predicate Device

Table 2 Predicate Device 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 CFR 870.1120	K151290
Secondary Predicate	Unimed Blood Pressure Cuff	Non-invasive Blood pressure cuff	Unimed Medical supplies Inc.	Class II, DXQ	21 CFR 870.1120	K112544

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

Med-link Reusable Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in neonatal, infant, 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 Reusable Blood Pressure Cuffs is rectangle soft inelastic sleeve with bladder, to which a single-tube or twin-tube is connected. It is wrapped around the patient's limb 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	Y000N1	6-11
2	Y000N2	6-11
3	Y000I1	10-15
4	Y000I2	10-15
5	Y000C1	14-21
6	Y000C2	14-21
7	Y000S1	20.5-28
8	Y000S2	20.5-28

9	Y000A1	27-35
10	Y000A2	27-35
11	Y000L1	34-43
12	Y000L2	34-43
13	Y000T1	42-54
14	Y000T2	42-54
15	Y000RC1	15-22
16	Y000RC2	15-22
17	Y000RSA1	17-25
18	Y000RSA2	17-25
19	Y000RA1	24-32
20	Y000RA2	24-32
21	Y000RAL1	28-37
22	Y000RAL2	28-37
23	Y000RLA1	32-42
24	Y000RLA2	32-42
25	Y000RT1	42-50
26	Y000RT2	42-50

8. Non-clinical Testing

A series of safety, essential performance and biocompatibility tests were performed to assess the safety and effectiveness of Med-link Reusable Blood Pressure Cuff. The tests listed below were conducted in accordance with

ISO 81060-1, non-invasive sphygmomanometers - part 1: requirements and test methods for non-automated measurement type.

IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

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

- Cytotoxicity Test
- Skin irritation Test
- Skin Sensitization Test

9. Substantial Equivalence Determination

Table 4 Comparison to Predicate Devices

Shenzhen Med-link Electronics Tech Co., Ltd.

Item	Proposed Device	Predicate Device	Secondary Predicate Device
Trade name	Med-link Reusable Blood Pressure Cuff	Reusable 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	K112544
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 Reusable Blood Pressure Cuff is accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile. It is available in neonatal, infant, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	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 disposable 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 not designed, sold, or intended for use except as indicated.
Patient populations	Adults/Pediatrics	Adults/Pediatrics	Adults/Pediatrics
Material Contacting patient	Cuff: Nonwoven Polyester with TPU laminate Air hose: PVC tap and Silicone tube	Cuff:: nylon TPU Air hose: PVC	Cuff: Pu Synthetic Leather Air Tubing: PVC
Tube configuration	One or two tube	One or two tube	One or two tube

Item	Proposed Device	Predicate Device	Secondary Predicate Device
Size	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (10-15cm) Pediatric (14-22cm) Small Adult (17-28cm) Adult (24-37cm) Large Adult (32-43cm) Adult Thigh (42-54cm)	Conform to AHA bladder sizes recommendations Infant (9-14.5cm) Pediatric (13-21.5cm) Small Adult (21-27cm) Adult (26-35.5cm) Large Adult (35-45cm)	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (10-19cm) Pediatric (18-26cm) Small Adult (20-28 cm) Adult (25-35 cm) Large Adult (33-47cm) Large Adult Long (33-47cm) Thigh (46-66cm)
Pressure limit	0-300mmHg	0-300mmHg	0-300mmHg
Sterile	No	No	No
Biocompatibility	Comply with ISO 10993-5 and ISO 10993-10 biocompatibility evaluation	Comply with ISO 10993-5 and ISO 10993-10 biocompatibility evaluation	Comply with ISO 10993-5 and ISO 10993-10 biocompatibility evaluation

Med-link Reusable 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, overweight. 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. Conclusion

Based on the comparison and analysis above, it can be concluded that: Med-link Reusable Blood Pressure Cuff are as safe and effective as the predicate devices.