February 13, 2026

Shenzhen Best Electronics Co., Ltd.
% Yijie You
General Manager
Qimmiq Medical Consulting Service Co., Ltd.
Rm.406, Bldg. C, Run Science Park
#18 Shenzhou Rd., Huangpu
Guangzhou, Guangdong 510663
China

Re: K253089
Trade/Device Name: NIBP Cuff (BCS-112, BCS-212, BCS-312, BCS-412, BCS-512, BCS-612, BCS-712, BCS-122, BCS-222, BCS-322, BCS-422, BCS-522, BCS-622, BCS-722, BCD-112, BCD-212, BCD-312, BCD-412, BCD-512, BCD-612, BCD-712, BCD-122, BCD-222, BCD-322, BCD-422, BCD-522, BCD-622, BCD-722)
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood pressure cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: January 27, 2026
Received: January 27, 2026

Dear Yijie You:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-

devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

KIMBERLY N. CROWLEY -S

Digitally signed by KIMBERLY N. CROWLEY -S

For: LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253089

Please provide the device trade name(s).

NIBP Cuff (BCS-112, BCS-212, BCS-312, BCS-412, BCS-512, BCS-612, BCS-712, BCS-122, BCS-222, BCS-322, BCS-422, BCS-522, BCS-622, BCS-722, BCD-112, BCD-212, BCD-312, BCD-412, BCD-512, BCD-612, BCD-712, BCD-122, BCD-222, BCD-322, BCD-422, BCD-522, BCD-622, BCD-722)

Please provide your Indications for Use below.

The NIBP 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 neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(K) Summary

1. 510(k) owner (Applicant)

Establishment Registration number:		K253089
Name:		Shenzhen Best Electronics Co., Ltd.
Address:		605 No.59 Building, the Second Industrial Park, Tianliao Community, Yutang Street, Guangming District, Shenzhen, P.R. China.
Contact Person	Name:	Martin Wong
	Address:	605 No.59 Building, the Second Industrial Park, Tianliao Community, Yutang Street, Guangming District, Shenzhen, P.R. China.
	TEL:	+86 13923770214
	Email:	307294149@qq.com

2. Contact Person (Authorized representative)

Name:	You Yijie
Address:	RM.406, Building C, Run Science Park, No.18 Shenzhou Road, Huangpu, Guangzhou, Guangdong 510663 P.R. China
TEL:	(+86)020-82245821
FAX:	(+86)020-82245821
Email:	jet.you@qimmiq-med.com

Date prepared: Sep. 22, 2025

3. Device Information

Device Common Name: Non-invasive Blood Pressure Cuff

Trade Name: NIBP cuff

Model: BCS-112, BCS-212, BCS-312, BCS-412, BCS-512, BCS-612, BCS-712, BCS-122, BCS-222, BCS-322, BCS-422, BCS-522, BCS-622, BCS-

	722, BCD-112, BCD-212, BCD-312, BCD-412, BCD-512, BCD-612, BCD-712, BCD-122, BCD-222, BCD-322, BCD-422, BCD-522, BCD-622, BCD-722
Classification name:	Blood pressure cuff
Review panel:	Cardiovascular
Product code:	DXQ
Regulation Class:	II
Regulation Number:	870.1120

4. Predicate Device and reference device Information

Predicate device:

510(k) submitter/holder:	Shenzhen Caremed Medical Technology Co., Ltd.
510(K) Number:	K182433
Trade Name:	Caremed Reusable Blood Pressure Cuff
Model:	N1A-PS, N1N-PS, N1N-PD, N1I-PS, N1I-PD, N1C-PS, N1C-PD, N1S-PS, N1S-PD, N1A-PD, N1AL-PS, N1AL-PD, N1L-PS, N1L-PD, N1T-PS, N1T-PD.
Classification name:	Blood pressure cuff
Review panel:	Cardiovascular
Product code:	DXQ
Regulation Class:	II
Regulation Number:	870.1120

Reference device

510(k) submitter/holder:	Shenzhen Changke Connect Electronics Co., Ltd.
510(K) Number:	K191253
Trade Name:	Reusable NIBP Cuff
Model:	CK-XT-78211-001, CK-XT-78211-003, CK-XT-78211-005, CK-XT-78211-006, CK-XT-78211-007, CK-XT-78211-008, CK-XT-78243-000, CK-XT-78243-001, CK-XT-78243-003, CK-XT-78243-005, CK-XT-78243-007, CK-XT-78243-008
Classification name:	Blood pressure cuff

Review panel:	Cardiovascular
Product code:	DXQ
Regulation Class:	II
Regulation Number:	870.1120

5. Device description

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

The subject device includes reusable non-invasive Blood Pressure Cuff(NIBP) cuff, all the reusable blood pressure cuff has same structure, which contains Cuff with bladder and Air Hose. Air hose has single tube and double tube.

The NIBP cuff is reusable device, Model BCS-X12 series and BCD-X12 series are made of PU synthetic leather (Cuff) and TPU (Air Hose), thereinto, the PU synthetic leather (Cuff) is the material used to contacting with the patient. Model BCS-X22 series and BCD-X22 series are made of Nylon (Cuff) and TPU (Air Hose), thereinto, and the Nylon (Cuff) is the material used to contacting with the patient's intact skin.

The NIBP cuff comes in 28 different sizes to fit different population of different arm sizes**.** Of these, 14 models(BCS-X12 series and BCS-X22 series) of 28 use a single tube of air hose, while the other 14 models(BCD-X12 series and BCD-X22 series) use a double tube of air hose, which is used for different noninvasive blood pressure measurement system.

6. Indications for Use

The NIBP 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 neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

7. Comparison to predicate device

Comparison Analysis: The subject device is substantially equivalent to the predicate devices, Caremed Reusable Blood Pressure Cuff, marketed by Shenzhen Caremed Medical Technology Co., Ltd., the substantial equivalence chart is provided as follows:

SE Comparisons	Subject device (Reusable NIBP cuff)	Predicate device (Caremed Reusable Blood Pressure Cuff)	Reference device (Shenzhen Changke Reusable NIBP Cuff)	Discussion of difference
510K Number	K253089	K182433	K191253	/
Classification Regulation	21CRF 870.1120	21CRF 870.1120	21CRF 870.1120	Same
Classification and Code	Class II, DXQ	Class II, DXQ	Class II, DXQ	Same
Common name	Non-invasive Blood Pressure Cuff	Non-invasive Blood Pressure Cuff	Non-invasive Blood Pressure Cuff	Same
Indications for Use	The NIBP 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 neonate, infant, child 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 neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for	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 neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended	Same

		use except as indicated.	for use except as indicated.	
Patient Populations	Adult/Pediatrics	Adults/Pediatrics	Adults/Pediatrics	Same
Tube Number	One or two	One or two	One	Same with the predicate device
Principles of Operation	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	Same
Limb Circumference (Range in cm)	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (10-19cm) Child (18-26cm) Small Adult (20-28cm) Adult (25-35cm) Adult Long (25-35cm) Large Adult (33-47cm)	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (10-19cm) Child (18-26cm) Small Adult (20-28cm) Adult (25-35cm) Adult Long (25-35cm) Large Adult (33-47cm)	Conform to AHA bladder sizes recommendations CK-XT-78211-XXX Series: Infant (10-15cm) Child (14-21.5cm) Small Adult (20.5-28cm) Adult (27-35cm) Large Adult (34-43cm) Adult Thigh (42-54cm)	Similar **See D1**

	Adult Thigh (46-66cm)	Adult Thigh (44-66cm)	CK-XT-78243-XXX Series: Neonatal (6-11cm) Infant (10-19cm) Child (18-26cm) Adult (25-35cm) Large Adult (33-47cm) Adult Thigh (44-66cm)	
Pressure Range	0-300 mmHg	0-300 mmHg	0-300 mmHg	Same
Sterility	Non-sterile	Non-sterile	Non-sterile	Same
Max. Leakage	< 4 mmHg/ min.	< 4 mmHg/ min.	< 4 mmHg/ min.	Same
Material	BCS-X12 series, BCD-X12 series： Cuff (Patient contacted): PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon BCS-X22 series, BCD-X22 series： Cuff (Patient contacted): Nylon Bladder: TPU Tubing: PVC	Cuff (Patient contacted): PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon	CK-XT-78211-XXX Series: Cuff (Patient contacted): PU Synthetic Leather Bladder: TPU Tubing: TPU Hook: Nylon Loop: Nylon CK-XT-78243-XXX Series: Cuff (Patient contacted): Nylon Bladder: TPU Tubing: Silica gel	Similar **See D2**

	Hook: Molded Nylon Loop: Nylon		Hook: Nylon Loop: Nylon	
Biocompatibility	No potential cytotoxicity; No sensitization observed; Negligible (no observed primary irritation)	No potential cytotoxicity; No sensitization observed (test sample score 0); Negligible (no observed primary irritation, test sample score 0)	No potential cytotoxicity; No sensitization observed; Negligible (no observed primary irritation)	Same

Justification of differences:

D1: Similar with the predicate device.

The subject device has the same limb circumference as the predicate device: Neonatal (6-11 cm), Infant (10-19 cm), Child (18-26 cm), Small Adult (20-28 cm), Adult (25-35 cm), Adult Long (25-35 cm) and Large Adult (33-47 cm). It also has a similar limb circumference to the predicate device: Adult Thigh (46-66 cm), which is covered by the circumference range of the predicate device(Adult Thigh(44-66 cm)). This is clearly disclosed in the user manual and marked on the cuff for selection.

Therefore, the difference of subject device with predicate device do not raise new questions of safety and effectiveness.

D2: The subject device, model BCS-X12 series and BCD-X12 series, have the same material with the predicate device(K182433), Caremed Reusable Blood Pressure Cuff.

The model BCS-X22 series, BCD-X22 series have Nylon for Cuff (Patient contacted), TPU for Bladder, PVC for Tubing, Molded Nylon for Hook, and Nylon for Loop, which is similar with the reference device (K191253, CK-XT-78243-XXX Series)(Nylon for Cuff (Patient contacted), TPU for Bladder, Silica gel for Tubing, Nylon for Hook, and Nylon for Loop). But both of them have the

same patient contacted material Nylon.

And the material of the subject device has been implemented biocompatibility evaluation in agreement with recommendations according to FDA Guidance-Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process", and Cytotoxicity, Sensitization and Irritation meet the requirement of ISO 10993- 5, ISO 10993-10 and ISO 10993-23 respectively. Therefore, the difference of subject device with predicate device do not raise new questions of safety and effectiveness.

8. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The device performed performance testing to demonstrate and support safety and effectiveness when compared to the predicate and the applicable standards.

Standards	Standards Name
ISO 81060-1 First edition 2007-12-01	Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation

- **Biocompatibility Testing**

According to FDA Guidance-Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and ISO 10993-1:2018, we performed the biocompatibility evaluation and test of skin surface direct-contacting components:

(1) In vitro Cytotoxicity test according to ISO 10993-5:2009
(2) Skin Sensitization test according to ISO 10993-10:2021
(3) Irritation test according to ISO 10993-23:2021

The subject devices are considered surface contacting for a duration of exceed 24 hours but not 30 days.

9. Concise summary for any performance testing

9.1 Summary of Performance testing – bench

The performance of device, such pressure, Max. Leakage, bladder length, and integrity, was

tested and complied with the applicable requirements of the following standards: ISO 81060-1 First edition 2007-12-01, demonstrated that the performance of the device met the requirements.

9.2 Performance Testing – Animal

Not applicable to this submission for the NIBP cuff. The subject of this premarket submission, NIBP cuff, did not require animal studies and test results to support substantial equivalence.

9.3 Performance Testing – Clinical

Not applicable to this submission for the NIBP cuff. The subject device of this premarket submission, NIBP cuff, did not require clinical studies to support substantial equivalence.

Based on summary of non-clinical tests, the devices meet all the requirement of the standards.

10. Substantial Equivalence Conclusion

The NIBP cuff has the same intended use and similar characteristics as the cleared predicate device Caremed Reusable Blood Pressure Cuff.

Moreover, the NIBP cuff meets the safety and performance standards required for NIBP cuffs, as verified by the bench tests included in this submission, which demonstrate that the differences that existed between the subject device and the predicate device(K182433) do not raise any new questions of safety or effectiveness.

Thus, the subject device NIBP cuff is Substantially Equivalent (SE) to the predicate device(K182433).