January 27, 2021

ShenZhen Changkun Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, 510000 China

Re: K193387
Trade/Device Name: Arm Electronic Sphygmomanometer
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 27, 2020
Received: December 31, 2020

Dear Cassie Lee:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 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,

for LT 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

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)*
K193387

Device Name
Arm Electronic Sphygmomanometer

Indications for Use *(Describe)*
Arm Electronic Sphygmomanometer is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home.

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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510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

510(k) Owner's Name: ShenZhen Changkun Technology CO., LTD.
Establishment Registration Number: Applying
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Contact Person (including title): Steve Li (Manger Representative)
E-mail: changkunkj@163.com

Application Correspondent:
Contact Person: Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

2. Subject Device Information

Type of 510(k): Traditional
Common Name: Non-invasive blood pressure measurement systems
Classification Name: System, Measurement, Blood-Pressure, Non-Invasive
Trade Name:Arm Electronic Sphygmomanometer
Model Name: CK-A120, CK-A136, CK-A138, CK-A139, CK-A155, CK-A156, CK-A158, CK-A168
Review Panel: Cardiovascular
Product Code: DXN
Regulation Number: 870.1130
Regulatory Class: 2

3. Predicate Device Information

Sponsor	Shenzhen BSX Technology Electronics Co., Ltd.
Device Name and Model	Arm-type Electronic Blood Pressure Monitor Model: BSX516, BSX523, BSX525, BSX583, BSX593, BSX595
510(k) Number	K183058
Product Code	DXN

Regulation Number	870.1130
Regulation Class	II

4. Device Description

The proposed devices are battery driven automatic non-invasive blood pressure Monitor. It is used for automatically conduct the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult at upper arm within its claimed range and accuracy by oscillometry technique. Devices are consisted of three main parts: external hardwares (such as cuff), analog circuit, and MCU. The devices have the data storage function in order for data reviewing, including the systolic pressure, diastolic pressure, pulse rate and measurement time.
The proposed devices are intended to be used in medical facilities or at home and provided non-sterile.

5. Intended Use / Indications for Use

Arm Electronic Sphygmomanometer is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home.

6. Test Summary

Arm Electronic Sphygmomanometer has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Electromagnetic compatibility test according to IEC 60601-1-6 standard
- Performance according to AAMI / ANSI / ISO 81060-2 standard
- Lithium battery report in accordance with IEC62133
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Usability test according to IEC62366 standard
- Software verification and validation test according to the requirements of the FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Arm Electronic Sphygmomanometer is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device 1	Remark

Elements of Comparison	Subject Device	Predicate Device 1	Remark
Company	ShenZhen Changkun Technology CO., LTD.	Shenzhen BSX Technology Electronics Co., Ltd.	--
Product Name	Arm Electronic Sphygmomanometer	Arm-type Electronic Blood Pressure Monitor	--
Model Name	CK-A120, CK-A136, CK-A138, CK-A139, CK-A155, CK-A156, CK-A158,CK-A168	BSX516, BSX523, BSX525, BSX583, BSX593 and BSX595	--
Classification Name	systems,measurement,blood pressure,Non-invasive	systems,measurement,blood pressure,Non-invasive	SE
510(k) Number	Applying	K183058	--
Product Code	DXN	DXN	SE
Intended Use and Indications for Use			
Intended Use / Indications for Use	Arm Electronic Sphygmomanometer is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home.	The blood pressure monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable CUFF is wrapped around the arm of which the circumference includes 22 cm~32 cm. It is intended to be used in hospital environment or at home.	SE
Electrical requirement			
Power Supply	4x1.5V AA Alkaline Battery (CK-A138, CK-A139) 4x1.5V AAA Alkaline Battery (CK-A120, CK-A136) 3.7V 400mAh Li-ion Battery (CK-A155, CK-A156, CK-A158, CK-A168)	4x1.5V AAA Alkaline Battery (BSX516, BSX525, BSX583, BSX593 and BSX595) 3.7V 400mAh Li-ion Battery (BSX523)	SE Note 1
Performance specification			
Measurement Site	Upper Arm	Upper Arm	SE
Measuring range	Pressure: 0mmHg~299 mmHg; Pulse: 40 bpm~199 bpm	Pressure: 0mmHg~299 mmHg Pulse: 40 bpm ~180 bpm	SE Note
Pressure resolution	1 mmHg or 0.1kPa	1 mmHg or 0.1kPa	SE
Measuring accuracy	Pressure: ± 3mmHg Pulse: ±5%	Pressure: ± 3mmHg Pulse: ±5%	SE
Cuff Circumference	22~32cm	22~32cm	SE
Inflation and	Automatic	Automatic	SE

Elements of Comparison	Subject Device	Predicate Device 1	Remark
Deflation			
Measuring Method	Non-invasive Oscillometric	Non-invasive Oscillometric	SE
Patient Population	Adult	Adult	SE
Display	LCD	LCD	SE
Operation condition	Temperature: +5 to +40 °C, Humidity: 15 to 90% Atmospheric Pressure: 80 kPa~106 kPa	Temperature: +5 to +40 °C, Humidity: 15 to 85% Atmospheric Pressure: 80 kPa~106 kPa	SE Note 2
Transport/storage environment	Temperature: -25°C to +70°C, Humidity: ≤93%R.H. Atmospheric Pressure: 70 kPa~106 kPa	Temperature: -20°C to +55 °C, Humidity: 10 to 93% Atmospheric Pressure: 70 kPa~106 kPa	SE Note 2
Safety	IEC 60601-1 IEC 60601-1-11 IEC 80601-2-30	IEC 60601-1 IEC 60601-1-11 IEC 80601-2-30	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	SE
Biocompatibility	ISO 10993	ISO 10993	SE

Comparison

Note 1:

Although the “Power Supply” of the subject device is a little different from the predicate device, they all complied with the requirements of safety standards as IEC 60601-1, IEC 60601-1-2, IEC 80601-2-30 required. So this difference will not raise any safety or effectiveness issue.

Note 2:

Although “Measuring scope”, “Operation condition” and “Transport/storage environment” of the subject device are a little different from the predicate devices, but the difference of subject device is very similar with the K183058. So these parameters’ differences will not raise any safety or effectiveness issue.

Final Conclusion：

The subject device Non-invasive Sphygmomanometer (Arm Electronic Sphygmomanometer) (Model: CK-A120, CK-A136, CK-A138, CK-A139, CK-A155, CK-A156, CK-A158, CK-A168) has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device K183058.

8. Date of the summary prepared: December 27, 2020