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: K193386
Trade/Device Name: Wrist Electronic Sphygmomanometer
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 28, 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)*
K193386

Device Name
Wrist Electronic Sphygmomanometer

Indications for Use *(Describe)*
Wrist Electronic Sphygmomanometer is non-invasive blood measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the wrist. It can be used by medical professionals or at home. The cuff circumference is limited to 13.5-19.5 cm.

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: Noninvasive blood pressure measurement systems
Classification Name: system, measurement, blood-pressure, non-invasive
Trade Name: Wrist Electronic Sphygmomanometer
Model Name: CK-101, CK-101S, CK-102S, CK-W118, CK-W132, CK-W133, CK-W135, CK-W175, CK-W176, CK-W355, CK-W356, CK-W358
Review Panel: Cardiovascular
Product Code: DXN
Regulation Number: 870.1130
Regulatory Class: 2

3. Predicate Device Information

Sponsor	Shenzhen Med-link Electronics Tech Co., Ltd.
Device Name and Model	Med-link Wrist Digital Blood Pressure Monitor Model: ESM101
510(k) Number	K181154

Product Code	DXN
Regulation Number	870.1130
Regulation Class	II

4. Device Description

The Wrist Electronic Sphygmomanometer is a battery driven automatic non-invasive blood pressure meter. It can automatically conduct the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult at wrist within its claimed range and accuracy via the oscillometric technique.

The device uses the oscillometric method to determine blood pressure. This is accomplished by means of a sensitive transducer, which measures cuff pressure and minute pressure oscillations within the cuff. The first determination sequence initially pumps up to a cuff pressure of about 180-230mmHg for adults. After inflating the cuff, the Wrist Electronic Sphygmomanometer begins to deflate it at a rate of 3-6 mmHg/sec, and measures systolic, mean, and diastolic pressure. The Wrist Electronic Sphygmomanometer deflates the cuff one step each time it detects two pulsations of relatively equal amplitude ("peak matching"). The time between deflation steps depends on the frequency of these matched pulses (pulse rate of the patient). However, if the Wrist Electronic Sphygmomanometer is unable to find any pulse within several seconds, it will deflate to the next step. The process of finding two matched pulses at each step provides artifact rejection due to patient movement and greatly enhances accuracy.

The device will obtain the pressure point, which is before the maximum peak and whose amplitude of peak is 0.45 times the reference amplitude, is determined to be the systolic pressure; and the pressure point, which is after the maximum peak and whose amplitude of peak is 0.75 times the reference amplitude, is determine to be the diastolic. When the diastolic pressure has been determined, the NIBP Meter finishes deflating the cuff and updates the screen.

5. Intended Use / Indications for Use

Wrist Electronic Sphygmomanometer is non-invasive blood measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the wrist. It can be used by medical professionals or at home. The cuff circumference is limited to 13.5-19.5 cm.

6. Test Summary

Wrist 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 Wrist 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	Verdict
Company	ShenZhen Changkun Technology CO., LTD.	Shenzhen Med-link Electronics Tech Co., Ltd.	--
Product Name	Wrist Electronic Sphygmomanometer	Med-link Wrist Digital Blood Pressure Monitor	--
Model Name	CK-101, CK-101S, CK-102S, CK-W118, CK-W132, CK-W133, CK-W135, CK-W175, CK-W176, CK-W355, CK-W356, CK-W358	ESM101	--
Classification Name	System, Measurement, Blood-pressure, Non-invasive	System, Measurement, Blood-pressure, Non-invasive	SE
510(k) Number	Applying	K181154	--
Product Code	DXN	DXN	SE
Intended Use and Indications for Use			
Intended Use / Indications for Use	Wrist Electronic Sphygmomanometer is non-invasive blood measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the wrist. It can be used by medical professionals or at home. The cuff circumference is limited to 13.5-19.5 cm.	Med-link Wrist Digital Blood Pressure Monitor is non-invasive blood measurement of arterial blood pressure values in adults. It is intended to measure the diastolic, systolic blood pressures and pulse rate through an inflatable cuff wrapped around the wrist. It can be used by medical professionals or at home. The cuff circumference is limited to 13.5-19.5 cm.	SE
Electrical requirement			
Power Supply	For model CK-101, CK-101S, CK-102S, CK-W118, CK-W132, CK-W133, CK-W135, , CK-W176: 2 x 1.5V “AAA” alkaline batteries; For model CK-W175, CK-W355, CK-W356, CK-W358: 3.7V 400mAh Li-ion Battery	DC 3.0V(2xAAA alkaline battery)	SE Note 1
Performance specification			
Measurement Site	Wrist	Wrist	SE

Elements of Comparison	Subject Device	Predicate Device	Verdict
Measuring range	Pressure:0~299mmHg Pulse 40~199 times/min	Pressure:0~280mmHg Pulse:40~199beats/minute	SE Note 2
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	13.5-19.5 cm	13.5-19.5 cm	SE
Inflation and Deflation	Automatic	Automatic	SE
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°C~+40°C, Humidity: 15%~85%RH	SE
Transport/storage environment	Temperature: -25°C to +70°C; Humidity: ≤93%R.H.; Atmospheric Pressure: 70 kPa~106 kPa	Temperature: -20°C~+55°C Humidity: ≤95%RH, non-condensing	SE
Safety	IEC 60601-1 IEC 60601-1-11 IEC 80601-2-30	IEC 60601-1 IEC 80601-2-30	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	SE
Biocompatibility	ISO 10993 series	ISO 10993 series	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” of the subject device are a little different from the predicate devices, but the difference of subject device is very similar with the K181154, and both they meet the requirements as safety and performance standards required. So these parameters’ differences will not raise any safety or effectiveness issue.

Final Conclusion：

The subject device Non-invasive Sphygmomanometer (Wrist Electronic Sphygmomanometer) (Model:CK-101, CK-101S, CK-102S, CK-W118, CK-W132, CK-W133, CK-W135, CK-W175, CK-W176, CK-W355,

CK-W356, CK-W358) 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.

8. Date of the summary prepared: December 28, 2020