November 27, 2019

Shenzhen Changke Connect Electronics Co., Ltd.
Yahui Zhou
General Manager
A2-4th floor of Xiang dali Technology Park
No.87 of HengPing Road, Henggang
Longgang District, Shenzhen, CN

Re: K191428
Trade/Device Name: ECG Cable
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient transducer and electrode cable (including connector)
Regulatory Class: Class II
Product Code: DSA
Dated: November 14, 2019
Received: November 14, 2019

Dear Yahui Zhou:

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 Jessica Paulsen
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
ECG Cables

Indications for Use *(Describe)*
The ECG Cable is intended to be used with ECG. The ECG Cable is used to connect electrodes placed at appropriate sites on the patient to ECG for general monitoring and/or diagnostic evaluation by health care professional.

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.

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"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."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2019/05/22

1. Submission sponsor

Name: Shenzhen Changke Connect Electronics Co., Ltd.
Address: A2-4th floor of Xiang dali Technology Park, No.87 of HengPing Road, Henggang, Longgang District, Shenzhen, P.R. China
Contact person: Yahui Zhou
Title: General Manager
E-mail: zhouyahui@szcklt.com
Tel: +86 136 1301 2560

2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
Address: No. A415, Block A, NanShan Medical devices Industrial Park Nanshan District, Shenzhen, Guangdong, P.R. China 518067
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E-mail: kevin@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	ECG Cable
Common Name	ECG Wire
Classification Name	Cable, Transducer and Electrode, Patient
Classification	Class II
Regulation Number	870.2900
Product Code	DSA
Review Panel	Cardiovascular
Submission type	Traditional 510(K)

4. Predicate Device

By submission of the Traditional 510(k), Shenzhen Changke Connect Electronics Co., Ltd. is requesting clearance for ECG Cable. It is comparable to the following legally marketed system:

1. Shenzhen Med-link Electronics Tech Co., Ltd., Cable / lead-wire under K120010.

5. Device Description

The ECG Cable is an external device used to transmit ECG signals from electrodes that are affixed to the patient’s body for both diagnostic and monitoring purposes. One end of each leadwire is attached to ECG patient electrodes; the other end is affixed / molded into one end of the trunk cable which are plug into an

ECG monitor.

6. Intended use & Indication for use

The ECG Cable is intended to be used with ECG. The ECG Cable is used to connect electrodes placed at appropriate sites on the patient to ECG for general monitoring and/or diagnostic evaluation by health care professional.

7. Comparison to the Predicate Device

Features	**Subject Device** **Changke ECG Cables**	**Predicate Device** **K120010**
Applicant	Shenzhen Changke Connect Electronics Co., Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.
Classification Regulation	21CRF 870.2900	21CRF 870.2900
Classification and Code	Class II, DSA	Class II, DSA
Intended use	The ECG Cable is intended to be used with ECG. The ECG Cable is used to connect electrodes placed at appropriate sites on the patient to ECG for general monitoring and/or diagnostic evaluation by health care professional.	Shenzhen Med-link Cable / lead-wire are intended to be used with ECG, EKG, SpO2 and Invasive Blood Pressure monitoring devices. The Cable / lead-wire are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by heath care professional.
Usage	Reusable	Reusable
Anatomical sites	Attached to electrodes placed at standard specified locations on chest or extremities	Attached to electrodes placed at standard specified locations on chest wall
Patient end termination	Banana, Snap	Clip, Snap
Sterile	No	No
Leadwire material	TPU, PET, Nickel plated brass	Shielded & Unshielded Copper with PVC or TPU Jacket
Electrical Safety	Complied with IEC 60601-1 and EC53	Complied with IEC 60601-1 and EC53
Biocompatibility		
Cytotoxicity	Complied with ISO 10993-5	Complied with ISO 10993-5
Skin Irritation	Complied with ISO 10993-10	Complied with ISO 10993-10

Features	Subject Device Changke ECG Cables	Predicate Device K120010
Sensitization	Complied with ISO 10993-10	Complied with ISO 10993-10

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Changke ECG Cables was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

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

Non-clinical data

The Changke ECG Cables have been tested according to the following standards:

- IEC 60601-1: 2005+CORR.1: 2006+CORR.2: 2007+A1: 2012, Medical Electrical Equipment-Part 1: General requirements for basic safety and essential performance
- ANSI/AAMI EC53: 2013 ECG Trunk Cables and Patient Leadwires.

The test was selected to show substantial equivalence between the subject device and the predicate.

Clinical data

No clinical study is included in this submission.

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.