October 01, 2020

Xinkang Medical Instrument Co., Ltd
% Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, GuangDong 518100
China

Re: K201359
Trade/Device Name: ECG Cables and Leadwires
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: August 25, 2020
Received: August 31, 2020

Dear Field Fu:

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

Jennifer Shih Kozen
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201359

Device Name
ECG Cables and Leadwires

Indications for Use *(Describe)*
The ECG Cables and Leadwires is intended to be used with ECG. The ECG Cables and Leadwires 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.

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510(k) Summary

This summary of 510(K) safety and effectiveness information is submitted as required by requirements of SMDA and 21 CFR §807.92.

5.1 Administrative Information

Date of Summary prepared	April 10, 2020
Manufacturer information	Company: Xinkang Medical Instrument Co., Ltd. Company address: 2 Floor, Puhua Science and Technology Park, Tongsheng Community Dalang Street, Longhua District, 518109 Shenzhen, People's Republic of China Contact person: Xu Changsheng Phone: +86-755-23776681 Fax: +86-755-23776861 E-mail: 751857289@qq.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen Contact person: James Tsai E-Mail: james_tsai@cefda.com, joyce@cefda.com,
Establishment registration number	

5.2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	ECG Cables and Leadwires
Model:	G2202B10A, E2101C5A,E2101C3A, E2101S3A E2101S5A, G2202C10A, G2202S10A
Classification name:	Cable, Transducer And Electrode, Patient, (Including Connector)

Review Panel:	Cardiovascular
Product Code:	DSA
Device Class:	II
Regulation Number:	870.2900

5.3 Predicate Device Information

Sponsor:	Shenzhen Med-link Electronics Tech Co.,Ltd.
Device:	Cable / Lead-wire
510(K) Number:	K120010

5.4 Device Description

The ECG Cables and Leadwire 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.

5.5 Intended Use/ Indications for Use

The ECG Cables and Leadwires is intended to be used with ECG. The ECG Cables and Leadwires 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.

5.6 Technological characteristics of the subject device compared to the predicate device

Predicate Device Information:

510(K) No.: K120010

Common name: ECG Cable / Leadwires

Classification name: Cable, Transducer and Electrode, Patient, (Including Connector)

Production regulation: 21 CFR § 870.2900

Product code: DSA

Panel: Cardiovascular

Comparison to predicate device:

Comparison item	Subject Device	Predicate Device (K120010)
Applicant	Xinkang Medical Instrument Co., Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.

Product name	ECG Cables and Leadwires	ECG Cables /Leadwires
Product Code	DSA	DSA
Regulation Number	21CRF 870.2900	21CRF 870.2900
Classification	Class II	Class II
Intended use & Indications for Use	The ECG Cables and Leadwires is intended to be used with ECG. The ECG Cables and Leadwires 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 / leadwire 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 or extremities
Patient end termination	Clip,Snap, Banana	Clip, Snap
Sterile	No	No
Leadwire material	TPU	Shielded & Unshielded Copper with PVC or TPU Jacket
Biocompatibility	Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization
Electrical Performance and Safety	Comply with AAMI/ANSI EC53: 2013 IEC 60601-1:2005+CORR.1: 2006+CORR. 2:2007+AM1: 2012	Comply with ANSI/AAMI EC 53:1995/(R)2001 IEC 60601-1:1998; Am1; A2:1995

The subject device and the predicate device have the same intended use and similar technological characteristics; they both measure ECG signals for the patients. Thus the subject device is substantially equivalent to the predicate devices.

5.7 Brief discussion of the nonclinical tests

ECG Cables and Leadwires conforms to the following standards:
IEC 60601-1:2005+CORR.1:2006+CORR.2007+A1:2012 Medical Electrical

Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

AAMI / ANSI EC53:2013, ECG Trunk Cables and Patient Leadwires.

ISO 10993-1:2018, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process.

5.8 Brief discussion of clinical tests

N/A.

5.9 Other information (such as required by FDA guidance/Test)

N/A.

5.10 Conclusions

Based on the above information, the subject device and the predicate device have the same intended use and same technological characteristics; we conclude the subject device, ECG Cables and Leadwires, is substantially equivalent to the predicate device.