June 28, 2022

Shenzhen Med-link Electronics Tech Co., Ltd.
Yi Liu
Regulatory Affairs Specialist
4th and 5th Floor, Building Two, Hualian Industrial Zone,
Xinshi Community, Dalang Street
Shenzhen, Guangdong 518109
China

Re: K220447
Trade/Device Name: Med-link Disposable ECG Cable 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: April 29, 2022
Received: May 9, 2022

Dear Yi Liu:

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,

Jennifer Shih Kozen
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220447

Device Name
Disposable ECG Cable and Leadwires

Indications for Use *(Describe)*
Disposable ECG Cable and Leadwires are intended to be used with ECG monitoring devices to measure a patient's ECG for general monitoring and/or diagnostic evaluation by heath care professional.
Disposable ECG Cable and Leadwires meets the requirements of the standard ANSI/AAMI EC53, ECG TRUNK CABLES and PATIENT LEADWIRES. This leadwire set is intended for single-patient use.

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.

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Shenzhen Med-link Electronics Tech Co., Ltd.

510(k) Summary

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter information:

Name and Address: Shenzhen Med-link Electronics Tech Co., Ltd.
4th and 5th Floor, Building Two,
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Dalang Street, Longhua District, Shenzhen,
Guangdong 518109 ,
People's Republic of China

Primary Contact: Yi Liu(Regulatory Affairs Specialist)
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Fax: 0086-755-61120055

Data of Preparation: 29, Apr. 2022

2. Device Information:

Trade Name: Disposable ECG Cable and Leadwires
Common Name: Cable and Leadwires
Classification number: 21 CFR 870.2900
Classification name: Cable, Transducer And Electrode, Patient, (Including Connector)
Product Code: DSA
Regulatory Class: II
Review Panel: Cardiovascular

3. Identification of the Predicate Device:

Device Name	Common Name	Manufacturer	510(k) number
Cable/ lead-wire (ECG, EKG, SPO2 and invasive blood pressure	Cable and Leadwires	Shenzhen Med-Link Electronics Tech Co., Ltd.	K120010

4. **Intended Use and Indications for Use of the Subject Device**

Disposable ECG Cable and Leadwires are intended to be used with ECG monitoring devices to measure a patient's ECG for general monitoring and/or diagnostic evaluation by heath care professional.

Disposable ECG Cable and Leadwires meets the requirements of the standard ANSI/AAMI EC53, ECG TRUNK CABLES and PATIENT LEADWIRES. This leadwire set is intended for single-patient use.

5. Device Description

Disposable ECG Cable and Leadwires with specific various lengths are the replacements for similar cables manufactured by Original Equipment Manufacturers (OEM) and other third party after market manufacturers for their respective monitors.

These devices consist of connectors on each cable end and a shielded bulk cable. The cables are used to transfer the signals from the electrodes to the patient monitor.

These devices use the same type of constructions and have the same technological characteristics as the predicate devices. They use a medical grade PVC and TPU cable jacket with medical grade PVC and ABS over molded connectors with integral relief.

8. Comparison to the Predicate Device

Item	Proposed Device	Predicate Device	Remark
Comparison	Disposable ECG Cable and Leadwires	Shenzhen Med-link Cable/lead-wire	/
510k number	K220447	K120010	/
510(K) Submitter	Shenzhen Med-link Electronics Tech Co., Ltd.	Shenzhen Med-link Electronics Tech Co., Ltd.	/
Intended use &Indications for Use	Disposable ECG Cable and Leadwires are intended to be used with ECG monitoring devices to measure a patient's ECG for general monitoring and/or diagnostic evaluation by heath care professional. Disposable ECG Cable and	Shenzhen Med-link Cable/lead-wire is 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	SE

	Leadwires meets the requirements of the standard ANSI/AAMI EC53, ECG TRUNK CABLES and PATIENT LEADWIRES. This leadwire set is intended for single-patient use.	appropriate sites on the patient to a monitoring device for general monitoring and/or diagnost ic evaluation by health care professional.	
Device description	Disposable ECG Cable and Leadwires with specific various lengths are the replacements for similar cables manufactured by Original Equipment Manufacturers (OEM) and other third party after market manufacturers for their respective monitors. These devices consist of connectors on each cable end and a shielded bulk cable. The cables are used to transfer the signals from the electrodes to the patient monitor.	Med-link Cable / Lead-wire with specific various lengths are the replacements for similar cables manufactured by Original Equipment Manufacturers (OEM) and other third party after market manufacturers for their respective monitors. These cables consist of connectors on each cable end and a shielded bulk cable. The cables are used to transfer the signals from the electrodes to the patient monitor.	SE
Anatomical Sites	Attached to electrodes placed at standard specified locations on chest wall	Attached to electrodes placed at standard specified locations on chest wall	SE
Design /Appearance	ECG and EKG Cables with various connectors (monitor,	ECG and EKG Cables with various connectors (monitor,	SE

	trunk / lead wire,electrode grabber & snapper)	trunk / lead wire,electrode grabber & snapper)	
Sterility	Non sterile	Non sterile	SE
Usage	Disposable	Reusable	Different1)
Patient end termination	Clip	Clip, Snap	Different2)
Material	PVC	Shielded & Unshielded Copper with PVC or TPU Jacket	Different3)
Cable Length	Various specified standard lengths	Various specified standard lengths	SE
Electrical Safety	Complied with IEC 60601-1 and EC53	Complied with IEC 60601-1 and EC53	SE
Biocompatibility	Complied with ISO 10993-1, ISO 10993-5, ISO 10993-10	Complied with ISO 10993-1, ISO 10993-5, ISO 10993-10	SE

Justifications for differences between proposed device and the predicate device are shown as below:

Different (1): The proposed device is disposable and the predicate device is reusable. The proposed device was tested according to IEC 60601-1 and EC53. Therefore, this difference does not raise new questions of safety and effectiveness for subject device as compared to the predicate device.

Different (2): The patient end termination is different. This end is intended to connect the electrodes. The proposed device was tested according to IEC 60601-1 and EC53. Therefore, this difference does not raise new questions of safety and effectiveness for subject device as compared to the predicate device.

Different (3): The material is different. The proposed device was tested according to ISO 10993-5 and ISO 10993-10. Therefore, this difference does not raise new questions of safety and effectiveness for subject device as compared to the predicate device.

9. Non-clinical Test

Compare to predicate product specified in K120010, our device and the predicate device are same in Essential Components, raw materials, physical features, and same manufacturing processes. The biocompatibility performance equivalence evidence of proposed electrode can be demonstrated.

The safety performances of subject device are demonstrated by the Third party, CTI through testing following IEC 60601-1 General requirements for basic safety and essential performance and ANSI AAMI EC53:2013 ECG Trunk Cables And Patient Leadwires.

The results of bench testing & type testing provide reasonable assurance that the proposed device has been designed and validated to assure conformance to the requirements for its indication for use.

Package integrity and functional performance testing were completed on the subject device following real time aging test to support the proposed shelf life.

11. Conclusion

Based on the comparison and analysis in this submission, it can be concluded that: Disposable ECG Cable and Leadwires is substantially equivalent to the predicate device.