June 7, 2024

Shenzhen Le Medical Technology Co., Ltd.
% You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.406, Building C, Run Science Park, No.18 Shenzhou Road,
Huangpu
Guangzhou, Guangdong 510663
China

Re: K232816
Trade/Device Name: Electrocardiograph, model: ECG301
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: May 6, 2024
Received: May 6, 2024

Dear You Yijie:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Kimberly Crowley

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)*
K232816

Device Name
Electrocardiograph, model: ECG301

Indications for Use *(Describe)*
The intended use of ECG301 is to acquire ECG signals from adult and pediatric patients(above 3 years old) through body surface ECG electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by ECG301 can help users to diagnose heart disease. ECG301 does not include any automated measurement or analysis of the ECG signal, and does not produce interpretative statements. The ECG recorded is not intended to be used for measurement or analysis of the ECG signal, or for the automated generation of interpretative statements.

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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Section 5: 510(k) Summary

1. Submitters Information

Establishment Registration Information

Name:	Shenzhen Le medical Technology Co., Ltd.
Address:	5F, Block A, XinYongFeng Industrial Park, No.2,Tianbao Road, YinRenShi Community, ShiYan Sub-District, Baoan District, ShenZhen, China.

Contact Person of applicant:

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Contact Person of the Submission:

Name:	You Yijie
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Date prepared: Sep. 12, 2023

2. Device Information

Trade Name:	Electrocardiograph
Model:	ECG301
Classification name:	Electrocardiograph
Common or Usual Name:	Cardiovascular Devices
Review panel:	Cardiovascular
Product code:	DPS
Regulation Class:	II
Regulation Number:	870.2340

3. Predicate Device Information

510(k) submitter/holder:	Edan Instruments, Inc.
510(K) Number:	K171943
Trade Name:	Electrocardiographs
Model:	SE-301, SE-300A, SE-300B, SE-3

Classification name:	Electrocardiograph
Review panel:	Cardiovascular
Product code:	DPS
Regulation Class:	II
Regulation Number:	870.2340

4. Device description

Electrocardiograph, models: ECG301, is to acquire multi-channel ECG signals from adult and pediatric patients(above 3 years old) through body surface ECG electrodes. The device can gather and record ECG signals of 12 leads simultaneously. The cardiogram recorded by ECG301 can help users to diagnose heart disease. ECG301 does not include any automated measurement or analysis of the ECG signal, and does not produce interpretative statements. The ECG recorded is not intended to be used for measurement or analysis of the ECG signal, or for the automated generation of interpretative statements.
Electrocardiograph, models: ECG301, has LCD display with touchscreen and functional buttons. The device can be powered from AC power or through an embedded re-chargeable battery. The device contains built-in thermal dot-matrix recorder for ECG report printing.
The Electrocardiograph includes main unit and an AC power cord.

5. Indications for Use

The intended use of ECG301 is to acquire ECG signals from adult and pediatric patients(above 3 years old) through body surface ECG electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by ECG301 can help users to diagnose heart disease. ECG301 does not include any automated measurement or analysis of the ECG signal, and does not produce interpretative statements. The ECG recorded is not intended to be used for measurement or analysis of the ECG signal, or for the automated generation of interpretative statements.

6. Summary of technological characteristics of device compared to the predicate devices (K171943)

SE Comparisons	**Subject device (Electrocardiograph, model: ECG301)**	**Predicate device (Electrocardiographs, Model: SE-301, SE-300A, SE-300B, SE-3)**	**Discussion of difference**
510K Number	**K232816**	**K171943**	**/**
Classification	21CFR 870.2340	21CFR 870.2340	**Same**
Product Code	DPS	DPS	**Same**
Model	ECG301	SE-301, SE-300A, SE-300B, SE-3	**/**
Indication for use	The intended use of ECG301 is to acquire ECG signals from adult and pediatric patients(above 3 years old) through body surface ECG electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by ECG301 can help users to diagnose heart disease.	The intended use of the 3-Channel Electrocardiograph is to acquire ECG signals from adult and pediatric patients (beginning at birth through 21 years of age) through body surface ECG electrodes. The electrocardiograph is intended to be used only in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the 3-Channel	Similar, the subject device has same indication about ECG signals with 12-lead synchronous acquisition and record through body surface ECG electrodes with predicate device,

	ECG301 does not include any automated measurement or analysis of the ECG signal, and does not produce interpretative statements. The ECG recorded is not intended to be used for measurement or analysis of the ECG signal, or for the automated generation of interpretative statements.	Electrocardiograph can help users to analyze and diagnose heart disease. However, the ECG with measurements and interpretive statements is offered to clinicians on an advisory basis only.	not have ECG with measurements and interpretive statements. Therefore, indication for use of subject device(ECG301) is covered by predicate device, the difference does not raise new questions of safety and effectiveness.
Safety Standards	ANSI AAMI ES 60601-1, IEC 60601-1-2, IEC 60601-2-25	IEC 60601-1 IEC 60601-1-2 IEC/EN60601-2-25	**Same**
Anti-electric-shock type	Class I with external power supply and internal power supply	Class I with internal power supply	**Different** (Discussion is indicated in D1)
Anti-electric-shock degree	Type CF	Type CF	**Same**
Degree of protection against harmful ingress of water	Ordinary equipment (Sealed equipment without liquid proof)	Ordinary equipment (Sealed equipment without liquid proof)	**Same**
Degree of safety of application in the presence of flammable gas	Equipment not suitable for use in the presence of flammable gas	Equipment not suitable for use in the presence of flammable gas	**Same**
Working mode:	Continuous operation	Continuous operation	
EMC:	CISPR 11 Group 1, Class A	CISPR 11 Group 1, Class A	**Same**
Environment Specifications			
Temperature			
Transport	-20℃~55℃	-20℃~55℃	**Same**
Storage	-20℃~55℃	-20ºC ~ +55ºC	**Same**
Working	5ºC ~40ºC	5ºC ~40ºC	**Same**
Relative Humidity:			
Transport & Storage	25% RH ~ 93% RH Non-Condensing	25% RH ~ 95% RH Non-Condensing	Similar
Working	25% RH ~ 85% RH Non-Condensing	25% RH ~ 80% RH Non-Condensing	Similar
Atmospheric Pressure:			
Transport & Storage	700 hPa ~ 1060 hPa	700 hPa ~ 1060 hPa	**Same**
Working	800 hPa ~ 1060 hPa	800 hPa ~ 1060 hPa	**Same**
Power Supply Specifications			
Mains Supply:	Operating voltage =100 V - 240 V	Operating voltage =100 V-115 V~/220 V-240 V~	**Different** (Discussion is indicated in D2)
	Operating frequency = 50 Hz / 60 Hz	Operating frequency = 50 Hz / 60 Hz	
	input power = 90 VA	input power = 35 VA	
Built-in Lithium Battery Pack:	Rated voltage = 7.4 V	Rated voltage = 14.4 V	**Different** (Discussion is indicated in D3)
	Rated capacity =4400 mAh	Rated capacity =1600 mAh	
	When the battery is fully charged, ECG301 can work normally 2 hours.	When the battery is fully charged, SE-3 can work normally 6 hours.	
	Cycle life ≥ 300 times	Cycle life ≥ 300 times	

Performance Specifications			
Recording			
Recorder:	Thermal dot-matrix recorder	Thermal dot-matrix recorder	**Same**
Recorder Paper:	Rolled thermal paper	Folded thermal paper Rolled thermal paper	**Same**
Effective Width:	80mm	72 mm	**Different** (Discussion is indicated in D4)
Paper Speed:	12.5 mm/s, 25 mm/s, 50mm/s（±3%）	5 mm/s, 6.25 mm/s, 10 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s(±3%)	Covered in predicate device
Accuracy of data:	±5% (x-axis), ±5% (y-axis)	±5% (x-axis), ±5% (y-axis)	**Same**
HR Recognition			
Technique:	Peak-Peak Detection	Peak-Peak Detection	**Same**
HR Range:	30 BPM ~ 300 BPM	30 BPM ~ 300 BPM	**Same**
Accuracy:	±1 BPM	±1 BPM	**Same**
ECG Unit			
Leads:	Standard 12 leads	Standard 12 leads	**Same**
Acquisition Mode:	Simultaneously 12 leads	Simultaneously 12 leads	**Same**
A/D Resolution:	12 bits	12 bits	**Same**
Time Constant:	≥ 3.2 s	≥ 3.2 s	**Same**
Frequency Response:	0.05 ~ 150Hz(-3db)	0.05 Hz ~ 150 Hz (-3 dB)	**Same**
Input Impedance:	≥50MΩ（10Hz）	≥50 MΩ (10 Hz)	**Same**
Input Circuit Current:	≤0.05 μA	≤0.05 μA	**Same**
Input Voltage Range	≤±10 mVpp	≤±5 mVpp	**Different** (Discussion is indicated in D5)
Calibration Voltage:	1mV±2%	1 mV±3%	**Different** (Discussion is indicated in D6)
DC Offset Voltage:	±500 mV	±500 mV	Same
Noise:	< 15μVp-p	≤12.5μVp-p	**Different** (Discussion is indicated in D7)
Multi-channel Crosstalk	≤0.5 mm	≤0.5 mm	Same
Filter	AC Filter: Off /50Hz/60Hz	AC Filter: On / Off	**Different** (Discussion is indicated in D8)
	DFT Filter: Off/0.05Hz / 0.5Hz	DFT Filter: 0.05Hz / 0.15Hz /0.25Hz / 0.32Hz / 0.5Hz /0.67Hz	
	EMG Filter: 25Hz / 35Hz /45Hz/75Hz/100Hz/150Hz	EMG Filter: 25 Hz/35 Hz/45Hz/OFF	
	/	LOWPASS Filter: 300 Hz/270 Hz/150 Hz/100 Hz/75 Hz	
CMRR	≥100dB	≥110 dB	**Different** (Discussion is indicated in D9)
Sampling Frequency	1000 Hz	1000 Hz	Same
External Input/ Output			
Input	> 100 kΩ; Sensitivity 10 mm/V±5%; Single ended	≥100 kΩ; Sensitivity 10 mm/V±5%; Single ended	Same
Output	≤100Ω; Sensitivity 1 V/mV ±5%; Single ended	≤100Ω; Sensitivity 1 V/mV ±5%; Single ended	Same

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1 for safety, IEC 60601-1-2 for electromagnetic compatibility, IEC 60601-2-25:2011 for performance and IEC 62304 for software verification are complied. See below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2:2014+A 1 :2020	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
IEC 60601-2-25:2011	Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
IEC 62304:2006+A1:2015	Medical device software - Software life cycle processes

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Content of Premarket Submissions for Device Software Functions - Guidance for Industry and FDA Staff, May 2023.

8. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Electrocardiograph, model ECG301 is substantially equivalent to the predicate devices.