June 1, 2018

Suzuken Co., Ltd.
% Rhona Shanker
President
Z&B Enterprises, Inc.
12154 Darnestown Rd. #236
Gaithersburg, Maryland 20878

Re: K172068
Trade/Device Name: Kenz Cardico 1211
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: May 3, 2018
Received: May 3, 2018

Dear Rhona Shanker:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K172068

Device Name
Kenz Cardico 1211

Indications for Use *(Describe)*

The Kenz Cardico 1211 is indicated for routine ECG acquisition and ECG signal analysis. It is equipped with an auto-analysis function and is not intended to replace the physician's reading of ECGs. Instead, it is intended to assist physicians and supplement their readings by: providing preliminary interpretations of ECG records which need to be confirmed or edited by the physician, who integrates ECG findings with other relevant clinical data; providing auto-analysed measurements of many ECG parameters, which need to be confirmed by the physician. The device is applicable only to adults (19 years or older age).

Applications: Cardico 1211 is intended to be used as part of health examination of general population, and as part of laboratory tests and clinical examination to diagnose various cardiac abnormalities including myocardial ischemia/ infarction, ventricular hypertrophy, cardiac arrhythmias, and atrioventricular (AV) block.

Locations: Hospitals.

Caution: US Federal law restricts this device to sale by or on the order of a physician.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

Section 5. 510(k) Summary

1. Date of Submission

July 1, 2017

2. Submitter

Name:	Suzuken Co., Ltd.
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3. Application Correspondent

Name:	Z&B Enterprises, Inc.
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Contact Person:	Rhona Shanker
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4. Device Name

Trade Name: Kenz Cardico 1211

Common Name: Electrocardiograph

5. Device Classification

Device Classification:	Class II
Regulation:	21 CFR 870.2340
Panel:	Cardiovascular
Product Code:	DPS

6. Predicate Device

Trade Name: Kenz Cardico 1201
Manufacturer: Suzuken Co., Ltd
510(k) Number: K870443

7. Device Description

Kenz Cardico 1211 is an electrocardiograph with the following functions and capabilities.

・Simultaneous acquisition of the 12-Lead electrocardiogram (ECG).
・The sampling frequency of P-QRS-T deflections is 1 kHz.
・The sampling frequency of the pacemaker pulse detection is 10 kHz.
・5.7 inch LCD display providing the following information.
  a) ECG waveform
  b) Patient's demographic data
  c) ECG diagnostic interpretation
  d) Summary of Internal Memory data
・Thermal printer that will print ECG waveforms and analysis reports.
・Digital filters to minimize AC interference, baseline drift and electromyogram interference.
・Built-in memory and external memory (Compact Flash card) for 1,000 12-Lead ECG data.
・As a measure against cybersecurity, in order to secure the integrity of the data in the external memory, only the CF card specially formatted by Suzuken Co., Ltd. can be used with Kenz Cardico 1211.
・Built-in power supply unit (AC 110-240 V).
・Built-in battery, after charged for 8 hours, supports one hour operation during emergency.
・ECG interpretation software providing the following information.
  a) Summary of measured values of ECG waveform in each Lead
  b) Rhythm analysis statements
  c) Morphology analysis statements
  d) Pacemaker pulse detection and Pacemaker rhythm diagnosis
  e) Provide multiple diagnostic outputs for a single ECG, if it contains multiple diagnostic findings
・Patient cable with D-sub 15 pin connector and 4.0 mm plugs is used for recording 12-Lead resting ECG with the device.
・ECG electrodes are not provided with the device (Kenz Cardico 1211). Disposable chest/limb electrodes connected to the ECG Adaptor Clips of the plug size 4.0 mm are compatible with the Kenz Cardico 1211.

8. Indications for Use

The Kenz Cardico 1211 is indicated for routine ECG acquisition and ECG signal analysis. It is equipped with an auto-analysis function and is not intended to replace the physician's reading of ECGs. Instead, it is intended to assist physicians and supplement their readings by: providing preliminary interpretations of ECG records which need to be confirmed or edited by the physician, who integrates ECG findings with other relevant clinical data; providing auto-analysed measurements of many ECG parameters, which need to be confirmed by the physician. The device is applicable only to adults (age $\geq$ 19 years).

Applications: Cardico 1211 is intended to be used as part of health examination of general population, and as part of laboratory tests and clinical examination to diagnose various cardiac abnormalities including myocardial ischemia/infarction, ventricular hypertrophy, cardiac arrhythmias, and atrioventricular (AV) block.

Locations: Hospitals.

Caution: US Federal law restricts this device to sale by or on the order of a physician.

9. Summary Table of Comparisons

The table below compares the Kenz Cardico 1211 to its predicate device, Kenz Cardico 1201.

	Parameter	**Kenz Cardico1211**	**Kenz Cardico1201 (K870443)**	**Remark about Kenz Cardico 1211 compared to Kenz Cardico 1201**
1	Indications for use	The Kenz Cardico 1211 is indicated for routine ECG acquisition and ECG signal analysis. It is equipped with an auto-analysis function and is not intended to replace the physician's reading of ECGs. Instead, it is intended to assist physicians and supplement their readings by: providing preliminary interpretations of ECG records which need to be confirmed or edited by the physician, who integrates ECG findings with other relevant clinical data; providing auto-analysed measurements of many ECG parameters, which need to be confirmed by the physician. The device is applicable only	The Kenz Cardico 1201 is used as diagnostic aid. However, the system is not intended to replace the doctor's expert review. For routine adult or pediatric ECG analysis, particularly when a cardiologist is not immediately available, and to aid in referring patients for immediate follow up, Kenz Cardico 1201 can assist strongly physician for prompt diagnosis. Also, Kenz Cardico 1201 can be used for pre-op ECG interpretations, especially when an analysis needed quickly. The system and its thoroughly evaluated programs help to save physicians time by providing a routine ECG report for physician review, with patient information, trace measurement and analysis on the report. The exclusion of the	ECG interpretation of Kenz Cardico 1211 is applicable only to adults.

		to adults (age > 19 years). Applications: Cardico 1211 is intended to be used as part of health examination of general population, and as part of laboratory tests and clinical examination to diagnose various cardiac abnormalities including myocardial ischemia/infarction, ventricular hypertrophy, cardiac arrhythmias, and atrioventricular (AV) block. Locations: Hospitals. Caution: US Federal law restricts this device to sale by or on the order of a physician.	need for routine ECG measurement and the ability of Kenz Cardico 1201 to analyze normal tracings can substantially reduce the workload of any ECG reporting service.	
2	Leads	12-Lead	12-Lead	Identical
3	Frequency response bandwidth	0.05-150 Hz	0.05-100 Hz	Wider frequency range
4	Input impedance	Over 10 M ohm	Over 50 M ohm	Improved noise handling
5	Input signal	Both analog and digital signal	Analog signal	Digital input added.
6	Common mode rejection ratio	Over 100 db	Over 90 db	Higher noise reduction range
7	Time constant	Over 3.2 sec	Over 3.2 sec	Identical
8	A/D conversion	13 bit	12 bit	Higher resolution
9	Sampling rate	1,000 samples/sec	500 samples/sec	Doubled sampling rate
10	Pacemaker pulse detection	10,000 samples/sec	None	Pacemaker pulse detection function is added (Att. 13-2).
11	Signal amplitude resolution	2.44 μV	4.88 μV	Higher resolution
12	Paper speed	10, 12.5, 25, 50 mm/sec	5, 12.5, 25, 50 mm/sec	The paper speed of 5 mm/sec available for Kenz Cardico 1201 is deleted. Instead, the paper speed of 10 mm/sec is added for Kenz Cardico 1211.
13	Recording sensitivity	2.5, 5, 10, 20 mm/mV	5, 10, 20 mm/mV	The recording sensitivity 2.5 mm/mV is added.

14	Writing system	Thermal head (8 dots/mm)	Thermal head (8 dots/mm)	Identical
15	Power source	AC 110-240 V	AC 100-110, 220-240 V	Equivalent
16	Mode of operation	Auto Manual Long-time	Automatic Manual Long-term	Equivalent
17	Battery operation	Nickel hydride battery, DC 12 V 3,700 mAh	None	The battery-drive mode is added for more versatility.
18	Internal memory	1,000 ECG data storage	None	The memory data function is added.
19	ECG interpretation software	Equipped with software, reflecting the results of many ECG clinical studies published after the development of the ECG interpretation software of Kenz Cardico 1201.	Equipped with ECG interpretation software which was developed and completed by 1987.	Diagnostic performance of Kenz Cardico 1211 is non-inferior to the Kenz Cardico 1201 (Att. 18-1).
20	Patient cable	Yes	Yes	Both devices require a Patient Cable

The main difference between the two devices is that the subject device (Kenz Cardico 1211) has ECG interpretive software that reflects many ECG clinical studies published after the development of the ECG interpretation software of the Kenz Cardico 1201. However, Kenz Cardico 1211 does not introduce a new scientific technology. Performance testing demonstrates that the automated diagnostic performance of Kenz Cardico 1211 is non-inferior to the predicate device, Kenz Cardico 1201.

10. Summary of Device Testing

10-1. Electrical safety and electromagnetic compatibility

Testing reports on the electrical safety and electromagnetic compatibility of Kenz Cardico 1211 device indicated its full compliance with the following standards.

1. IEC 60601-1: 2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2: 2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
3. IEC 60601-2-25: 2011, Medical electrical equipment – Part 2-25: Particular requirements for basic safety and essential performance of electrocardiographs
4. ANSI/AAMI EC11: 2007, Diagnostic electrocardiograph devices
5. ANSI/AAMI EC53: 2013, ECG trunk cables and patient lead wires

10-2. Diagnostic performance testing

Diagnostic performance of Kenz Cardico 1211 (Cardico 1211 hereafter) and its predicate device, Kenz Cardico 1201 (Cardico 1201 hereafter) in ECG interpretation was tested in a total of 2,451 ECGs recorded from 2,451 subjects. Interpretive statements were classified as Type A, B and C according to the Tenth Bethesda Conference Report, 1978 (Att. 18-1).

Statistical analysis was carried out separately in Type A, B and C statements (see a Table below). Reference of truth employed in the performance evaluation was "Cardiologist Consensus" or "Clinical Truth" for the Type A statements, and "Cardiologist Consensus" for all the Type B and Type C statements. Creation of Cardiologist Consensus is described in detail in Att. 18-1.

Statement	Database	Analysis	Reference
Type A	CSE Database	Total Agreement (Non-inferiority test) Sensitivity/Specificity (95% CI)	Cardiologist Consensus
	Suzuken Database-2 (Acute MI)	Sensitivity/Specificity (95% CI)	Cardiologist Consensus
		Sensitivity/Specificity (95% CI)	Clinical Truth
Type B	CSE Database + Suzuken Database-1	Sensitivity/Specificity (95% CI)	Cardiologist Consensus
	Suzuken Database-3 (Pacemaker rhythm)	Sensitivity/Specificity (95% CI)*	Cardiologist Consensus
Type C	CSE Database + Suzuken Database-1	Sensitivity/Specificity (95% CI)	Cardiologist Consensus

CSE: Common Standards for Electrocardiography

*Not applicable to Cardico 1201, which is not equipped with pacemaker pulse detection circuit.

The ECGs from the CSE Database were used to test the statistical hypothesis that Cardico 1211 is non-inferior to Cardico 1201 in the performance of diagnosis for Type A statements. Total agreement of Cardico 1211 with Cardiologist Consensus was greater than that of Cardico 1201, giving rise to an overall sensitivity of 93.1% for Cardico 1211 vs. 76.1% for Cardico 1201. In addition, the Cardico 1211 had a higher sensitivity than did the Cardico 1201 for most individual statement of Type A, B and C, while the specificities of the two devices tended to be similar. The results demonstrate substantial equivalence of the Cardico 1211 to the Cardico 1201 in diagnostic performance.

11. Conclusions

Based on the statistical results derived from the study conducted by Suzuken Co., Ltd. we conclude that the Kenz Cardico 1211 is substantially equivalent to the predicate device, Kenz Cardico 1201.