September 25, 2023

Edan Instruments, Inc.
Lavender Wang
Regulatory Engineer
#15 Jinhui Road, Jinsha Community,
Kengzi Sub-District Pingshan District
Shenzhen, Guangdong 518122
China

Re: K230184
Trade/Device Name: Holter ECG and ABP System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: DSH, MWJ, DXN
Dated: August 25, 2023
Received: August 25, 2023

Dear Lavender Wang:

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,

Jennifer W. Shih -S

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)*
K230184

Device Name
Holter ECG and ABP SystemModel: SA-20, SA-19, SA-18, SA-15, SA-16

Indications for Use *(Describe)*
The SA-20 Series recorder combines ambulatory ECG Holter and BP monitor.
It is intended to acquire, store and display ambulatory ECG signals from adult and pediatric patient. It is capable of measuring systolic and diastolic blood pressures of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are displayed and stored in the recorder.
It is intended to be used by trained personnel under the direction of doctors.

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
Prepared in accordance with the content and format regulatory Requirements of 21 CFR Part 807.92

1. Submitter:

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Contact person: Liu Yongying

Preparing date: January 16, 2023

2. Device name and classification:

Trade Name: Holter ECG and ABP System
Common/Usual Name: SA-20 Series
Model: SA-20, SA-19, SA-18, SA-15, SA-16

Classification Name	Product code
21 CFR 870.2800 Recorder, Magnetic Tape, Medical	DSH
21 CFR 870.2800 Electrocardiograph, Ambulatory (Without Analysis)	MWJ
21 CFR 870.1130 System, Measurement, Blood-Pressure, Non-Invasive	DXN

Regulatory Class: Class II

3. Predicate Device(s):

1) Vasomedical, Inc., Combined 12 Channel Ambulatory EGG and Blood Pressure Recorder, Model 2302, cleared under K111096 (Primary).
2) Vasomedical, Inc., Combined Ambulatory EGG and Blood Pressure Recorder, cleared under K092785 (Reference).
3) Edan Instruments, Inc., Holter System, cleared under K151787 (Reference).
4) Edan Instruments, Inc., Ambulatory Blood Pressure Monitor, cleared under K210139 (Reference).

4. Device Description:

Holter ECG and ABP System (Model: SA-20, SA-19, SA-18, SA-15, SA-16) is composed of the recorder, NIBP cuff, lead wire. The ambulatory blood pressure adopts the principle of the oscillometric method for non-invasive blood pressure measurement. ECG signals are obtained by placing electrodes on the patient's surface to record the potential change signal of the human heart and then processing the data to form an ECG waveform and store it in the Recorder to monitor the ECG signal.

Contraindications：

Do not use it on patients with erratic, accelerated, or mechanically controlled irregular heart rhythms, including the patient with arrhythmias.

Due to the strangulation risk posed by the cuff and hose, the SA-20 Series must not be within reach of unsupervised children. It must not be used on unsupervised patients with limited cognitive abilities.

The SA-20 Series is not intended for alarm triggering monitoring purposes in intensive care units. It must not be used for blood pressure monitoring purposes in intensive care units or during surgery.
ABP is not intended for pregnant, including pre-eclamptic patients.

5. Indication for Use

The SA-20 Series recorder combines ambulatory ECG Holter and BP monitor. It is intended to acquire, store and display ambulatory ECG signals from adult and pediatric patient. It is capable of measuring systolic and diastolic blood pressures of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are displayed and stored in the recorder.
It is intended to be used by trained personnel under the direction of doctors.

6. Predicate Device Comparison

Comparison to the predicate devices, the subject device has the same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following tables:

Table 1: Comparison between SA-20 Series and 2302 (primary predicate device)

Item	Subject Device（Model：SA-20 Series）	Predicate Device （ Model：2302）	Comparison Result
Manufacturer	Edan Instruments, Inc	Vasomedical, Inc	——
K#	K230184	K111096	——
Indications for Use			
Indications for Use	The SA-20 Series recorder combines ambulatory ECG Holter and BP monitor. It is intended to acquire, store and display ambulatory ECG signals	Vasomedical-Biox Combined 12 Channel Ambulatory ECG and Blood Pressure Recorder, Model 2302 is a Non-Invasive device intended to acquire ambulatory 12 channel ECG	*Similiar*

	from adult and pediatric patient. It is capable of measuring systolic and diastolic blood pressures of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are displayed and stored in the recorder. It is intended to be used by trained personnel under the direction of doctors.	signals and non-invasive oscillometric blood pressure signals from the upper body surfaces. Cardiac rhythm is acquired via ECG signals. Vasomedical-Biox Model 1804 Ambulatory BP Recorder is a noninvasive device intended to acquire ambulatory non-invasive oscillometric Blood Pressure signals from the upper body surfaces. This ABP Recorder functions exactly the same as Model 2301/2302 for measurement and recording of Blood Pressure signals. The Recorders are intended for adults and children who are over the age of six years.	
Physical properties			
System Components	Recorder, blood pressure cuff, lead wire.	Recorder, blood pressure cuff, lead wire, and analysis software.	*Different*
Energy Used and/or Delivered	Two AA alkaline batteries	four AA alkaline batteries	*Different*
Interface	USB Interface Cable SD card	USB Interface Cable SD card	same
Patient Connections	Blood pressure cuff Patient cable	Blood pressure cuff Patient cable	same
Performance Specifications			
Channels	12 channels	12 channels	same
Electrodes	10	10	same
A/D Sampling Frequency	25.6 ksps	10000Hz	*Different*
A/D	24 bits	12 bits	*Different*

Table 2: Comparison between SA-20 Series and 2301 (reference device)

Item	Subject Device（Model：SA-20 Series）	Reference Device（Model：2301）	Comparison Result
Manufacturer	Edan Instruments, Inc	Vasomedical, Inc	——
K#	K230184	K092785	——
Indications for Use			

Indications for Use	The SA-20 Series recorder combines ambulatory ECG Holter and BP monitor. It is intended to acquire, store and display ambulatory ECG signals from adult and pediatric patient. It is capable of measuring systolic and diastolic blood pressures of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are displayed and stored in the recorder. It is intended to be used by trained personnel under the direction of doctors.	Vasomedical-Biox Combined Ambulatory ECG and Blood Pressure Recorder is a Non-Invasive device intended to acquire Ambulatory 3 Channel ECG signals and non-invasive oscillometric Blood Pressure signals from the upper body surfaces. Cardiac rhythm is acquired via 3 Channel ECG signals. The Recorders are intended for adults and children who are over the age of six years. Vasomedical-Biox Ambulatory ECG CB Series Analysis System Software allows transfer of ECG and Blood Pressure data from the Recorder to a Windows based PC program via a removable and large capacity storage card (SD) for the purpose of creating reports and printouts. The software does not perform diagnostics. Physicians carry out diagnostic evaluations of this data. The system is only for measurement, recording and display. It makes no diagnosis.	*Similiar*
Physical properties			
System Components	Recorder, blood pressure cuff, lead wire.	Recorder, blood pressure cuff, lead wire, and analysis software.	*Different*
Energy Used and/or Delivered	Two AA alkaline batteries	four AA alkaline batteries	*Different*
Interface	USB Interface Cable/SD card	USB Interface Cable/SD card	same
Patient Connections	Blood pressure cuff; Patient cable	Blood pressure cuff; Patient cable	same
Performance Specifications			
Channels	3 channels	3 channels	same
Electrodes	5 or 7	5 or 7	same
A/D Sampling Frequency	25.6 ksps	10000Hz	*Different*
A/D	24 bits	10 bits	*Different*

As seen in the comparison tables, the subject device and predicate devices have similar design features and performance specifications. The technological differences between the subject device and predicate

devices do not raise different questions of safety or effectiveness.

7. Performance Data:

Non-clinical data:

Electrical safety and electromagnetic compatibility (EMC)

The Holter ECG and ABP System was assessed for conformity with the relevant requirements of the following standards and complys:

- ANSI AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R) 2012 and A2:2010/(R) 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- IEC 60601-1-2:2014 (Fourth Edition) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: electromagnetic disturbances – Requirements and tests.

Performance testing-Bench

Edan has conducted functional and system level testing to validate the performance of the devices. The results of the bench testing show that the subject device meets its accuracy specification and meet relevant consensus standards.

- IEC 60601-2-47 Edition 2.0 2012-02 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performanceof ambulatory electrocardiographic systems
- IEC 80601-2-30: Edition 2.0 2018-03 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ANSI AAMI EC53:2013/(R) 2020 ECG trunk cables and patient leadwires
- IEC 60601-1-11 Edition 2.1 2020-07, Medical electrical equipment - Part 1-11 General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Software Verification and Validation Testing

Software verification and validation testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

Clinical data: Not applicable.

Summary

The non-clinical performance testing showed that the subject devices are as safe and as effective as the predicate device.

8. Conclusion

The bench testing data and software verification and validation demonstrate that Holter ECG and ABP System is substantially equivalent to the predicate devices.