October 1, 2021

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

Re: K210139
Trade/Device Name: Ambulatory Blood Pressure Monitor, Models: SA-10, SA-05, SA-06, SA-08 and SA-09
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 26, 2021
Received: August 31, 2021

Dear Ying Dai:

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,

LCDR Stephen Browning
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)*
K210139

Device Name
Ambulatory Blood Pressure Monitor, Models: SA-10, SA-05, SA-06, SA-08 and SA-09

Indications for Use *(Describe)*
The Ambulatory Blood Pressure Monitor is capable of measuring systolic and diastolic blood pressures, and pulse of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are stored in the monitor and can be transferred to analysis system via wire or wireless transmission. It is intended for use as an aid or adjunct to diagnosis and treatment.

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 requirements of 21 CFR Part 807.92

1. Submitter:

Edan Instruments, Inc.
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Tel: +86-755-2685 6469 Fax: +86-755-2689 8330

Contact person: Ying DAI

Preparing date: Jan 5th, 2021

2. Device name and classification:

Trade name: Ambulatory Blood Pressure Monitor, Model**:** SA-10, SA-05, SA-06, SA-08 and SA-09

Common/Usual Name: Noninvasive blood pressure measurement system

Classification Name	Product code
21 CFR 870.1130 System, Measurement, Blood-Pressure, Non-Invasive/	DXN

Regulatory Class: Class II

3. Predicate Device(s):

Suntech Medical, Inc., Oscar 2 NIBP Monitor, cleared under K151520 (Primary)

A&D MEDICAL DIV, TM-2430 Ambulatory Blood Pressure Monitors, clear under K992808 (reference)

4. Device Description:

The SA Series ABPM (Ambulatory Blood Pressure Monitor), primarily composed of Ambulatory Blood Pressure Monitor (ABPM) and ABPM Analysis software (Smart ABPM View), is designed to measure systolic and diastolic blood pressures, and pulse of adults and pediatrics (> 12 years) over a preprogrammed period of time.

The monitor inflates and deflates the cuff on the upper arm to measure blood pressures and pulse by the oscillometric method and stores the measurement. The stored measurements are transferred into analysis software installed in generally used PC via wire transfer or Bluetooth.

The monitor is carried around by patients. Patients are requested to come back to medical treatment site after recording time. The systolic and diastolic blood pressures, and pulse data recorded in monitor will be transferred into PCs and then analyzed, displayed and edited by Analysis software.

5. Indication for Use

The Ambulatory Blood Pressure Monitor is capable of measuring systolic and diastolic blood pressures, and pulse of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are stored in the monitor and can be transferred to analysis system via wire or wireless transmission. It is intended for use as an aid or adjunct to diagnosis and treatment.

6. Predicate Device Comparison

Item	**<Subject Device>**	**<Predicate Device>**	**Comparison Result**
Manufacturer/ K#	Current Submission	K151520	——
Indications for Use			
Indication for use	The Ambulatory Blood Pressure Monitor is capable of measuring systolic and diastolic blood pressures, and pulse of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are stored in the monitor and can be transferred to analysis system via wire or wireless transmission. It is intended for use as an aid or adjunct to diagnosis and treatment.	The Oscar 2, Model 250 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses. Optionally, The Model 250 will provide a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided noninvasively through the use of a brachial cuff. It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits (excludes pediatric subjects). Bluetooth, wireless connectivity will be offered as an option.	Different

Intended Patient Population	adults and pediatrics（>12yrs.）	adult and pediatric（>3yrs.） patients	Different
Intended Application Environment	Physician's office, clinic, research center(under supervision of physician) and patient home environment	Physician's office, clinic, research center(under supervision of physician) and patient home environment	Same
Measurement	Systolic and Diastolic Blood Pressure Heart Rate	Systolic and Diastolic Blood Pressure Heart Rate Central Blood Pressure (Sp/Dp/MAP/Pp) Central Augmentation Index & Pressure, and Index at HR 75	Different
Physical properties			
System Components	Electronics Module (EDAN SA Series) EDAN NIBP Cuff sleeve Software Disc Operator's Manual Cables Carrying pouch	Electronics Module (Oscar 2, Model 250) SunTech BP Cuff Software download Operator's Manual Cables Pouch	Same
Interface	USB Interface Cable Wireless-Bluetooth	USB Interface Cable Wireless-Bluetooth	Same
Software Section			
Software Operating Platform	Windows XP, Windows 7, Windows 8, or Windows 10	Microsoft Windows® 7, 8	Different
PC Software	Smart ABPM View	AccuWin Pro	Different
NIBP Algorithm	NIBP iCUFS	SunTeck Oscar 2	Different
CBP Algorithm	N/A	SphygmoCor® XCEL	Different
Performance Specifications			
Operation Principle	Oscillometric with step deflation	Oscillometric with step deflation	Same
Blood Pressure Range	Systolic: 25 to 290 mmHg (3.3 to 38.6 kPa) Diastolic: 10 to 250 mmHg (1.3 to 33.2 kPa)	Systolic: 40-260 mmHg Diastolic: 25-200 mmHg	Different
Accuracy of	Mean error: ±5 mmHg (±0.67 kPa)	Blood Pressure results meet or exceed	Same

Blood Pressure	Standard deviation: Max. 8 mmHg (1.07 kPa)	ANSI/AAMI/ISO 81060-2:2013 standards for non-invasive accuracy: ±5 mmHg mean error & 8 mmHg standard deviation.	
Heart Rate Range	40-240 bpm	40-200 bpm	Different
Error of Heart Rate	Heart Rate accurate within ±3 bpm or ±3.5%, whichever is greater.	Heart Rate accurate within ±2% or ±3 bpm, whichever is greater.	Different **Cleared under K992808**
Environmental Specifications			
Temperature			
Operating	+5 ℃ (+41 ℉) ~ +40 ℃ (+104 ℉)	+10 ℃ (+50 ℉) ~ +50 ℃ (+122 ℉)	Different
Transport/Storage	-20 ℃ (-4 ℉) ~ +55 ℃ (+131 ℉)	-20 ℃ ~ +70 ℃	
Humidity			
Operating	15%RH~95%RH Non-Condensing	20%RH~95%RH Non-Condensing	
Transport/Storage	15%RH~95%RH Non-Condensing	15%RH~95%RH Non-Condensing	

The subject and predicate device have same general intended use, similar design features and performance specifications. The technological differences between the subject and predicate device do not raise different questions of safety or effectiveness.

7. Performance Data:

Clinical test:

The subject devices have been undertaken clinical investigation in accordance with ISO 81060-2:2018+A1:2020 to validate the clinical safety and effectiveness within its intended use. From the investigation with qualified subject distribution, SA series ambulatory blood pressure monitor with its accessories are concluded to be safe and effective in both resting state and ambulatory monitoring within its intended use.

Non-clinical test:

The SA series Ambulatory Blood Pressure Monitor complies with:

(1) 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

(2) IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

(3) IEC 60601-1-11 Edition 2.0 2015-01, 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

(4) IEC 80601-2-30 Edition 1.1 2013-07 Medical electrical equipment - Part 2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

(5) ISO 81060-2 Third edition 2018-11 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type [including: Amendment 1 (2020)]

(6) ISO 14971 Second edition 2007-03-01 Medical devices - Application of risk management to medical devices

The following biocompatibility standards are complied with on the subject device:

(7) ISO 10993-1: 2018, ISO 10993-5:2009 and ISO 10993-10:2010

Software Verification and Validation Testing

Software verification and validation testing were 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".

Summary

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

8. Conclusion

Verification and validation testing has been conducted on the SA series Ambulatory Blood Pressure Monitor. This premarket notification submission demonstrates that SA series Ambulatory Blood Pressure Monitor is substantially equivalent to the predicate device.