April 2, 2020

Edan Instruments, Inc.
Alice Yang
Regulatory Engineer
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
Shenzhen, 518122 Cn

Re: K192514
Trade/Device Name: Patient Monitor – Models: X8, X10, X12
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm (Including St-Segment Measurement and Alarm)
Regulatory Class: Class II
Product Code: MHX, DRT, DXN, DSK, FLL, DQA, CCK, DSI, MLD, DSB
Dated: February 27, 2020
Received: March 2, 2020

Dear Alice Yang:

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,

LT 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192514

Device Name
Patient Monitor - Models: X8, X10, X12

Indications for Use *(Describe)*
The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.
The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.).
The arrhythmia detection and ST Segment analysis are intended for adult patients.
The monitors are not intended for MRI environments.

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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510(K) Summary

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

1. Submitter:

Edan Instruments, Inc.
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Contact person: Alice Yang
Preparing date: September 9, 2019

2. Device name and classification:

Device Name: Patient Monitor
Model: X8,X10,X12
Classification Name/ Product code:
21 CFR 870.1025 Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms) / MHX
21 CFR 870.2300 Cardiac monitor (including cardiotachometer and rate alarm)/ DRT
21 CFR 870.1130 Non-Invasive blood pressure measurement System/ DXN
21 CFR 870.1110 Blood pressure computer/ DSK
21 CFR 880.2910 Clinical Electronic Thermometers-Temperature Monitor with Probe/ FLL
21 CFR 870.2700 Oximeter, Pulse/ DQA
21 CFR 870.1400 Carbon Dioxide Gas Analyzer/ CCK
21 CFR 870.1025 Detector and Alarm, Arrhythmia/ DSI
21 CFR 870.1025 Monitor, ST Segment with Alarm/ MLD
21 CFR 870.2770 Impedance plethysmograph/ DSB
Regulatory Class: Class II

3. Predicate Device(s):

1) Edan Instruments, Inc, Patient Monitor Model elite V5 elite V6 elite V8, K160981 (Primary)
2) Shenzhen Mindray Bio-Medical Electronics Co., LTD. BeneVision N Series Patient Monitors, K182075 (Reference)
3) Shenzhen Mindray Bio-Medical Electronics Co., LTD. Accutorr 7 Vital Signs Monitor, K182821 (Reference)

4. Device Description: The X8 X10 X12 Patient Monitor (hereinafter called X series) can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of storing, displaying, analyzing and controlling measurements, and it will indicate alarms in case of abnormity so that doctors and nurses can deal with them in time.

5. Indication for Use The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.).

The arrhythmia detection and ST Segment analysis are intended for adult patients.

The monitors are not intended for MRI environments.

6. Predicate Device Comparison

The table below compares the indication for use and key technological feature of the subject devices to the predicate device (Patient Monitor Model V5 V6 V8, K160981). The features in grey are the features that are different from the predicate device.

Item	<Predicate Device> (elite V5, elite V6, elite V8)	<Subject Device> (X8 X10 X12)
Manufacturer/K#	K160981	Current Submission
Intended Use		
Description	The monitors are intended to be used for monitoring, storing, and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.	The monitors are intended to be used for monitoring, storing, recording and reviewing of, and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates. The monitors are intended for use by trained healthcare professionals in hospital environments.

	The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), anesthetic gas (AG), bispectral index (BIS), respiration mechanics (RM) and impedance cardiography (ICG). BIS is intended for use on adult and pediatric patients. ICG monitoring is intended for use on adults only. The arrhythmia detection and ST Segment analysis are intended for adult patients. The monitors are additionally intended for use during patient transport inside hospitals.	The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.). The arrhythmia detection and ST Segment analysis are intended for adult patients. The monitors are not intended for MRI environments.
ECG monitor		
ECG	3-Lead; 5-Lead; 12-lead ST segment analysis Pace detection Heart Rate(HR) Arrhythmia Analysis	3-Lead; 5-Lead; **6-Lead**; 12-lead ST segment analysis Pace detection Heart Rate(HR) Arrhythmia Analysis **QT/QTc Analysis**
RESP monitor		
Measurement Range	Adult: 0 to 120 rpm Pediatric/neonate: 0 rpm to 150rpm	Same
Accuracy	Adult: 6 to 120 rpm: ±2 rpm, 0 to 5 rpm: not specified Pediatric/neonate: 6 to 150 rpm: ±2 rpm, 0 to 5 rpm: not specified	Same
NIBP monitor		
Measurement Range	Measurement range: Adult Pediatric Neonate	Measurement range: Adult Pediatric Neonate

	Systolic 40-270 40-200 40-135 Diastolic 10-215 10-150 10-100 Mean 20-235 20-165 20-110	Systolic 25-290 25-240 25-140 Diastolic 10-250 10-200 10-115 Mean 15-260 15-215 15-125
Accuracy	Maximum average error: ±5mmHg Maximum standard deviation: 8mmHg	Same
Measuring interval in AUTO Mode	1/2/3/4/5/10/15/30/60/90/120/240/480 mins	1/2/3/4/5/10/15/30/60/90/120/180/240/360/480 **and User Define**
PR from NIBP		
Measurement range	40 to 240 bpm	Same
Accuracy	±3 bpm or ±3.5%, whichever is greater	Same
SpO2 monitor		
Measurement Range	SpO2 0-100% Pulse Rate 25 to 300 bpm	Same
Accuracy	**Saturation** Adult/pediatric, non-motion conditions 70 to 100% ±2 % 0-69% unspecified Neonate 70 to 100% ±3% 0-69% unspecified **Pulse Rate** Adult and Neonate ±2bpm (non-motion conditions)	**Same**
Temperature monitor		
Measurement Range	0 to 50℃	Same
Accuracy	±0.1℃(excluding the sensor)	Same
IBP monitor		
Measurement Range	-50~300mmHg	Same

Accuracy	± 2% or ±1 mmHg, whichever is larger	Same
C.O. Monitor		
Measurement range	C.O.: 0.1 to 20L/min TB: 23 to 43℃ TI: -1 to 27℃	Same
Accuracy	C.O.: ±5% or ±0.2L/min, which is greater TB,TI: ±0.1℃(without sensor)	Same
CO2 Monitor		
Measuring Range	0 mmHg to 150 mmHg (0 % to 20%) AwRR: 2 rpm to 150 rpm	Same
Sample Gas Flowrate	70 ml/min or 100 ml/min (default), accuracy: ±15 ml/min	Same
Accuracy	± 2 mmHg, 0 mmHg to 40 mmHg ± 5% of reading, 41 mmHg to 70 mmHg ± 8% of reading, 71 mmHg to 100 mmHg ± 10% of reading, 101 mmHg to 150 mmHg ±12% or ± 4 mmHg of reading, whichever is greater	Same
Clinical scores	/	MEWS,NEWS
Safety Classifications		
Type of protection against electric shock	Class I	Same
The degree of RF	Group 1, Class A	Same
Anti-electroshock degree	ECG, RESP, TEMP, IBP, C.O. CF NIBP, SpO2, CO2,AG BF	ECG, RESP, NIBP, SpO2,TEMP, IBP, C.O. ,CO2 CF
Wireless connection	2.4GHz Module	**2.4GHz and 5G Module**

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

7. Performance Data:

Non-clinical data:

Electrical safety and electromagnetic compatibility (EMC)

X Series Patient Monitors were assessed for conformity with the relevant requirements of the following standards and found to comply:

- 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 60601-1-8:2006 + Am1:2012 Medical electrical equipment - part 1-8: general requirements for basic safety and essential performance - collateral standard: general requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-2-25:2011 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs
- IEC 60601-2-27:2011 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
- IEC 80601-2-30:2013 Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- IEC 60601-2-34:2011 Medical electrical equipment - part 2-34: particular requirements for the basic safety, including essential performance, of invasive blood pressure monitoring equipment
- IEC 60601-2-49:2011 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55: 2011 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56: 2009 Medical electrical equipment - part 2-56: particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

- ISO 80601-2-61: 2011 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment

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".

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 X series Patient Monitor are substantially equivalent to the predicate device.