August 11, 2022

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

Re: K220308
Trade/Device Name: Patient Monitor: RespArray
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, MLD, DSI, DSB
Dated: July 1, 2022
Received: July 11, 2022

Dear Joan. Wei:

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,

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)*
K220308

Device Name
Patient Monitor (RespArray)

Indications for Use *(Describe)*
The RespArray™ patient monitor is intended to be used for monitoring, storing, 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 monitor is for prescription use only.
The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), and carbon dioxide (CO2).
The arrhythmia detection and ST Segment analysis are intended for adult patients.
The SpO2 (NellcorTM) module is intended to be used for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), in motion and no motion conditions, and in patients who are well or poorly perfused.
The MicrostreamTM capnography module is intended for continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath (etCO2) and respiration rate (RR).
The monitor also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is not intended for patients up to the age of one year. A/hr and ODI are intended for ages 22 and up.
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.
#15 Jinhui Road, Jinsha Community,
Kengzi Sub-District, Pingshan District,
Shenzhen, 518122 P.R.China.
Tel: +86(0755) 84513592

Contact person: Joan Wei

Preparing date: August 10, 2022

2. Device name and classification:

Device Name: Patient Monitor

Model: RespArray

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 X8, X10, X12 - K192514 (Primary)
2) Covidien LP, Nellcor Portable SpO2 Patient Monitoring System - K141542 (Reference)
3) Capnostream™ 35 Portable Respiratory Monitor - K200594 (Reference)
4) SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.

ePM Series Patient Monitors (including ePM 10/ePM 12/ePM 15/ ePM 10M/ePM 12M/ePM 15M monitors) - K200015 (Reference).

5) Philips Medizin Systeme Boeblingen GmbH .IntelliVue Patient Monitors MX750 and MX850 and IntelliVue 4-Slot Module Rack FMX-4 - K210906 (Reference).

6) Edan Instruments, Inc. Patient Monitor, Model: iM50, iM60, iM70, iM80 - K202336 (Reference)

4. Device Description: The RespArray patient monitor (hereinafter called RespArray) 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 RespArray™ patient monitor is intended to be used for monitoring, storing, 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 monitor is for prescription use only.

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

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

The SpO2 (NellcorTM) module is intended to be used for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2) and pulse rate (PR), in motion and no motion conditions, and in patients who are well or poorly perfused.

The MicrostreamTM capnography module is intended for continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath (etCO2) and respiration rate (RR).

The monitor also provides the clinician with integrated pulmonary index (IPI),

apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is not intended for patients up to the age of one year. A/hr and ODI are intended for ages 22 and up.

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 X8, X10, X12 - K192514).

Item	Subject Device RespArray	Predicate Device X8 X10 X12	Comparison Result
Manufacturer/K#	Current Submission	Edan Instrument, Inc. - K192514	——
Indications for Use			
Description	The RespArray™ patient monitor is intended to be used for monitoring, storing, 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 monitor is for prescription use only. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), oxygen saturation of arterial blood (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), and carbon dioxide (CO_2). The arrhythmia detection and ST Segment analysis are intended for adult patients. The SpO_2 (Nellcor™) module is intended to be used for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial	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 (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO_2), cardiac output (C.O.). The arrhythmia detection and ST Segment analysis are intended for adult patients. The monitors are not intended for MRI environments.	**Similiar**

	hemoglobin (SpO_2) and pulse rate (PR), in motion and no motion conditions, and in patients who are well or poorly perfused. The Microstream™ capnography module is intended for continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath ($etCO_2$) and respiration rate (RR). The monitor also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is not intended for patients up to the age of one year. A/hr and ODI are intended for age 22 and up. The monitors are not intended for MRI environments.		
ECG monitor			
Lead Mode	3 Electrodes; 5 Electrodes;	3 Electrodes; 5 Electrodes; **6 Electrodes; 10 Electrodes;**	**Different**
Arrhythmia Analysis	ASYSTOLE, VFIB/VTAC, COUPLET, VT > 2, BIGEMINY, TRIGEMINY, VENT, R on T, PVC, TACHY, BRADY, MISSED BEATS, IRR, VBRADY, PNC, PNP	ASYSTOLE, VFIB/VTAC, COUPLET, VT > 2, BIGEMINY, TRIGEMINY, VENT, R on T, PVC, TACHY, BRADY, MISSED BEATS, IRR, VBRADY, PNC, PNP	Same
RESP monitor from ECG			
Principle of Operation	Thoracic impedance	Thoracic impedance	Same
Measurement Range	0 rpm to 200 rpm	Adult: 0 to 120 rpm Pediatric/neonate: 0 rpm to 150rpm	**Different**
NIBP monitor			

Principle of Operation	oscillation	oscillation	Same
Measurement Range	Measurement range: Adult Pediatric Neonate Systolic 25-290 25-240 25-140 Diastolic 10-250 10-200 10-115 Mean 15-260 15-215 15-125	Measurement range: Adult Pediatric Neonate Systolic 25-290 25-240 25-140 Diastolic 10-250 10-200 10-115 Mean 15-260 15-215 15-125	same
PR from NIBP			
Measurement range	40 bpm to 240 bpm	40 to 240 bpm	Same
Temperature monitor			
Measurement Range	0 °C to 50 °C (32 ºF to 122 ºF)	0 °C to 50 °C (32 ºF to 122 ºF)	Same
Wireless			
Wireless connection	Wi-Fi	Wi-Fi	Same
Power supply			
AC power	Yes	Yes	Same
Rechargeable Battery	Yes	Yes	Same
CO2 Monitor			
Module	MicrostreamTM micorMediCO2 EtCO2	/	It is substantial equivalent to the CO2 Module cleared by K200594
SpO2 monitor			
Module	Nell-1	/	It is substantial equivalent to the SpO2 Module cleared by K141542

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)

RespArray 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.
- AIM Standard 7351731:2017 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers - An AIM Standard

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 ?
- 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 80601-2-30:2018 Medical electrical equipment - part 2-30: particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- 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: 2018 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: 2017 Medical electrical equipment - part 2-61: particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEEE ANSI C63.27:2017 American National Standard for Evaluation of Wireless Coexistence
- ANSI AAMI EC53:2013/(R)2020 ECG trunk cables and patient leadwires

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 device is substantially equivalent to the predicate device.

8. Conclusion

The bench testing data and software verification and validation demonstrate that Patient Monitor RespArray are substantially equivalent to the predicate device.