June 28, 2024

Edan Instruments, Inc
Tracy Yue
Regulatory Affairs Engineer
15 Jinhui Road, Jinsha Community, Kengzi Sub-district,
Pingshan District,
Shenzhen, Guangdong 518122
China

Re: K240320
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, DSI, MLD, DRT, DXN, DSK, FLL, DQA, CCK, DSB
Dated: February 2, 2024
Received: May 24, 2024

Dear Tracy Yue:

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,

Kimberly N. Crowley -S

For: Jennifer Shih Kozen
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices

OHT2: 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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K240320

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 (Nellcor™) 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 Microstream™ 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.**

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:

**Applicant:** Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community,
Kengzi Sub-District, Pingshan District,
Shenzhen, 518122 P.R.China.
Tel: +86(0755) 26858736
Fax: +86(0755) 26882223

**Contact person:** Tracy Yue

**Preparing date:** February 02, 2024

## 2. Device name and classification:

**Trade name:** Patient Monitor, Model: RespArray

**Common/Usual Name:** Patient Monitor

**Classification Name:** 21 CFR 870.1025
Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)

**Regulatory class:** Class II

**Primary product code:** MHX-Monitor, Physiological, Patient (With Arrhythmia Detection Or Alarms)

**Subsequent product code:**

| Regulation number/Device | Product Code |
|---|---|
| 21 CFR 870.2340<br>Detector and Alarm, Arrhythmia | DSI |
| 21 CFR 870.1025<br>Monitor, ST Segment with Alarm | MLD |
| 21 CFR 870.2300<br>Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm) | DRT |
| 21 CFR 870.1130<br>System, Measurement, Blood-Pressure, Non-Invasive | DXN |
| 21 CFR 870.1110<br>Computer, Blood-Pressure | DSK |
| 21 CFR 880.2910<br>Thermometer, Electronic, Clinical | FLL |
| 21 CFR 870.2700<br>Oximeter | DQA |
| 21 CFR 870.1400<br>Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase | CCK |

| | |
|---|---|
| 21 CFR 870.2770<br>Impedance plethysmograph | DSB |

**3. Predicate Device(s):**

1) Edan Instruments, Inc., Patient Monitor, Model: RespArray, K220308 (Primary predicate device)
2) Edan Instruments, Inc., Vital Signs Monitor, Model: iM3s, iM3As, iM3Bs, iHM3s K202892 (Reference device)
3) Covidien LLC., MicrostreamTM CO2 NanoPod, K213911 (Reference device)

**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 (Nellcor$^{TM}$) 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 Microstream$^{TM}$ capnography module is intended for continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath and carbon dioxide concentration of the exhaled breath and inspired (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 age 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 RespArray, K220308).

| Item | <Subject Device> RespArray | <Predicate Device> RespArray | Comparison Result |
|---|---|---|---|
| **Manufacturer/K#** | Current Submission | Edan Instrument.Inc/K220308 | —— |
| **Intended 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.<br><br>The monitor is for prescription use only.<br><br>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 ($CO_2$).<br><br>The arrhythmia detection and ST Segment analysis are intended for adult patients.<br><br>The $SpO_2$ (Nellcor™) module is intended to be used for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$) and pulse rate (PR), in motion and no motion conditions, and in patients who are well or poorly perfused.<br><br>The Microstream™ capnography module is intended for continuous | 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.<br><br>The monitor is for prescription use only.<br><br>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 ($CO_2$).<br><br>The arrhythmia detection and ST Segment analysis are intended for adult patients.<br><br>The $SpO_2$ (Nellcor™) module is intended to be used for spot-check or continuous non-invasive monitoring of functional oxygen saturation of arterial hemoglobin ($SpO_2$) and pulse rate (PR), in motion and no motion conditions, and in patients who are well or poorly perfused.<br><br>The Microstream™ capnography module is intended for continuous | Same |

| | | | |
|---|---|---|---|
| | non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath ($etCO_2$) and respiration rate (RR).<br><br>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.<br><br>The monitors are not intended for MRI environments. | non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath ($etCO_2$) and respiration rate (RR).<br><br>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.<br><br>The monitors are not intended for MRI environments. | |
| **ECG monitor** | | | |
| Lead Mode | 3 Electrodes; 5 Electrodes; | 3 Electrodes; 5 Electrodes; | Same |
| 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 | 0 rpm to 200 rpm | Same |
| **NIBP monitor** | | | |
| Principle of Operation | oscillation | oscillation | Same |
| Measurement Range | Measurement range:<br>Adult Pediatric Neonate<br>Systolic 25-290 25-240 25-140<br>Diastolic 10-250 10-200 10-115<br>Mean 15-260 15-215 15-125 | Measurement range:<br>Adult Pediatric Neonate<br>Systolic 25-290 25-240 25-140<br>Diastolic 10-250 10-200 10-115<br>Mean 15-260 15-215 15-125 | Same |

| | | | |
|---|---|---|---|
| **PR from NIBP** | | | |
| Measurement range | 40 bpm to 240 bpm | 40 to 240 bpm | Same |
| **Continuous TEMP** | | | |
| Measurement Range | 0 °C to 50 °C (32 ºF to 122 ºF) | 0 °C to 50 °C (32 ºF to 122 ºF) | Same |
| **$SpO_2$ monitor** | | | |
| Module | Nell-1 | Nell-1 | Same |
| **Spot Temp** | | | |
| **Measuring Range** | 16 °C ~ 43 °C (61 °F ~ 110 °F) | \ | The added spot temp is substantial equivalent to the Spot Temp Module cleared in K202892 |
| **Power supply** | | | |
| AC power | 100 V to 240 V~<br>50 Hz/60 Hz | 100 V to 240 V~<br>50 Hz/60 Hz | Same |
| Rechargeable Battery | Yes | Yes | Same |
| Battery Capacity | 6800 mAh | 5000 mAh | The battery comply with IEC 62133-2. |
| **CO2 Monitor** | | | |
| Module | Microstream™ NanoMediCO2 EtCO2 | Microstream™ microMediCO2 EtCO2 | The changed CO2 module is substantial equivalent to the CO2 module cleared in K213911 |

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)

The Resparray Patient Monitors were assessed for conformity with the relevant requirements of the following

standards and found to comply:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021] 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 60601-1-8:2020 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 60601-2-27:2011 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 60601-2-49:2018 Medical electrical equipment –Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- ISO 80601-2-55:2018 Medical electrical equipment - part 2-55: particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-56:2017+A1:2018 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

**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 Food and Drug Administration Staff, *"Content of Premarket Submissions for Device Software Functions"*.

**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 RespArray Patient Monitor is substantially equivalent to the predicate device.