July 29, 2025

Edan Instruments Inc.
Tracy Yue
Official Correspondent
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District
Shenzhen, Guangdong 518122
China

Re: K250179
Trade/Device Name: Patient Monitor (CX10, CX12, CX15, UX10, UX12, UX15)
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, DPS, DSI, MLD, DRT, DXN, DSK, FLL, DQA, BZQ, CCK, CCL
Dated: July 7, 2025
Received: July 1, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250179

Device Name

Patient Monitor (CX10, CX12, CX15, UX10, UX12, UX15)

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 and pediatrics (including neonates).
The monitors are intended for use by trained healthcare professionals in hospital environments.
The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), and cardiac output (C.O.).
The arrhythmia detection and ST Segment analysis are intended for adult patients.
The NIBP monitoring supports iCUFS algorithm and iFAST algorithm. The iCUFS algorithm is intended for adult, pediatric and neonatal patients. The iFAST algorithm is intended for adult and pediatric patients (≥3 years of age). Both measurement algorithms are also intended for use with pregnant women, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women.
The Spot Temp with T2A module can only measure temperature of adult and pediatric (> 1 year of age) patients.
The monitors are not intended for MRI environments.
The cardiac output (C.O.) is only intended for adult patients.

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:

Applicant: Edan Instruments, Inc.
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Kengzi Sub-District, Pingshan District,
Shenzhen, 518122 P.R.China.
Tel: +86(0755) 26858736
Fax: +86(0755) 26882223

Contact person: Tracy Yue
Preparing date: July 25, 2025

2. Device name and classification:

Trade name: Patient Monitor, Model: CX10, CX12, CX15, UX10, UX12, UX15
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 868.2375 Electrocardiograph	DPS
21 CFR 870.2340 Detector and Alarm, Arrhythmia	DSI
21 CFR 870.1025 Monitor, ST Segment with Alarm	MLD
21 CFR 870.2300 Monitor, Cardiac (Incl. Cardiotachometer & Rate Alarm)	DRT
21 CFR 870.1130 System, Measurement, Blood-Pressure, Non-Invasive	DXN
21 CFR 870.1110 Computer, Blood-Pressure	DSK
21 CFR 880.2910 Thermometer, Electronic, Clinical	FLL
21 CFR 870.2700 Oximeter	DQA

21 CFR 868.2375 Monitor, Breathing Frequency	BZQ
21 CFR 870.1400 Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase	CCK
21 CFR 868.1720 Analyzer, Gas, Oxygen, Gaseous-Phase	CCL

3. Predicate Device(s):

1) Edan Instruments, Inc., Patient Monitor Model iX10, iX12, iX15, K232962 (Primary Predicate)
2) Edan Instruments, Inc., Vital signs monitor Model iM3, K180380 (Reference)

4. Device Description:

The CX&UX series Patient Monitor including CX10/CX12/CX15/UX10/UX12/UX15 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 abnormalities so that doctors and nurses can respond to the patient's situation as appropriate.

Minor differences from the predicate device are limited to some modifications of monitoring parameter specifications. These updates do not change the fundamental scientific technology of the cleared predicate device and thus do not raise any questions about the safety and effectiveness of the subject device.

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 and pediatrics (including neonates). The monitors are intended for use by trained healthcare professionals in hospital environments.

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

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

The NIBP monitoring supports iCUFS algorithm and iFAST algorithm. The iCUFS algorithm is intended for adult, pediatric and neonatal patients. The iFAST algorithm is intended for adult and pediatric patients (≥3 years of age). Both measurement algorithms are also intended for use with pregnant women, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women.

The Spot Temp with T2A module can only measure temperature of adult and pediatric (> 1 year of age) patients.

The monitors are not intended for MRI environments.

The cardiac output (C.O.) is only intended for adult patients.

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 iX10, iX12, iX15, K232962).

Item	<Subject Device> (CX10, CX12, CX15, UX10, UX12, UX15)	<Predicate Device> (iX10, iX12, iX15)
Manufacturer/K#	Current Submission	K232962
Intended Use/Indications for Use		
Description	The monitors are intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults and pediatrics (including neonates). The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), and cardiac output (C.O.). The arrhythmia detection and ST Segment analysis are intended for adult patients. The NIBP monitoring supports iCUFS algorithm and iFAST algorithm. The iCUFS algorithm is intended for adult, pediatric and neonatal patients. The iFAST algorithm is intended for adult and pediatric patients (≥3 years of age). Both measurement algorithms are also intended for use with pregnant women, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women. The Spot Temp with T2A module can only measure temperature of adult and pediatric (> 1 year of age) patients.	The monitors are intended to be used for monitoring, storing, recording, and reviewing of, and to generate alarms for, multiple physiological parameters of adults and pediatrics (including neonates). The monitors are intended for use by trained healthcare professionals in hospital environments. The monitored physiological parameters include: ECG, respiration (RESP), temperature (TEMP), functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), carbon dioxide (CO2), cardiac output (C.O.), and Anaesthesia gas (AG). The arrhythmia detection and ST Segment analysis are intended for adult patients. The NIBP monitoring supports iCUFS algorithm and iFAST algorithm. The iCUFS algorithm is intended for adult, pediatric and neonatal patients. The iFAST algorithm is intended for adult and pediatric patients (≥3 years of age). Both measurement algorithms are also intended for use with pregnant women, including pre-eclamptic patients. NIBP MAP is not applicable to pregnant women. The Spot Temp with T2A module can only

	The monitors are not intended for MRI environments. The cardiac output (C.O.) is only intended for adult patients.	measure temperature of adult and pediatric (> 1 year of age) patients. The monitors are not intended for MRI environments. The cardiac output (C.O.) is only intended for adult patients.
ECG module		
Lead Mode	3 Electrodes; 5 Electrodes; 6 Electrodes; 10 Electrodes	3 Electrodes; 5 Electrodes; 6 Electrodes; 10 Electrodes
Arrhythmia analyses	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
ST value		
Measurement Range	-2.0 mV to +2.0 mV	-2.0 mV to +2.0 mV
Pace		
Pulse Indicator	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2.0 ms Ascending time: 10 μs to 100 μs
PVC		
Range	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min	ADU: (0 to 300) PVCs/ min PED/NEO: (0 to 350) PVCs/ min
HR		
Measurement range	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm	ADU: 15 bpm to 300 bpm PED/NEO: 15 bpm to 350 bpm
QT Analysis		
QT/QTc/ΔQTc measurement	QT Range: 200 ms ~ 800 ms QTc Range :200ms ~ 800 ms Δ QTc Range: -600 ms ~ 600 ms	QT Range: 200 ms ~ 800 ms QTc Range :200ms ~ 800 ms Δ QTc Range: -600 ms ~ 600 ms
RESP module		
Principle of Operation	Impedance between RA-LL, RA-LA	Impedance between RA-LL, RA-LA
Measurement Range	6 rpm to 200 rpm	0 rpm to 200 rpm
Accuracy	**6 rpm to 200 rpm: ±2 rpm**	6 rpm to 200 rpm: ±2 rpm 0 rpm to 5 rpm: not specified
NIBP module (EDAN)		
Technique	Oscillometry	Oscillometry
Measurement Mode	iCUFS, iFAST	iCUFS, iFAST

Intended population	iCUFS: Adult, pediatric, neonates iFAST: Adult, pediatric	iCUFS: Adult, pediatric, neonates iFAST: Adult, pediatric
Measurement Range (mmHg)	Adult Pediatric Neonate Systolic 25-290 25-240 25-140 Diastolic 10-250 10-200 10-115 MAP 15-260 15-215 15-125	Adult Pediatric Neonate Systolic 25-290 25-240 25-140 Diastolic 10-250 10-200 10-115 MAP 15-260 15-215 15-125
PR from NIBP		
Measurement range	40 bpm to 240 bpm	40 bpm to 240 bpm
SpO2 module(EDAN)		
Measurement Range	0% to 100%	0% to 100%
PR from SpO2		
Measurement Range	**20 bpm to 300 bpm**	25 bpm to 300 bpm
Temperature(TEMP) module		
Number of channels	2	2
Measurement Range	0 °C to 50 °C(32 ºF to 122 ºF)	0 °C to 50 °C(32 ºF to 122 ºF)
Spot Temp Module		
EDAN T2A	Measurement site: oral/axillary Monitor mode: 25 ℃ ~ 45 ℃ Predict mode: 35.5 ℃ ~ 42 ℃ Accuracy (Monitor mode): 0.1 ℃ (25 ℃ ~ 45 ℃)	Measurement site: oral/axillary Monitor mode: 25 ℃ ~ 45 ℃ Predict mode: 35.5 ℃ ~ 42 ℃ Accuracy (Monitor mode): 0.1 ℃ (25 ℃ ~ 45 ℃)
F3000 module	**Measurement site: oral/axillary/rectal** **Monitor mode: 30 °C~43 °C** **Predict mode: 35 °C ~43 °C** **Accuracy (Monitor mode): ±0.1 °C**	/
The T2A module is the same as K232962 The F3000 module is similar to K180380		
The Spot Temp module is applicable to CX10/CX12 and UX10/UX12.		
IBP module		
Channel	**2**	iX15: 4 channels iX10/iX12: 2 channels
Measurement Range	**(-50 to +360) mmHg**	ART, Ao, UAP, BAP, FAP, LV, P1-P4: (-50 to +400) mmHg PA/PAWP: (-6 to +120) mmHg CVP/RAP/LAP/ICP: (-10 to +40) mmHg
Accuracy	**±2% or ±1 mmHg, whichever is greater (excluding sensor error)**	±2 % or ±1 mmHg, whichever is greater ICP: 0 mmHg to 40 mmHg: ±2 % or ±1 mmHg, whichever is greater;

		-10 mmHg to -1 mmHg: undefined
C.O. Module		
Technique	Thermodilution Technique	Thermodilution Technique
Measurement range	C.O.: 0.1 to 20L/min TB: 23 ºC to 43 ºC(73.4 ºF to 109.4 ºF) TI: -1 ºC to 27 ºC(30.2 ºF to 80.6 ºF)	C.O.: 0.1 to 20L/min TB: 23º C to 43 ºC(73.4 ºF to 109.4 ºF) TI: -1 ºC to 27 ºC(30.2 ºF to 80.6 ºF)
CO2 Module (EDAN G2)		
Intended Patient	Adult, pediatric, neonatal	Adult, pediatric, neonatal
Measure Parameters	$EtCO_2$, $FiCO_2$, AwRR	$EtCO_2$, $FiCO_2$, AwRR
Measuring Range	CO2: 0 mmHg to **152 mmHg** (0 % to 20%) AwRR: 0 rpm to 150 rpm	CO2: 0 mmHg to 150 mmHg (0 % to 20%) AwRR: 0 rpm to 150 rpm
Wi-Fi		
IEEE	802.11a/b/g/n	802.11a/b/g/n
Frequency Band	2.4 GHz ISM band & 5 G ISM band	2.4 GHz ISM band & 5 G ISM band
Power supply		
AC power		
Requirement	100-240V, 50/60Hz	100-240V, 50/60 Hz
Battery		
Rechargeable Battery	Yes	Yes

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)

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

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION-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 60601-1-8:2020 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 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 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 80601-2-49:2018 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 USEMCSC C63.27 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: The subject device did not require new clinical studies to support substantial equivalence.

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 CX&UX series Patient Monitor is substantially equivalent to the predicate device.