August 6, 2026

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

Re: K251508
Trade/Device Name: Telemetry Monitor (iT30, iT50)
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, MSX, DPS, DSB, DSI, MLD, DRT, DXN, FLL, DQA
Dated: January 9, 2026
Received: January 9, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

KIMBERLY N. CROWLEY -S

For: 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251508

Please provide the device trade name(s).

Telemetry Monitor (iT30, iT50)

Please provide your Indications for Use below.

The iT30 and iT50 Telemetry Monitor are intended for use on Adult and Pediatric patients (over three years old) to monitor monitor physiological parameters include ECG, SpO2, PR, NIBP (Applicable to iT50 only), and Skin TEMP. The physiological data can be analyzed, alarmed, stored locally on the monitor, and the Edan Central Monitoring System can configure, display and review the physiological parameters from the iT30 and iT50 Telemetry Monitor.
The arrhythmia detection and ST Segment analysis of ECG are intended for adult patients.
The SpO2 and PR are used under no motion conditions.
The NIBP is used under no motion conditions for patients over 12 years old and excluding pregnant women.
The iT30 and iT50 Telemetry Monitor must be used by professional trained clinical medical staff in healthcare facilities.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: January 09, 2026

2. Device name and classification:

Trade name: Telemetry Monitor, Model: iT30, iT50
Common/Usual Name: Telemetry 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 870.2300 System, network and communication, physiological monitors	MSX
21 CFR 868.2375 Electrocardiograph	DPS
21 CFR 870.2770 Plethysmograph, impedance	DSB
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 880.2910	FLL

Thermometer, Electronic, Clinical	
21 CFR 870.2700 Oximeter	DQA

3. Predicate Device(s):

1) Primary Predicate Device: Shenzhen Mindray Bio-Medical Electronics Co., LTD., Telemetry Monitor TM80 (K193391)

2) Reference Device: Edan Instruments, Inc., Patient Monitor iX10/iX12/iX15 (K232962)

4. Device Description: The iT30&iT50 telemetry monitor can perform long-time continuous monitoring of multiple physiological parameters. Also, it is capable of displaying, storing, and transferring of multiple physiological parameters connecting to Central Monitoring System. It will indicate alarms in case of abnormalities so that doctors and nurses can respond to the patient's situation as appropriate.

5. Indication for Use The iT30 and iT50 Telemetry Monitor are intended for use on Adult and Pediatric patients (over three years old) to monitor physiological parameters include ECG, SpO2, PR, NIBP (Applicable to iT50 only), and Skin TEMP. The physiological data can be analyzed, alarmed, stored locally on the monitor, and the Edan Central Monitoring System can configure, display and review the physiological parameters from the iT30 and iT50 Telemetry Monitor.
The arrhythmia detection and ST Segment analysis of ECG are intended for adult patients.
The SpO2 and PR are used under no motion conditions.
The NIBP is used under no motion conditions for patients over 12 years old and excluding pregnant women.
The iT30 and iT50 Telemetry Monitor must be used by professional trained clinical medical staff in healthcare facilities.

6. Predicate Device Comparison

The table below compares the indication for use and key technological feature of the subject devices to the predicate device.

Characteristic	**<Subject Device> (iT30, iT50 Telemetry Monitor)**	**<Predicate Device> (TM80 Telemetry Monitor)**
Manufacturer/K#	K251508	K193391
Intended Use/Indications for Use		
Description	The iT30 and iT50 Telemetry Monitor are intended for use on Adult and Pediatric patients	The TM80 telemetry monitor is intended for use on Adult and Pediatric patients over three

	(over three years old) to monitor physiological parameters include ECG, SpO2, PR, NIBP (Applicable to iT50 only), and Skin physiological data can be analyzed, alarmed, stored locally on the monitor, and the Edan Central Monitoring System can display and review the physiological parameters from the iT30 and iT50 Telemetry Monitor. The arrhythmia detection and ST Segment analysis of ECG are intended for adult patients. The SpO2 and PR are used under no motion conditions. The NIBP is used under no motion conditions for patients over 12 years old and excluding pregnant women. The iT30 and iT50 Telemetry Monitor must be used by professional trained clinical medical staff in healthcare facilities.	years old to monitor ECG, SpO2, NIBP and Resp physiological data. The physiological data can be analyzed, alarmed, stored, reviewed locally on the display of the monitor, and the CentralStation can configure and display the physiological parameters from the TM80. The TM80 telemetry monitor is intended for use in professional healthcare facilities under the direct supervision of a licensed healthcare practitioner.
ECG module		
Lead Mode	3 Electrodes; 5 Electrodes; 6 Electrodes; **10 Electrodes**	3 Electrodes; 5 Electrodes; 6 Electrodes
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 to2.0 ms Ascending time: 10 μs to 100 μs	Amplitude: ±2 mV to ±700 mV Width: 0.1 ms to 2 ms Rise time: 10 μs to 100 μs
HR		
Measurement range	ADU: 15 bpm to 300 bpm PED: 15 bpm to 350 bpm	Adult: 15 bpm to 300 bpm Pediatric: 15 bpm to 350 bpm
QT Analysis		
QT/QTc/ΔQTc measurement	QT Range: 200 ms ~ 800 ms QTc Range :200ms ~ 800 ms ∆ QTc Range: -600 ms ~ 600 ms	QT Range: 200 ms ~ 800 ms QTc Range :200ms ~ 800 ms ∆ QTc Range: -600 ms ~ 600 ms
Arrhythmia Analysis		
Arrhythmia analysis	**ASYSTOLE, VFIB/VTAC, COUPLET, VT > 2, BIGEMINY, TRIGEMINY, VENT, R on T, PVC, TACHY, BRADY, MISSED**	Asystole, V-Fib/V-Tach, V-Tach, Vent Brady, Extreme Tachy, Extreme Brady, PVCs/min, Pauses/min, R on T, Run PVCs,

	BEATS, IRR, VBRADY, PNC, PNP	Couplet, Multiform PVC, PVC, Bigeminy, Trigeminy, Tachy, Brady, Pacer Not Pacing, Pacer Not Capture, Missed Beats, Nonsus V-Tach, Vent Rhythm, Pause, Irr Rhythm, A-Fib
NIBP module (EDAN)		
Technique	Oscillometry	Oscillometry
Measurement Mode	**Manual, Auto, STAT**	Manual, Automatic, Continuous, Sequence and ABPM
Measurement Algorithm	iCUFS	The method principle is equivalent to the iCUFS algorithm
Measurement Range	Adult SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg Pediatric SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg	Adult SYS: 25 mmHg to 290 mmHg DIA: 10 mmHg to 250 mmHg MAP: 15 mmHg to 260 mmHg Pediatric SYS: 25 mmHg to 240 mmHg DIA: 10 mmHg to 200 mmHg MAP: 15 mmHg to 215 mmHg
PR from NIBP		
Measurement range	**40 bpm to 240 bpm**	30 bpm to 300 bpm
SpO_2 module		
Measurement Range	0% to 100%	Nellcor SpO_2 0% to 100%
Accuracy	Adult/pediatric, non-motion conditions ±2% (70% to 100% SpO_2) Undefined (0% to 69% SpO_2)	Nellcor SpO_2 70-100%: ±2% 0-69%: Not specified
The subject device supports SpO2 sensors SH1, SH4, SH5, SHD-A, SHD-P, 02.57.225230 and 02.57.225231.		
PR from SpO_2		
Measurement Range	20 bpm to 300 bpm	20 bpm to 300 bpm
Accuracy	**± 2 bpm**	20 bpm to 250 bpm: ±3 bpm 251 bpm to 300 bpm: Not specified
Skin Temperature (Skin TEMP) module		
Number of channels	1	/
Measurement Range	0 °C to 50 °C(32 ºF to 122 ºF)	
Measurement Site	Skin	
The TEMP measurement is a newly-added function and is similar to the reference device K232962		
Wi-Fi		
Radio Technology	**IEEE 802.11 a/b/g/n**	IEEE 802.11 a/b/g/n/ac
Frequency Range	**2412 MHz-2472 MHz**	2412 MHz to 2472 MHz

	5180 MHz-5240 MHz **5745 MHz-5825 MHz**	5180 MHz to 5825 MHz
Power Supply		
Power Type	AA batteries Rechargeable Li-ion battery	AA batteries Rechargeable lithium-ion battery
Charger	Charger stand	Central Charger

As seen in the comparison tables, the subject and predicate device 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)

iT30 and iT50 Telemetry 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 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 80601-2-56:2017+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
- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- 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: Not applicable.

Summary

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

8. Conclusion

The bench testing data and software verification and validation demonstrate that iT30&iT50 Telemetry Monitor are substantially equivalent to the predicate device.