



February 9, 2026

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

Re: K251591

Trade/Device Name: Holter ECG and ABP system (HolterABP)
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: Class II
Product Code: DQK
Dated: May 23, 2025
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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

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

Indications for Use

510(k) Number (if known)

K251591

Device Name

Holter ECG and ABP system (HolterABP)

Indications for Use (Describe)

The Holter ECG and ABP system is intended to acquire, analyze, display, edit and generate report of ambulatory ECG, ambulatory blood pressure and combined Holter ECG and ABP data. The analysis results are offered to doctors on an advisory basis only.

Data acquired may be used for the following indications:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
- Evaluation of patients for ST segment changes.
- Evaluation of drug response in patients taking anti-arrhythmic medications.
- Evaluation of patients with pacemakers.

The ambulatory blood pressure function is intended for use in patients over 12 years of age from data collected from an FDA cleared ambulatory blood pressure cuff.

The ECG Analysis function is intended for use in adults and pediatric, but arrhythmia detection is intended for use in patients over 12 years of age.

The Holter ECG and ABP system is intended to be used only in hospital and healthcare facilities by physicians or trained healthcare professionals.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary**Prepared in accordance with the requirements of 21 CFR Part 807.92**

- 1. Submitter:** Edan Instruments, Inc.
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Shenzhen, 518122 P.R.China.
Tel: +86(0755) 84513592
Fax: +86(0755) 26882223
- 2. Contact person:** Tracy Yue
Preparing date: February 7, 2026
- 3. Device name and classification:** **Trade name:** Holter ECG and ABP system, Model: HolterABP
Classification Name/ Product code:
21 CFR 870.1425 Computer, Diagnostic, Programmable
DQK
Regulatory Class: Class II
- 4. Predicate Device(s):** 1) Edan Instruments, Holter System, models SE-2003 and SE-2012, cleared under K151787
2) Edan Instruments, Ambulatory Blood Pressure Monitor, models: SA-10, SA-05, SA-06, SA-08 and SA-09, cleared under K210139
- 5. Reason for Submission** By submission of the Traditional 510(k), Edan Instruments is requesting clearance for Holter ECG and ABP system, Model: HolterABP
- 6. Device Description:** The Holter ECG and ABP system (Model: HolterABP) is a Windows-based application software. It is intended to acquire, analyze, display, edit and generate report of ambulatory ECG data, ambulatory blood pressure data and combined Holter ECG and ABP data that has been stored by the compatible recorders.
The Holter ECG and ABP system provides automatic QRS detection and classification, automatic arrhythmia detection, ST segment measurement and creates summary tables, trends.
The Holter ECG and ABP system display the ABP data, then form the summary table, and statistics information.
The final report can be previewed, printed and saved after the data analysis

is completed.

All results obtained from automatic analysis and the resulting unconfirmed reports must be considered as suggestions only.

The subject device is intended only for retrospective analysis, and not for use in real-time monitoring or alarming.

8. Indication for Use

The Holter ECG and ABP system is intended to acquire, analyze, display, edit and generate report of ambulatory ECG, ambulatory blood pressure and combined Holter ECG and ABP data. The analysis results are offered to doctors on an advisory basis only.

Data acquired may be used for the following indications:

- Evaluation of symptoms suggesting arrhythmia or myocardial ischemia.
- Evaluation of patients for ST segment changes.
- Evaluation of drug response in patients taking anti-arrhythmic medications.
- Evaluation of patients with pacemakers.

The ambulatory blood pressure function is intended for use in patients over 12 years of age from data collected from an FDA cleared ambulatory blood pressure cuff.

The ECG Analysis function is intended for use in adults and pediatric, but arrhythmia detection is intended for use in patients over 12 years of age.

The Holter ECG and ABP system is intended to be used only in hospital and healthcare facilities by physicians or trained healthcare professionals.

9. Predicate Device Comparison

The subject device is technologically equivalent to predicate devices. Any differences are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness. The table below compares the intended use and technological characteristics of the subject and predicate devices:

Table 1: Comparison to Primary Predicate Device

Item	<i>Primary Predicate Device</i> K151787 Holter System (Model: SE-2003,SE-2012)	<i>Subject Device</i> Holter ECG and ABP system (Model: HolterABP)	Comparison Result
Manufacturer	Edan Instruments, Inc	Edan Instruments, Inc	Same
K#	K151787	K251591	-
Regulation Number	21 CFR 870.1425	21 CFR 870.1425	Same

Regulation Name	Programmable Diagnostic Computer	Programmable diagnostic computer	Same
Classification	II	II	Same
Intended Use	<p>The SE-2003/SE-2012 Holter System (including recorder and analysis software) is intended to record, analyze, display, edit and generate report of ambulatory ECG. The Holter System is intended to be used by trained personnel under the direction of doctors. The analysis results are offered to doctors on an advisory basis only. The Holter System is intended for adult, pediatric patients including infants weighing less than 10 kg.</p> <p>It can be used for the following indications:</p> <ol style="list-style-type: none"> 1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia. 2. Evaluation of patients for ST segment changes. 3. Evaluation of drug response in patients taking anti-arrhythmic medications. 4. Evaluation of patients with pacemakers. 	<p>The Holter ECG and ABP system is intended to acquire, analyze, display, edit and generate report of ambulatory ECG, ambulatory blood pressure and combined Holter ECG and ABP data. The analysis results are offered to doctors on an advisory basis only.</p> <p>Data acquired may be used for the following indications:</p> <ol style="list-style-type: none"> 1. Evaluation of symptoms suggesting arrhythmia or myocardial ischemia. 2. Evaluation of patients for ST segment changes. 3. Evaluation of drug response in patients taking anti-arrhythmic medications. 4. Evaluation of patients with pacemakers. <p>The Ambulatory blood pressure function is intended for use in patients over 12 years of age from data collected from an FDA cleared ambulatory blood pressure cuff.</p> <p>The ECG Analysis function is intended for use in adults and pediatric, but arrhythmia detection is intended for use in patients over 12 years of age.</p> <p>The Holter ECG and ABP system is intended to be used only in hospital and healthcare facilities by physicians or trained healthcare</p>	Different

		professionals.	
Review Modes	ECG strip review, ECG template review, ECG Poincare Plot review , ECG Superimposed Graph , ECG Histogram , ECG Event review, ECG Trend review, Tabular and Page review,	ECG strip review, ECG template review, ECG Poincare Plot review , ECG Superimposed Graph , ECG Histogram , ECG Event review, ECG Trend review, Tabular and Page review	same
Rhythm Analysis	Bradycardia, Tachycardia, Ventricular pairs, Ventricular tachycardia, Supraventricular pairs, Long R-R interval, Pause, Min/max heart rate, ST depression, ST elevation	Bradycardia, Tachycardia, Ventricular pairs, Ventricular tachycardia, Supraventricular pairs, Long R-R interval, Pause, Min/max heart rate, ST depression, ST elevation	same
ST Segment Measurement	3/12 lead ST segment measurement, max ST depression, max ST elevation, 3/12 lead trends	3/12 lead ST segment measurement, max ST depression, max ST elevation, 3/12 lead trends	same
Pacemaker Analysis	Atrial, ventricular and dual pacemaker detection; capture failure, Output failure, under sensing	Atrial, ventricular and dual pacemaker detection; capture failure, Output failure, under sensing	same
QT analysis	QT Measurement	QT Measurement	same
HRV analysis	Frequency domain analysis, Time domain analysis	Frequency domain analysis, Time domain analysis	same
Heart rate calculation	heart rate of a single beat Maximum and minimum heart rate Average heart rate	heart rate of a single beat Maximum and minimum heart rate Average heart rate	Same
HRT	Turbulence onset (TO), Turbulence slope(TS)	Turbulence onset (TO), Turbulence slope(TS)	Same
VCG	Display waveform of three orthogonal leads X, Y and Z, and display QRS loop, P loop, and T loop of frontal plane, horizontal plane, and right sagittal plane.	Display waveform of three orthogonal leads X, Y and Z, and display QRS loop, P loop, and T loop of frontal plane, horizontal plane, and right sagittal plane.	Same
VLP	Time domain analysis, Frequency domain analysis	Time domain analysis, Frequency domain analysis	Same
ABPM data viewer	-	Display BP Data Table, Day & Night BP Profile, BP Histogram, Supports displaying BP Pie Chart	Different
Intended population of algorithm	Adult and pediatric population	Adult and pediatric population	Same

Applicable standards	IEC60601-2-47:2012	IEC60601-2-47:2012	Same
Software Operating Platform	Windows 10,11	Windows 11	Different

Table 2: Comparison to Secondary Predicate Device

Item	<i>Secondary Predicate device</i> K210139 Ambulatory Blood Pressure Monitor Models: SA-10, SA-05, SA-06, SA-08 and SA-09	<i>Subject Device</i> Holter ECG and ABP system (Model: HolterABP)	Comparison Result
Manufacturer	Edan Instruments, Inc	Edan Instruments, Inc	Same
K#	K210139	K251591	--
Intended Use/ Indication for use	<p>The Ambulatory Blood Pressure Monitor is capable of measuring systolic and diastolic blood pressures, and pulse of adults and pediatrics (> 12 years) over a preprogrammed period of time. These measurements are stored in the monitor and can be transferred to analysis system via wire or wireless transmission. It is intended for use as an aid or adjunct to diagnosis and treatment.</p>	<p>The Holter ECG and ABP system is intended to acquire, analyze, display, edit and generate report of ambulatory ECG, ambulatory blood pressure and combined Holter ECG and ABP data. The analysis results are offered to doctors on an advisory basis only. Data acquired may be used for the following indications:</p> <ul style="list-style-type: none"> ● Evaluation of symptoms suggesting arrhythmia or myocardial ischemia. ● Evaluation of patients for ST segment changes. ● Evaluation of drug response in patients taking anti-arrhythmic medications. ● Evaluation of patients with pacemakers. <p>The ambulatory blood pressure function is intended for use in patients over 12 years of age from data collected from an FDA cleared ambulatory blood</p>	Different

		<p>pressure cuff.</p> <p>The ECG Analysis function is intended for use in adults and pediatric, but arrhythmia detection is intended for use in patients over 12 years of age.</p> <p>The Holter ECG and ABP system is intended to be used only in hospital and healthcare facilities by physicians or trained healthcare professionals.</p>	
Intended Patient Population	Ambulatory BP part: adult patients and pediatrics (>12yrs.)	Ambulatory BP part: adult patients and pediatrics (>12yrs.)	Same
ABP data viewer	<p>Display BP Data Table,</p> <p>Day & Night BP Profile(including White-Coat phenomenon),</p> <p>BP Histogram,</p> <p>Supports displaying BP Pie Chart,</p> <p>Supports BP thresholds and data elimination thresholds setting</p> <p>Supports Day/Night Setting</p>	<p>Display BP Data Table,</p> <p>Day & Night BP Profile(including White-Coat phenomenon),</p> <p>BP Histogram,</p> <p>Supports displaying BP Pie Chart,</p> <p>Supports BP thresholds and data elimination thresholds setting</p> <p>Supports Day/Night Setting</p>	Same
ABP data statistics show	<p>Based on the blood pressure values stored in the received record, the following results can be statistically output:</p> <p>SBP, DBP, PR, PP, Valid Data(%), Morning Surge, BP Load, BPR, Morning BP, Asleep Dip, coefficient of variation (CV)</p>	<p>Based on the blood pressure values stored in the received record, the following results can be statistically output:</p> <p>SBP, DBP, PR, PP, Valid Data(%), Morning Surge, BP Load, BPR, Morning BP, Asleep Dip, coefficient of variation (CV)</p>	Same

Although there are differences between the subject device and the predicate device, after verification, the difference between them does not raise different questions of safety and effectiveness of Subject device.

10. Performance Data:

Non-clinical test:**Biocompatibility Testing**

Not applicable.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable.

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."

Bench Testing:

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 relevant consensus standards.

- IEC 60601-2-47 Edition 2.0 2012-02 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems

Performance validation:

EDAN used the public datasets (AHA, MIT-BIH, NST, ESC, QT database) and independent EDAN proprietary datasets to validate the subject device. Performance metrics assessed include sensitivity, positive predictive value, and false positive rate for QRS detection and classification, arrhythmia and event detection, as well as mean error, standard deviation for ST and QT interval measurements and RMS error for HR calculation. All the outcomes were compared against clinically derived acceptance criteria and demonstrated the substantial equivalence of the subject device.

Clinical testing:

Not applicable. Clinical testing is not required to establish substantial equivalence to the predicate device.

11. Conclusion

The bench testing data and software verification and validation demonstrate that Holter ECG and ABP system, Model: HolterABP is substantially equivalent to the predicate devices.