December 23, 2025

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

Re: K251268
Trade/Device Name: Diagnostic Ultrasound System (Nano C5, Nano C5 EXP, Nano L12, and Nano L12 EXP)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: November 28, 2025
Received: November 28, 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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of Radiological Health
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.	K251268

Please provide the device trade name(s).

Diagnostic Ultrasound System (Nano C5, Nano C5 EXP, Nano L12, and Nano L12 EXP)

Please provide your Indications for Use below.

The Nano Series Diagnostic Ultrasound System is intended for use by an appropriately trained and qualified healthcare professional for ultrasound evaluation in hospitals, clinics, road ambulances or at home. Nano Series Diagnostic Ultrasound System clinical applications include Abdominal, Gynecology, Obstetric, Small parts, Musculoskeletal, Urology, Peripheral vascular, Pediatric, Pleural/Thoracic and Cardiac.
The Modes of Operation for Nano Series include B mode, M mode, Doppler modes, Harmonic Imaging and their combination modes.

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.
#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: December 23, 2025

2. Device name and classification:

Trade name: Diagnostic Ultrasound System, Model: Nano C5, Nano C5 EXP, Nano L12, and Nano L12 EXP
Common/Usual Name: Diagnostic Ultrasound System
Classification Name: 21 CFR 892.1550
System, Imaging, Pulsed Doppler, Ultrasonic
Regulatory class: Class II
Primary product code: IYN- System, Imaging, Pulsed Doppler, Ultrasonic
Subsequent product code:

Regulation number/Device	Product Code
21 CFR 892.1570 Transducer, Ultrasonic, Diagnostic	ITX
21 CFR 892.1560 System, Imaging, Pulsed Echo, Ultrasonic	IYO

3. Predicate Device(s):

1) Philips Ultrasound, Inc., Lumify Diagnostic Ultrasound System, K203406 (Primary)
2) Edan Instruments, Inc., Acclarix AX8&A9 Series Diagnostic Ultrasound System, K250214 (Reference)

4. Device Description: The Nano Series ultrasound diagnostic system consists of an app which can be installed on iOS or Android devices, and convex and linear transducers which use wired or wireless technology for communication.
The Nano series diagnostic ultrasound systems transducers are available in four

models: Nano C5, Nano C5 EXP, Nano L12 and Nano L12 EXP. Nano C5 and Nano C5 EXP are convex transducers, and Nano L12 and Nano L12 EXP are linear transducers.
The system also supports various software features, including: Dual imaging, Speckle Reduction Imaging (eSRI), Auto Trace, Zoom, ECG Wave, eVocal, eWorks, Remote Diagnosis, etc.
This system is a Track 3 device to acquire and display ultrasound data in various imaging modes.

5. Indication for Use

The Nano Series Diagnostic Ultrasound System is intended for use by an appropriately trained and qualified healthcare professional for ultrasound evaluation in hospitals, clinics, road ambulances or at home. Nano Series Diagnostic Ultrasound System clinical applications include Abdominal, Gynecology, Obstetric, Small parts, Musculoskeletal, Urology, Peripheral vascular, Pediatric, Pleural/Thoracic and Cardiac. The Modes of Operation for Nano Series include B mode, M mode, Doppler modes, Harmonic Imaging and their combination modes.

6. Predicate Device Comparison

Item	**<Subject Device> Nano series**	**<Predicate Device> Lumify**	**Comparison**
Manufacturer/K#	**Edan Instruments, Inc.**	Philips Ultrasound, Inc. / K203406	——
Indications for Use	The Nano Series Diagnostic Ultrasound System is intended for use by an appropriately trained and qualified healthcare professional for ultrasound evaluation in hospitals, clinics, road ambulances or at home. Nano Series Diagnostic Ultrasound System clinical applications include Abdominal, Gynecology, Obstetric, Small parts, Musculoskeletal, Urology, Peripheral vascular, Pediatric, Pleural/Thoracic and Cardiac. The Modes of Operation for Nano Series include B mode, M mode, Doppler modes, Harmonic Imaging and their combination modes.	Philips Lumify Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), Color Doppler, Combined (B+Color), and M modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Pediatric, Cephalic, Urology, Gynecological, Cardiac Fetal Echo, Small Organ, Musculoskeletal, Peripheral Vessel, Carotid, Cardiac, Lung. Lumify is a transportable ultrasound system intended for use in environments where healthcare is provided by healthcare professionals.	The predicate device has more clinical applications than the subject device
FDA Product Codes	IYN, IYO, ITX	IYN, IYO, ITX	Same

Display	iOS or Android	IOS or Android	Same
Portability	Portable ultrasound system	Portable ultrasound system	Same
System Components	Transducers/scanners Software	Transducers/scanners Software	Same
Imaging Technology	Ultrasound Imaging	Ultrasound Imaging	Same
Mode of Operation	B mode, M mode, Doppler modes, Harmonic Imaging and their combination modes	B (2D), Color, Combined (B+Color), PW, M modes and Harmonic Imaging	Same Note: The B mode, Doppler modes and combination modes of the subject device are same as the B(2D), PW and Combined (B+Color) of the predicate device.
Measurements	B mode: Distance, Circumference, Area, Angle. M mode: Distance, Time, Heart Rate Doppler mode: Velocity, Time， Heart Rate	B mode: Distance, Circumference, Area, Angle. M mode: Distance, Time, Heart Rate Doppler mode: Velocity, Time，Heart Rate	Same
Rechargeable battery	Yes	Yes	Same

The subject device and predicate device have identical imaging modes, similar special functions. And the proposed subject device has the ECG function which has been cleared in K250214.

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)

Nano series were assessed for conformity with the relevant requirements of the following standards and found to comply:

- IEC 60601-1:2005+A1:2012+A2:2020 Medical electrical equipment - Part 1: General requirements for

basic safety and essential performance

- IEC 60601-1-2:2014+A1:2020 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 relevant guidance and consensus standards.

- IEC 60601-2-37: 2007+A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- FDA's Guidance "*Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"*
- IEC 60601-1-11: 2015+A1:2020, Medical Electrical Equipment - Part 1 - 11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment.
- IEC 60601-1-12: 2014+A1: 2020, Medical Electrical Equipment - Part 1- 12: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Intended For Use In The Emergency Medical Services Environment.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance *"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 Nano series Diagnostic Ultrasound System are substantially equivalent to the predicate device.