February 20, 2025

Edan Instruments Inc.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K250214
Trade/Device Name: Acclarix AX8 Series Diagnostic Ultrasound System (Model: Acclarix AX7, Acclarix AX8**,** Acclarix AX75, Acclarix AX78, Acclarix AX8 Exp, Acclarix AX8 Super), Acclarix AX9 Series Diagnostic Ultrasound Szystem (Model: Acclarix AX9 Basic, Acclarix AX9, Acclarix AX9 Exp, Acclarix AX9 Super, Acclarix AX85, Acclarix AX88)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 24, 2025
Received: January 24, 2025

Dear Prithul Bom:

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

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)*

K250214

Device Name

Acclarix AX8 Series Diagnostic Ultrasound System (Model: Acclarix AX7, Acclarix AX8, Acclarix AX75, Acclarix AX78, Acclarix AX8 Exp, Acclarix AX8 Super), Acclarix AX9 Series Diagnostic Ultrasound System (Model: Acclarix AX9 Basic, Acclarix AX9, Acclarix AX9 Exp, Acclarix AX9 Super, Acclarix AX85, Acclarix AX88)

Indications for Use *(Describe)*

The Acclarix AX8 Series Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations in hospitals and clinics.
The Acclarix AX8 Series Diagnostic Ultrasound System clinical applications include Abdominal, Gynecology, Obstetric, Cardiac, Small parts, Urology, Peripheral vascular, Musculoskeletal, Pediatric, Neonatal, Adult Cephalic, Thoracic/Pleural and Trans-esophageal Cardiac.
The Modes of Operation for Acclarix AX8 Series include B mode, M mode, Doppler mode, Harmonic Imaging, Elastography Imaging, Contrast imaging and their combination modes.

The Acclarix AX9 Series Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations in hospitals and clinics.
The Acclarix AX9 Series Diagnostic Ultrasound System clinical applications include Abdominal, Gynecology, Obstetric, Cardiac, Small parts, Urology, Peripheral vascular, Musculoskeletal, Pediatric, Neonatal, Adult Cephalic, Thoracic/Pleural and Trans-esophageal Cardiac.
The Modes of Operation for Acclarix AX9 Series include B mode, M mode, Doppler mode, Harmonic Imaging, Elastography Imaging, Contrast imaging and their combination modes.

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 19th, 2025

2. Device name and classification:

Trade name: Acclarix AX8 Series Diagnostic Ultrasound System (Model: Acclarix AX7, Acclarix AX8**,** Acclarix AX75, Acclarix AX78, Acclarix AX8 Exp, Acclarix AX8 Super), Acclarix AX9 Series Diagnostic Ultrasound Szystem (Model: Acclarix AX9 Basic, Acclarix AX9, Acclarix AX9 Exp, Acclarix AX9 Super, Acclarix AX85, Acclarix AX88)

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) Edan Instruments, Inc., Acclarix AX8 Series Diagnostic Ultrasound System/Acclarix LX9 Series Diagnostic Ultrasound System, K192879 (Predicate)

2) Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Resona I9 Diagnostic

Ultrasound System, K210699 (Reference)

3) Shenzhen Wisonic Medical Technology Co., Ltd., Carnation series Diagnostic Ultrasound System, K230066 (Reference)

4) Shenzhen Mindray Bio-Medical Electronics Co., Ltd., MX7/MX8 series Diagnostic Ultrasound System, K212900 (Reference)

4. Device Description: The Acclarix AX8 Series & Acclarix AX9 Series Diagnostic Ultrasound System is a software controlled Diagnostic Ultrasound System, which consists of a main unit along with associated transducers. It is intended for use by a qualified physician or allied health professional for ultrasound evaluations in hospitals and clinics. This system is a Track 3 device to acquire and display ultrasound data in various imaging modes.

5. Indication for Use The Acclarix AX8 Series Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations in hospitals and clinics.
The Acclarix AX8 Series Diagnostic Ultrasound System clinical applications include Abdominal, Gynecology, Obstetric, Cardiac, Small parts, Urology, Peripheral vascular, Musculoskeletal, Pediatric, Neonatal, Adult Cephalic, Thoracic/Pleural and Trans-esophageal Cardiac.
The Modes of Operation for Acclarix AX8 Series include B mode, M mode, Doppler mode, Harmonic Imaging, Elastography Imaging, Contrast imaging and their combination modes.

The Acclarix AX9 Series Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations in hospitals and clinics.
The Acclarix AX9 Series Diagnostic Ultrasound System clinical applications include Abdominal, Gynecology, Obstetric, Cardiac, Small parts, Urology, Peripheral vascular, Musculoskeletal, Pediatric, Neonatal, Adult Cephalic, Thoracic/Pleural and Trans-esophageal Cardiac.
The Modes of Operation for Acclarix AX9 Series include B mode, M mode, Doppler mode, Harmonic Imaging, Elastography Imaging, Contrast imaging and their combination modes.

6. Predicate Device Comparison

The subject devices Acclarix AX8 Series & Acclarix AX9 Series Diagnostic Ultrasound System have the same intended use and basic technological characteristics with the primary predicate device Acclarix AX8 Diagnostic Ultrasound System/Acclarix LX9 Series Diagnostic Ultrasound System (K192879), except the following main differences.

1. Addition of new models: Acclarix AX7, Acclarix AX75, Acclarix AX78, Acclarix AX8 Exp, Acclarix AX8 Super, Acclarix AX9 Basic, Acclarix AX9, Acclarix AX9 Exp, Acclarix AX9 Super, Acclarix AX85, Acclarix AX88.
2. Addition of new operation mode: Contrast imaging, which has similar specifications with the predicate device Acclarix LX9 Series Diagnostic Ultrasound System (K192879).
3. Deletion of clinical application: Intra-operative.
4. Addition of new clinical applications: Thoracic/Pleural, which has similar specifications with reference device MX7/MX8 series Diagnostic Ultrasound System (K212900); Trans-esophageal Cardiac, which has similar specifications with reference device Resona I9 Diagnostic Ultrasound System (K210699).
5. Addition of new transducers: L12-5HQ, L12-4HQ, C5-1XQ, and C6-2MQ, which have the same intended use and similar specifications with the predicate device Acclarix AX8 Diagnostic Ultrasound System/Acclarix LX9 Series Diagnostic Ultrasound System (K192879); P7-3MQ, which has the same intended use and similar specifications with reference device Resona I9 Diagnostic Ultrasound System (K210699).
6. Update transducers: C5-2Q, C5-2XQ, MC8-4Q, P5-1XQ, P7-3Q and E10-3HQ, which have the same intended use and similar specifications with the predicate device Acclarix AX8 Diagnostic Ultrasound System (K192879).
7. Addition new needle guide brackets: BGK-007, BGK-009, and BGK-012, which have similar specifications with the predicate device Acclarix AX8 Diagnostic Ultrasound System (K192879).
8. Addition of features: Stress Echo, Respiratory Wave, eVocal, eWorks, eLive, and eHIP, which have similar specifications with reference device Resona I9 Diagnostic Ultrasound System (K210699); Auto LVOT-D and Live.VF, which have similar specifications with reference device Carnation series Diagnostic Ultrasound System (K230066).
9. Other changes: Update appearance structure, add battery capacity, add new trolley, etc.

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)

Acclarix AX8 Series & Acclarix AX9 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
- IEC 60601-2-18: 2009 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- FDA's Guidance "*Marketing Clearance of Diagnostic Ultrasound Systems and Transducers"*

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 Acclarix AX8 Series & Acclarix AX9 Series Diagnostic Ultrasound System are substantially equivalent to the predicate device.