November 27, 2019

Edan Instruments, Inc.
% Stella Guo
Regulatory Engineer
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
Shenzhen, Guangdong 518122
CHINA

Re: K192791
Trade/Device Name: Acclarix AX3 Series Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX, IYN
Dated: September 25, 2019
Received: September 30, 2019

Dear Stella Guo:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192791

Device Name

Acclarix AX3 Series Diagnostic Ultrasound System (including Acclarix AX3/Acclarix AX3 Exp/Acclarix AX3 Super/Acclarix AX25/Acclarix AX28/Acclarix AX2/Acclarix AX2 Exp/Acclarix AX2 Super/Acclarix AX15/Acclarix AX18)

Indications for Use *(Describe)*

The Acclarix AX3 series Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations in hospitals and clinics. General clinical applications include:

- Abdominal
- Gynecology
- Obstetric
- Cardiac
- Small parts
- Urology
- Musculoskeletal
- Peripheral vascular
- Adult Cephalic

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 K192791

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

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Tel: +86-755-2685 8736 Fax: +86-755-2689 8330

Contact person: Stella Guo

Preparing date: September 25, 2019

2. Device name and classification:

Device Name: Diagnostic Ultrasound System

Model: Acclarix AX3, Acclarix AX3 Exp, Acclarix AX3 Super, Acclarix AX25, Acclarix AX28, Acclarix AX2, Acclarix AX2 Exp, Acclarix AX2 Super, Acclarix AX15, Acclarix AX18

Classification Name/ Product code:

21 CFR 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic / IYN

21 CFR 892.1560, Ultrasonic, Pulsed echo, Imaging / IYO

21 CFR 892.1570, Transducer, Ultrasonic, Diagnostic / ITX

Regulatory Class: Class II

3.Premarket Notification Class III Certification and Summary

Not applicable, the subject device is Class II.

4. Predicate Device(s):

1) Edan Instruments, Acclarix AX4 Diagnostic Ultrasound System, cleared under K171900 (Primary)
2) Edan Instruments, Acclarix U50 Diagnostic Ultrasound System, cleared under K173003 (Reference)
3) Edan Instruments, Acclarix AX8 Diagnostic Ultrasound System, cleared under K180862 (Reference)

5. Reason for Submission

By submission of the Traditional 510(k), Edan Instruments is requesting clearance for new devices Acclarix AX3 Series Diagnostic Ultrasound System

6.Pre-Submission, IDE

Not applicable, there is no pre-submission.

7. Device Description: Acclarix AX3 Series 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. This system is a Track 3 device to acquire and display ultrasound data in various imaging modes.

8. Indication for Use The Acclarix AX3 series Diagnostic Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations in hospitals and clinics. General clinical applications include:

- Abdominal
- Gynecology
- Obstetric
- Cardiac
- Small Parts
- Urology
- Musculoskeletal
- Peripheral Vascular
- Adult Cephalic

9. Predicate Device Comparison

The subject device Acclarix AX3 Series is same as the primary predicated device Acclarix AX4 (K171900) in items such as:

1) Intended Use/ Indications for Use;
2) Mode of Operations;
3) Transducer Types
4) Acoustic Output, which are below the limits of FDA;

The differences of subject device Acclarix AX3 Series with the predicated devices are described as below:

1) The subject device Acclarix AX3 Series is not intended to do Intra-operative, Pediatric and Neonatal clinical ultrasound evaluation, which are already cleared in the primary predicated device Acclarix AX4 (K171900).

2) The subject device Acclarix AX3 Series does not support 3D/4D, which are already cleared in the primary predicated device Acclarix AX4 (K171900).

3) The subject device does not support four transducers that are already cleared in the primary predicated device Acclarix AX4 (K171900)

4) The subject device additionally support two new transducers L17-7HQ and L17-7Q. L17-7HQ is already cleared in the reference predicate device Acclarix AX8 (K180862). And L17-7Q is modified from the transducer L15-7b cleared by the reference predicate device U50 (K173003) by only changing the shape of the transducer connector.

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.

10. Performance Data:

Clinical test:

Clinical testing is not required.

Non-clinical test:

The Acclarix AX3 Series Diagnostic Ultrasound System comply with:

(1) ANSI/AAMI ES60601-1 Electrical Safety

(2) IEC 60601-1-2 Electromagnetic Compatibility

(3) IEC 60601-2-37 Requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

(4) Acoustic output testing as per the guideline "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated June 27, 2019.

The following biocompatibility standards are conducted on the subject device:

(5) ISO 10993-1, ISO 10993-5 and ISO 10993-10

The tests were selected to show substantial equivalence between the subject device and the predicate.

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

11. Conclusion

Verification and validation testing has been conducted on the Acclarix AX3 Series Diagnostic Ultrasound System. This premarket notification submission demonstrates that Acclarix AX3 Series Diagnostic Ultrasound System are substantially equivalent to the predicate devices.