Edan Instruments, Inc.
% Ying Dai
Regulatory Engineer
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District
Shenzhen, Guangdong 518122
P R CHINA

January 25, 2021

Re: K202856
Trade/Device Name: Diagnostic Ultrasound System, Models: Acclarix AX3, Acclarix AX3 Exp, Acclarix AX3 Super, Acclarix AX25, Acclarix AX28, Acclarix AX2, Acclarix AX2 Exp, Acclarix AX2 Super, Acclarix AX15, Acclarix AX18, Acclarix LX3, Acclarix LX3 Exp, Acclarix LX3 Super, Acclarix LX25 and Acclarix LX28
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 25, 2020
Received: December 28, 2020

Dear Ying Dai:

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 and Part 809); 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,

For

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202856

Device Name
Diagnostic Ultrasound System; Models: Acclarix AX3, Acclarix AX3 Exp, Acclarix AX3 Super, Acclarix AX25, Acclarix AX28, Acclarix AX2, Acclarix AX2 Exp, Acclarix AX2 Super, Acclarix AX15, Acclarix AX18; Acclarix LX3, Acclarix LX3 Exp, Acclarix LX3 Super, Acclarix LX25, Acclarix LX28

Indications for Use *(Describe)*

The Acclarix AX3 series/Acclarix LX3 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, Intra-operative, Pediatric, Neonatal , Adult Cephalic.

The modes of operation for Acclarix AX3 series/Acclarix LX3 series include B mode, M mode, Doppler mode, Harmonic 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.

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Diagnostic Ultrasound Indications for Use Form

Acclarix AX3 Series/Acclarix LX3 Series Diagnostic Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	Note[1]	Note[2] [3] [4]
	Abdominal****	P	P	P	P	P	Note[1]	Note[2] [3]
	Intra-operative (Specify)	N	N	N		N	Note[1]	Note[2] [3]
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N	N	N	Note[1]	Note[2] [3]
	Small Organ (Specify) **	P	P	P		P	Note[1]	Note[2] [3]
	Neonatal Cephalic	N	N	N	N	N	Note[1]	Note[2] [3]
	Adult Cephalic	P	P	P	P	P	Note[1]	Note[2] [3]
	Trans-rectal	P	P	P		P	Note[1]	Note[2] [3]
	Trans-vaginal	P	P	P		P	Note[1]	Note[2] [3]
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]]
	Intravascular							
	Other (Specify) ***	P	P	P		P	Note[1]	Note[2] [3]
Cardiac	Adult Cardiac	P	P	P	P	P	Note[1]	Note[2] [3] [5] [6]
	Pediatric Cardiac	N	N	N	N	N	Note[1]	Note[2] [3] [5] [6]
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	Note[1]	Note[2] [3]
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note: * Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

****Abdominal includes ABD and lung scanning.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

C5-2Q Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	Note[1]	Note[2] [3]
	Abdominal ****	P	P	P		P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***	P	P	P		P	Note[1]	Note[2] [3]
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note: * Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

****Abdominal includes ABD and lung scanning.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

C7-2XQ Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	Note[1]	Note[2] [3]
	Abdominal ****	P	P	P		P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***	P	P	P		P	Note[1]	Note[2] [3]
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note: * Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

****Abdominal includes ABD and lung scanning.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging.This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

C5-1Q Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	Note[1]	Note[2] [3]]
	Abdominal ****	P	P	P		P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***	P	P	P		P	Note[1]	Note[2] [3]
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note: * Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

****Abdominal includes ABD and lung scanning.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

C6-2MQ Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	Note[1]	Note[2] [3] [4]
	Abdominal	P	P	P		P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) ***	P	P	P		P	Note[1]	Note[2] [3]
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note:

* Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

L12-5Q Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal ****	P	P	P		P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **	P	P	P		P	Note[1]	Note[2] [3]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	Note[1]	Note[2] [3]
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note: * Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

****Abdominal includes lung scanning.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

L17-7HQ Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **	P	P	P		P	Note[1]	Note[2] [3]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	Note[1]	Note[2] [3]
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note: * Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging.This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

L17-7SQ Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)	P	P	P		P	Note[1]	Note[2] [3]
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	Note[1]	Note[2] [3]
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note:

* Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

E8-4Q Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	Note[1]	Note[2] [3]
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note[1]	Note[2] [3]
	Trans-vaginal	P	P	P		P	Note[1]	Note[2] [3]
	Trans-urethral							
	Musculo-skeletal(Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) ***	P	P	P		P	Note[1]	Note[2] [3]
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note:

* Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

E10-3BQ Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	Note[1]	Note[2] [3]]
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note[1]	Note[2] [3]
	Trans-vaginal	P	P	P		P	Note[1]	Note[2] [3]
	Trans-urethral							
	Musculo-skeletal(Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) ***	P	P	P		P	Note[1]	Note[2] [3]
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note:

* Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

E10-3HQ Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	Note[1]	Note[2] [3]
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note[1]	Note[2] [3]
	Trans-vaginal	P	P	P		P	Note[1]	Note[2] [3]
	Trans-urethral							
	Musculo-skeletal(Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) ***	P	P	P		P	Note[1]	Note[2] [3]
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note: * Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

MC8-4Q Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal	P	P	P		P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note[1]	Note[2] [3]
	Small Organ (Specify) **							
	Neonatal Cephalic	N	N	N		N	Note[1]	Note[2] [3]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N		N	Note[1]	Note[2] [3]
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note:

* Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

MC9-3TQ Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal	P	P	P		P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note[1]	Note[2] [3]
	Small Organ (Specify) **							
	Neonatal Cephalic	P	P	P		P	Note[1]	Note[2] [3]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	Note[1]	Note[2] [3]
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note:

* Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

P5-1Q Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal	P	P	P	P	P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	Note[1]	Note[2] [3]
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) ***							
Cardiac	Adult Cardiac	P	P	P	P	P	Note[1]	Note[2] [3] [5][6]
	Pediatric Cardiac	P	P	P	P	P	Note[1]	Note[2] [3] [5][6}
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note:

* Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

P7-3Q Transducer on Acclarix AX3 Series/Acclarix LX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal	P	P	P	P	P	Note[1]	Note[2] [3]
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	P	P	P	P	P	Note[1]	Note[2] [3]
	Small Organ (Specify) **							
	Neonatal Cephalic	P	P	P	P	P	Note[1]	Note[2] [3]
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Specify) ***							
Cardiac	Adult Cardiac	P	P	P	P	P	Note[1]	Note[2] [3][5][6]
	Pediatric Cardiac	P	P	P	P	P	Note[1]	Note[2] [3] [5][6]
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note:

* Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

L17-7Q Transducer on Acclarix AX3 Series

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Clinical Application	Mode of Operation						
General	Specific	B	M	PW	CW	Color*	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) **	P	P	P		P	Note[1]	Note[2] [3]
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(Conventional)	P	P	P		P	Note[1]	Note[2] [3]
	Musculo-skeletal (Superficial)	P	P	P		P	Note[1]	Note[2] [3]
	Intravascular							
	Other (Specify) ***							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	Note[1]	Note[2] [3]
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note: * Color Doppler includes Color imaging, PDI(Power Doppler Imaging) and DPDI(Directional Power Doppler Imaging)

** Small Organ includes Thyroid, Testes, Breast. ***Other use includes Urology and Gynecology.

[1]: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW	[2]: Biopsy Guidance	[3]: Harmonic Imaging. This feature does not use contrast agent.	[4]: 3D/4D
[5]: TDI.	[6]: Anatomic M		

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Concurrence of Center for Devices and Radiological Health (CDRH), Prescription Use (Per 21 CFR 801.109)

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Edan Instruments, Inc.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, Shenzhen, Guangdong, 518122 P.R.China.
Tel: +86-755-2685 6469 Fax: +86-755-2689 8330

Contact person: Ying DAI

Preparing date: Sep 25th, 2020

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; Acclarix LX3, Acclarix LX3 Exp, Acclarix LX3 Super, Acclarix LX25 and Acclarix LX28

Classification Name/ Product code:

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

21 CFR 892.1560, System, Imaging, Pulsed Echo, Ultrasonic/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 AX3 series Diagnostic Ultrasound System, cleared under K192791 (Primary)
2) Edan Instruments, Acclarix LX9 series Diagnostic Ultrasound System, cleared under K192879 (reference)
3) George J. Hattub, LVivo Software Application, cleared under K200232 (reference)
4) Shenzhen Mindray Bio-Medical Electronics Co., Ltd, DC-90 Diagnostic Ultrasound System cleared under K201693 (reference)

5. Reason for Submission

By submission of the Traditional 510(k), Edan Instruments is requesting clearance for an updated version of Acclarix AX3 series Diagnostic Ultrasound System and new models of Acclarix LX3 series Diagnostic

Ultrasound System.

6.Pre-Submission, IDE Not applicable, there is no pre-submission.

7. Device Description: Acclarix AX3 Series/ Acclarix LX3 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/Acclarix LX3 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, Intra-operative, Pediatric, Neonatal , Adult Cephalic.

The modes of operation for Acclarix AX3 series/Acclarix LX3 series include B mode, M mode, Doppler mode, Harmonic Imaging, and their combination modes.

9. Predicate Device Comparison

The subject devices Acclarix AX3 series/ Acclarix LX3 series are the same as the primary predicated devices Acclarix AX3 series (K192791) in items such as:

1) Intended Use/ Indications for Use;
2) Mode of Operations;
3) Design principles;
4) Hardware and software platforms;
5) Transducer types;
6) Acoustic Output, which are below the limits of FDA;
7) The materials of transducers and needle guide brackets.

The differences of subject devices Acclarix AX3 series/ Acclarix LX3 series with the primary predicated device Acclarix AX3 series (K192791) are described as below:

1) Addition of clinical applications: Pediatrics, Neonatal and Intra-operative, which are cleared by Acclarix LX9 series via K192879.

2) Addition of new transducers: MC8-4Q, MC9-3TQ, L17-7SQ, P7-3Q, C7-2XQ, C5-1Q, E10-3BQ, E10-3HQ, C6-2MQ, which are cleared by Acclarix LX9 series via K192879.

3) Addition of imaging modes: Anatomic M mode, TDI mode, 3D/4D mode, which are cleared by Acclarix LX9 series via K192879.

4) Addition of measurement function: Auto IMT, which is cleared by Acclarix LX9 series via K192879.

5) Addition of new needle guide brackets: BGK-004, BGK-005, BGK-006, BGK-007 and BGK-009, which are cleared by Acclarix LX9 series via K192879 except for the BGK-009 bracket. BGK-009 bracket uses the same material as the BGK-005 bracket previously cleared under LX9 series (K192879).

6) Addition of measurement function: Auto EF measurement, which is cleared by K200232.

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 and Acclarix LX3 Series Diagnostic Ultrasound Systems comply with:

(1) ANSI/AAMI ES 60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

(2) IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

(3) IEC 60601-2-37 Edition 2.1 2015, Medical electrical equipment - Part 2-37: Particular 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: 2018, ISO 10993-5:2009 and ISO 10993-10:2010

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 and Acclarix LX3 Series Diagnostic

Ultrasound Systems. This premarket notification submission demonstrates that Acclarix AX3 Series and Acclarix LX3 Series Diagnostic Ultrasound Systems are substantially equivalent to the predicate devices.