DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Edan Instruments, Inc.
% Mr. Doug Worth
Sr. Dir. US RA/QA
Edan Medical
1200 Crossman Avenue, Suite 200
SUNNYVALE CA 94089

August 18, 2017

Re: K171900
Trade/Device Name: Acclarix AX4 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 22, 2017
Received: June 26, 2017

Dear Mr. Worth:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171900

Device Name
Acclarix AX4 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Edan AX4 Ultrasound system is intended for use by a qualified physician or allied health professional for ultrasound evaluations. Specific clinical applications include:

- Abdominal
- Gynecology (including endovaginal)
- Obstetric
- Cardiac
- Small parts (Breast, Testes, Thyroid, etc.)
- Urology
- Musculoskeletal
- Peripheral vascular
- Intra-operative
- Pediatric
- Neonatal (including abdominal and cephalic)
- 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.

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Diagnostic Ultrasound Indications for Use Form

Acclarix AX4 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) [1]	Other (Specify) [2][3][4]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	P	P
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Specify)	P	P	P		P	P	P
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Specify) *	P	P	P		P	P	P
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	P	P	P		P	P	P
	Musculo-skeletal (**Superficial**)	P	P	P		P	P	P
	Intravascular							
	Other (Specify) **	P	P	P		P	P	P
Cardiac	Adult Cardiac	P	P	P	P	P	P	P
	Pediatric Cardiac	P	P	P	P	P	P	P
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	P	P
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

[1]: PDI: Power Doppler Imaging, DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

[4]: 3D/4D

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Acclarix AX4 with C5-2Q Transducer

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) [1]	Other (Specify) [2][3]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	P	P
	Abdominal	P	P	P		P	P	P
	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	P	P
	Musculo-skeletal (**Superficial**)	P	P	P		P	P	P
	Intravascular							
	Other (Specify) **	P	P	P		P	P	P
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 PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

[1]: PDI: Power Doppler Imaging, DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Acclarix AX4 with L12-5Q Transducer

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) [1]	Other (Specify) [2][3]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	P	P	P		P	P	P
	Musculo-skeletal (**Superficial**)	P	P	P		P	P	P
	Intravascular							
	Other (Specify) **	P	P	P		P	P	P
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	P	P
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast.

** Other use includes Urology.

[1]: PDI: Power Doppler Imaging, DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

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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

Acclarix AX4 with MC8-4Q Transducer

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) [1]	Other (Specify) [2][3]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	P	P	P		P	P	P
	Small Organ (Specify) *							
	Neonatal Cephalic	P	P	P		P	P	P
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	P	P	P		P	P	P
	Musculo-skeletal (**Superficial**)	P	P	P		P	P	P
	Intravascular							
	Other (Specify) **	P	P	P		P	P	P
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	P	P
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast.

** Other use includes Neonatal abdominal.

[1]: PDI: Power Doppler Imaging, DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

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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

Acclarix AX4 with E8-4Q Transducer

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) [1]	Other (Specify) [2][3]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	P	P
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **	P	P	P		P	P	P
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 PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

[1]: PDI: Power Doppler Imaging ,DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

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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

Acclarix AX4 with P5-1XQ Transducer

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) [1]	Other (Specify) [2][3]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal	P	P	P	P	P	P	P
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P	P	P	P	P
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac	P	P	P	P	P	P	P
	Pediatric Cardiac	P	P	P	P	P	P	P
	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 PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M,B+PW,B+CW,B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

[1]: PDI: Power Doppler Imaging, DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

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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

Acclarix AX4 with P5-1Q Transducer

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) [1]	Other (Specify) [2][3]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N	N	N	N	N
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac	N	N	N	N	N	N	N
	Pediatric Cardiac	N	N	N	N	N	N	N
	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 PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M,B+PW,B+CW,B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

[1]: PDI: Power Doppler Imaging, DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

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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

Acclarix AX4 with L17-7SQ Transducer

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) [1]	Other (Specify) [2][3]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)	P	P	P		P	P	P
	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	P	P
	Musculo-skeletal (**Superficial**)	P	P	P		P	P	P
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	P	P
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

[1]: PDI: Power Doppler Imaging, DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

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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

Acclarix AX4 with C5-2MQ Transducer

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) [1]	Other (Specify) [2][3][4]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	P	P	P		P	P	P
	Abdominal							
	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) **							
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 PDI= Power Doppler Imaging

Additional comments: Combined mode: B+M, B+PW, B+Color, B+PDI/DPDI, B+Color+PW, B+PDI/DPDI +PW

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

[1]: PDI: Power Doppler Imaging, DPDI: Directional Power Doppler Imaging

[2]: Biopsy Guidance

[3]: Harmonic Imaging, This feature does not use contrast agent.

[4]: 3D/4D

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

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, 518122 P.R.China. Tel.: (0755) 26858736 Fax: +1 (408) 418-4059
Contact Person:	Crystal Cai
Date prepared:	June 22, 2017
2. Device name and classification:	**Device Name:** Diagnostic Ultrasound System **Model:** Acclarix AX4 **Classification Name:** 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic Product code: IYN 892.1560 Ultrasonic, Pulsed echo, Imaging Product code: IYO 892.1570 Transducer, Ultrasonic, Diagnostic Product code: 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):	Edan Instruments, Inc., Acclarix AX8 Diagnostic Ultrasound System cleared under K171824 (Predicate)
5. Reason for Submission	By submission of the Traditional 510(k), Edan Instruments is requesting for Diagnostic Ultrasound System, model Acclarix AX4 after the change on the previous cleared version.
6. Pre-Submission, IDE	Not applicable, there is no prior submission.

7. Device Description:

The Acclarix AX4 is a portable laptop diagnostic ultrasound system, intended for use by a qualified physician or sonographer for ultrasound evaluation in Point of Care environments such as Emergency Departments, Interventional procedures and mobile imaging centers.

8. Intended Use:

The Edan Acclarix AX4 Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations. Specific clinical applications include:

- Abdominal
- Gynecology (including endovaginal)
- Obstetric
- Cardiac
- Small parts (Breast, Testes, Thyroid, etc.)
- Urology
- Musculoskeletal
- Peripheral vascular
- Intra-operative
- Pediatric
- Neonatal (including abdominal and cephalic)
- Adult Cephalic

9. Predicate Device Comparison

Comparison to the predicate devices, the subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device as summarized in the following table:

Table 9-1 Comparison between the subject Acclarix AX4 and the previous cleared Acclarix AX8 R1.3

Item	Acclarix AX4	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Comparison Result
510(k) Number	Current Submission	K171824	-
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Same
Indications for Use	The Edan Acclarix AX4 Ultrasound System is intended for use by a qualified physician or allied health professional for ultrasound evaluations. Specific clinical applications include: Abdominal, Gynecology (including endovaginal), Obstetric, Cardiac, Small parts (Breast, Testes, Thyroid, etc.), Urology, Musculoskeletal, Peripheral vascular, and	The Acclarix AX8 Diagnostic Ultrasound System is intended for use by a qualified physician or sonographer for ultrasound evaluation. Clinical applications include: Abdominal, Gynecology (including endovaginal), Obstetric, Cardiac, Small parts (Breast, Testes, Thyroid, etc.), Urology, Musculoskeletal, Peripheral vascular, Intra-operative, Pediatric and Neonatal	Difference

Item	Acclarix AX4	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Comparison Result
	Intra-operative, Pediatric and Neonatal (including abdominal and cephalic), Adult Cephalic	(including abdominal and cephalic), and Adult cephalic.	
Installation and Use	Portable (laptop) Mobile Equipment	Portable (laptop) Mobile Equipment	Same
Design	64 channel	128 channel	Difference
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD 3	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD 3	Same
Patient Contact Materials	Complies with ISO 10993	Complies with ISO 10993	Same
Mode of Operations	B-Mode, M-Mode, Color, PDI/DPDI, PW, CW, 3D/4D	B-Mode, M-Mode, Color, PDI/DPDI, PW, CW, 3D/4D	same
Measurements	B-Mode: Distance, Circ/Area, Angle, Volume, Stenosis ratio M-Mode: Distance, Time, Slope and Heart Rate D-Mode: Velocity, RI, Time, PI, Heart Rate, Auto Trace PG, S/D, ΔV, Acceleration, PHT, VTI	B-Mode: Distance, Circ/Area, Angle, Volume, Stenosis ratio M-Mode: Distance, Time, Slope and Heart Rate D-Mode: Velocity, RI, Time, PI, Heart Rate, Auto Trace PG, S/D, ΔV, Acceleration, PHT, VTI	Same
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect reflected echo to construct diagnostic image	Applying high voltage burst to the Piezoelectric material in the transducer and detect reflected echo to construct diagnostic image	Same
Acoustic Output	Track 3: MI, TIS, TIC, TIB (TI Range 0-6.0) Derated I_{SPTA}: 720 mW/cm^2 maximum, Mechanic Index ≤ 1.9 maximum or Derated I_{SPPA} 190 W/cm2 max Ophthalmic use: TI = Max (TIS_as, TIC) ≤1; ISPTA.3 ≤ 50 m/W/cm2; and MI ≤ 0.23	Track 3: MI, TIS, TIC, TIB (TI Range 0-6.0) Derated I_{SPTA}: 720 mW/cm^2 maximum, Mechanic Index ≤ 1.9 maximum or Derated I_{SPPA} 190 W/cm2 max Ophthalmic use: TI = Max (TIS_as, TIC) ≤1; ISPTA.3 ≤ 50 m/W/cm2; and MI ≤ 0.23	Same
Transducer Types	Convex Array Linear Array Endocavity-Micro Convex Array Phased Array Micro Convex Array	Convex Array Linear Array Endocavity-Micro Convex Array Phased Array Micro Convex Array	Same
Transducer Frequency	1-17 MHz	1-17 MHz	Same

Item	Acclarix AX4	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Comparison Result
Dimensions/ Weight	407mm (W) x 388mm (L) x77mm (H) Weight: 9.1Kg (with rechargeable battery, without power adaptor or transducers.)	407mm (W) x 388mm (L) x77mm (H) Weight: 9.1Kg (with rechargeable battery, without power adaptor or transducers.)	Same
Power Requirements	100-240V, 50/60Hz	100-240V, 50/60Hz	Same
Rechargeable Battery	Yes	Yes	Same
Features	3D/4D, CW, HPRF, Dual screen display, Panorama, Spatial Compounding Imaging, Frequency Compounding Imaging, Multi-Beam-Forming, Speckle Resistance Imaging(eSRI), One-Key-Optimization, B-Steer, Digital Zoom, Needle Visualization, Auto IMT	3D/4D, CW, HPRF, Dual screen display, Panorama, Spatial Compounding Imaging, Frequency Compounding Imaging, Multi-Beam-Forming, Speckle Resistance Imaging(eSRI), One-Key-Optimization, B-Steer, Digital Zoom, Needle Visualization, Auto IMT	Same

The subject device has same intended use, similar product design, same performance effectiveness, and performance safety as the predicate device.

The differences between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

10. Effectiveness and Safety Considerations:

Clinical test:
Clinical testing is not required.

Non-clinical test:
The Acclarix AX4 Ultrasound Imaging System complies with:

(1) IEC 60601-1 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) NEMA UD 3 Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment.
(5) Acoustic output testing as per the guideline “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” dated September 9, 2008.

The following biocompatibility standards are conducted on the subject device:

(1) 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.

11. Substantially Equivalent Determination

Verification and validation testing has been conducted on the Acclarix AX4 Ultrasound Imaging System. This premarket notification submission demonstrates that Acclarix AX4 Ultrasound Imaging System is substantially equivalent to the predicate devices.