



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

May 31, 2016

Re: K161300  
Trade/Device Name: Acclarix AX8 Diagnostic Ultrasound System  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulatory Class: II  
Product Code: IYO, ITX, IYN  
Dated: May 5, 2016  
Received: May 9, 2016

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 yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a large, stylized "R" and "O".

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

Form Approved: OMB No. 0910-0120  
Expiration Date: December 31, 2013  
See PRA Statement on last page.

**Indications for Use**

510(k) Number (if known)

K161300

Device Name

Acclarix AX8 Diagnostic Ultrasound System

Indications for Use (Describe)

The Edan Acclarix AX8 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

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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Paperwork Reduction Act (PRA) Staff  
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## Diagnostic Ultrasound Indications for Use Form

### Acclarix AX8 Diagnostic Ultrasound System

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

	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
General	Specific							
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							
	Small Organ (Specify) *	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	P	P
	Trans-vaginal	P	P	P		P	P	P
	Trans-urethral							
	Musculo-skeletal( <b>Conventional</b> )	P	P	P		P	P	P
	Musculo-skeletal ( <b>Superficial</b> )	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.

(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 AX8 with C5-2Q Transducer

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

	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
General	Specific							
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal( <b>Conventional</b> )							
	Musculo-skeletal ( <b>Superficial</b> )							
	Intravascular							
Other (Specify) **	N	N	N		N	N	N	
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 AX8 with L12-5Q Transducer

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

	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
General	Specific							
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal( <b>Conventional</b> )	N	N	N		N	N	N
	Musculo-skeletal ( <b>Superficial</b> )	N	N	N		N	N	N
Intravascular								
Other (Specify) **	N	N	N		N	N	N	
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N		N	N	N
	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 AX8 with MC8-4Q Transducer

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

General	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	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( <b>Conventional</b> )	N	N	N		N	N	N
	Musculo-skeletal ( <b>Superficial</b> )	N	N	N		N	N	N
	Intravascular							
Other (Specify) **								
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	N	N	N		N	N	N
	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 AX8 with L10-4Q Transducer

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

General	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
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( <b>Conventional</b> )	P	P	P		P	P	P
	Musculo-skeletal ( <b>Superficial</b> )	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 AX8 with E8-4Q Transducer

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

	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
General	Specific							
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( <b>Conventional</b> )							
	Musculo-skeletal ( <b>Superficial</b> )							
	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.

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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 AX8 with L17-7HQ Transducer

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

	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
General	Specific							
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( <b>Conventional</b> )	P	P	P		P	P	P
	Musculo-skeletal ( <b>Superficial</b> )	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 AX8 with C5-2XQ Transducer

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

	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
General	Specific							
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( <b>Conventional</b> )							
	Musculo-skeletal ( <b>Superficial</b> )							
	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 AX8 with P5-1XQ Transducer

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

General	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
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							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal( <b>Conventional</b> )							
	Musculo-skeletal ( <b>Superficial</b> )							
	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 AX8 with L17-7SQ Transducer

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

	Clinical Application	Mode of Operation						
		B	M	PW	CW	Color	Combined (Specify) <sup>[1]</sup>	Other (Specify) <sup>[2][3]</sup>
General	Specific							
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( <b>Conventional</b> )	P	P	P		P	P	P
	Musculo-skeletal ( <b>Superficial</b> )	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							
	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)

## 510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

- 1. Submitter:** Edan Instruments, Inc.  
3/F-B, Nanshan Medical Equipments Park, Nanhai Rd 1019#, Shekou,  
Nanshan Shenzhen, 518067 P.R. China  
Tel.: (0755) 26858739  
Fax: +1 (408) 418-4059
- Contact Person:** Erico Li
- Date prepared:** April 28, 2016
- 2. Device name and classification:** **Device Name:** Diagnostic Ultrasound System  
**Model:** Acclarix AX8  
**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):** Acclarix AX8 Diagnostic ultrasound system/ K150999/ Shenzhen Edan Instruments, Inc.  
U50 Diagnostic ultrasound system/ K142511/ Shenzhen Edan Instruments, Inc.
- 5. Reason for Submission** Modification for previous cleared product Diagnostic ultrasound system, model Acclarix AX8.
- 6. Pre-Submission, IDE** Not applicable, there is no prior submission.

**7. Device Description:**

The Acclarix AX8 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, which applies advanced technologies such as 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, etc. Various image parameter adjustments, 15 inch LCD display with 10 inch touch screen and 5 inch track pad and diverse probes are configured to acquire and display clear and stable ultrasound images.

**8. Intended Use:**

The Edan Acclarix AX8 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 Intra-operative.

**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 tables:

**Table 9-1: Comparison between the subject Acclarix AX8 and the previous cleared Acclarix AX8**

<b>Item</b>	<b>Acclarix AX8 r1.2 Diagnostic Ultrasound System (Edan Instruments)</b>	<b>Acclarix AX8 r.10 Diagnostic Ultrasound System (Edan Instruments)</b>	<b>Comparison Result</b>
510(k) Number	Current Submission	K150999	-
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 AX8 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 Intra-operative.	The Edan Acclarix AX8 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 Intra-operative.	Same
Installation and Use	Portable (laptop) Mobile Equipment	Portable (laptop) Mobile Equipment	Same
Design	128 channel	128 channel	Same

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	B-Mode, M-Mode, Color, PDI/DPDI, PW, CW	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, $\Delta V$ , 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, $\Delta V$ , 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 ISPTA: 720W/cm <sup>2</sup> maximum, Mechanic Index $\leq 1.9$ maximum or Derated ISPPA 190 W/cm <sup>2</sup> max Ophthalmic use: TI = Max (TIS <sub>as</sub> , TIC) $\leq 1$ ; ISPTA.3 $\leq 50$ m/W/cm <sup>2</sup> ; and MI $\leq 0.23$	Track 3: MI, TIS, TIC, TIB (TI Range 0-6.0) Derated ISPTA: 720W/cm <sup>2</sup> maximum, Mechanic Index $\leq 1.9$ maximum or Derated ISPPA 190 W/cm <sup>2</sup> max Ophthalmic use: TI = Max (TIS <sub>as</sub> , TIC) $\leq 1$ ; ISPTA.3 $\leq 50$ m/W/cm <sup>2</sup> ; and MI $\leq 0.23$	Same
Transducer Types	Convex Array Linear Array Endocavity-Micro Convex Array Phased Array	Convex Array Linear Array Endocavity-Micro Convex Array Phased Array	Same
Transducer Frequency	2.5-15.0 MHz	2.5-15.0 MHz	Same
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

**Table 9-2: Comparison between the subject Acclarix AX8 and U50**

<b>Item</b>	<b>Acclarix AX8 r1.2 Diagnostic Ultrasound System (Edan Instruments)</b>	<b>U50 Diagnostic Ultrasound System (Edan Instruments)</b>	<b>Comparison Result</b>
510(k) Number	Current Submission	K142511	-
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 AX8 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 Intra-operative.	The diagnostic ultrasound system (U50) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), endovaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.	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
Transducer Needle Guide adaptors	Mechanical Needle guide adaptors which clip on transducer to provide a fixed angle of insertion for needle.	Mechanical Needle guide adaptors which clip on transducer to provide a fixed angle of insertion for needle.	Same

The subject device has similar intended use, similar product design, and same performance effectiveness, as the predicate device. There are no significant differences between the primary predicate, nor the reference device. There are no new questions of safety and/or effectiveness. There are no changes to the intended use, indications for use, nor fundamental scientific technology.

### **10. Effectiveness and Safety Considerations:**

#### **Clinical test:**

Clinical testing is not required.

#### **Non-clinical test:**

The Acclarix AX8 Ultrasound Imaging System complies with:

- (1) IEC 60601-1 Electrical Safety
- (2) IEC 60601-1-2 Electromagnetic Compatibility
- (3) 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, ISO 10993-12

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 AX8 Ultrasound Imaging System. This premarket notification submission demonstrates that Acclarix AX8 Ultrasound Imaging System is substantially equivalent to the predicate devices.