



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

EDAN INSTRUMENTS, INC.  
% Mr. Mark Job  
Responsible Third Party Official  
Regulatory Technology Services LLC  
1394 25<sup>th</sup> Street NW  
BUFFALO MN 55313

April 4, 2016

Re: K160790  
Trade/Device Name: Acclarix LX8 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: March 21, 2016  
Received: March 22, 2016

Dear Mr. Job:

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 blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

For

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

**K160790**

Device Name

Acclarix LX8 Diagnostic Ultrasound System

Indications for Use (Describe)

The Acclarix LX8 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, and Peripheral vascular, and 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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## Diagnostic Ultrasound Indications for Use Form

### Acclarix LX8 Diagnostic Ultrasound System

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][4]</sup>
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N		N	N	N
	Abdominal	N	N	N	N	N	N	N
	Intra-operative (Specify)	N	N	N		N	N	N
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N
	Trans-vaginal	N	N	N		N	N	N
	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	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	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, B+CW, B+Color+CW, B+PDI/DPDI +CW,

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

(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)

## Diagnostic Ultrasound Indications for Use Form

### ACCLARIX LX8 with L10-4D 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) *	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) **								
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 CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### ACCLARIX LX8 with E8-4D 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	N	N	N		N	N	N
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	N	N	N		N	N	N
	Trans-vaginal	N	N	N		N	N	N
	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 CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### ACCLARIX LX8 with L17-7HD 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) *	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) **								
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 CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### ACCLARIX LX8 with C5-2XD 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	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> )	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							
	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 CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### ACCLARIX LX8 with P5-1XD 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	N	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) **								
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, B+Color+CW, B+PDI/DPDI+CW

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

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### ACCLARIX LX8 with L17-7SD 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)	N	N	N		N	N	N
	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							
	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 CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Prescription Use (Per 21 CFR 801.109)

## Diagnostic Ultrasound Indications for Use Form

### ACCLARIX LX8 with C5-2MD 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) <sub>[2][3][4]</sub>
General	Specific							
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N		N	N	N
	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> )							
	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.

[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.  
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:** Queena Chen
- Date prepared:** March 28, 2016
- 2. Device name and classification:** **Device Name:** Diagnostic Ultrasound System  
**Model:** Acclarix LX8  
**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.  
ZS3 Ultrasound System / K141641 (Reference) / ZONARE  
Medical Systems, Inc
- 5. Reason for Submission** Acclarix LX8 is a new device.
- 6. Pre-Submission, IDE** Not applicable, there is no prior submission.

**7. Device Description:**

The Edan Acclarix LX8 Ultrasound system consists of a main system along with associated transducers.

The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into an ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The waves are then reflected within the body and detected by the transducer, which then converts back to an electrical signal. The Acclarix LX8 system then analyzes the returned signal to generate an image or conduct Doppler processing.

The Acclarix LX8 system gives the operator the ability to measure anatomical structures, and offers analysis packages that provide information used by competent health care professionals to make a diagnosis.

The system provides both touch screen and hard buttons for the User Interface.

**8. Intended Use:**

The ACCLARIX LX8 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, and 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 table:

<b>Item</b>	<b>Acclarix LX8 Diagnostic Ultrasound System (Edan Instruments)</b>	<b>Acclarix AX8 Diagnostic Ultrasound System (Edan Instruments)</b>	<b>ZS3 Ultrasound Systems (ZONARE Medical Systems)</b>
510(k) Number	Current Submission	K150999	K141641
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Same	Same
Indications for Use	The Acclarix LX8 Diagnostic Ultrasound System is intended for use by a qualified physician or sonographer for ultrasound evaluation. Clinical applications include:	Same	The ZS3 Ultrasound System is intended for use by a qualified physician for ultrasound evaluation of Ophthalmic; Fetal/obstetric, gynecological; Abdominal (renal, GYN/Pelvic);

	Abdominal, Gynecology (including endovaginal), Obstetric, Cardiac, Small parts (Breast, Testes, Thyroid, etc.), Urology, Musculoskeletal, and Peripheral vascular, and Intra-operative.		Intra-operative (abdominal, thoracic, and vascular), Intra-operative neurological; Pediatric: small organ (thyroid, breast, testes, etc.), Adult & Neonatal Cephalic; Trans-rectal, Trans-vaginal, Trans-cranial, Trans-esophageal (non-cardiac and cardiac); Musculoskeletal (conventional & superficial); 3D/4D; Cardiac – Adult/ Pediatric/ Fetal; Echo, Intra-Cardiac; Pelvic; Peripheral vascular; harmonic tissue and contrast imaging and Tissue elasticity.
Installation and Use	Trolley Mobile Equipment	Portable (laptop) Mobile Equipment	Same
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	Same	Same
Patient Contact Materials	Complies with ISO 10993	Same	Same
Mode of Operations	B-Mode, M-Mode, Color, PDI/DPDI, PW, CW, 3D (Note 1)	Same except 3D	B-Mode, M-Mode, PWD Mode, CWD, CD Mode, Elastography, Contrast Enhanced, 3D/4D, ECG(for cardiac cycle referenced timing only) Combined Modes include B+CD, B+PW, B+CD+PW, B+M, M+CM, B+CD+M+CM, B+Elastography, B+CEUS, and + ECG Trace
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	Same	B-mode (2D): Depth, Distance, Circ/Area/Volume  M-Mode: Depth, Distance, HR  PWD(Manual): Velocity, Velocity Pairs, RI, Accl, S/D, A/B, PI, HR/ PWD(AutoTrace: RI, PI, Accl, S/D, HR, AT, TAMX

			and TAMN)
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect reflected echo to construct diagnostic image	Same	Same
Acoustic Output	Track 3: MI, TIS, TIC, TIB(TI Range 0-6.0) Derated $I_{SPTA}$ : 720 W/cm <sup>2</sup> maximum, Mechanic Index $\leq 1.9$ maximum or Derated $I_{SPPA}$ 190 W/cm <sup>2</sup> max	Same	Same
Transducer Types	Convex Array Linear Array Endocavity-Micro Convex Array Phased Array	Same	Linear Array Curved Linear Array Phased Array Trans-esophageal Pencil Probe Intracavitary
Transducer Frequency	2.5-15.0 MHz	Same	1.0 – 20.0 MHz
Primary Display	Primary Screen: 21.5 inch (1920 x 1080) (Note 2)	Primary Screen: 15 inch (1920x1080)	Color 19” Liquid Crystal Display (LCD)
Transducer Ports	Multi-Transducer Port (Four) (Note 3)	One	Multi-Transducer Port (Three)
Dimensions/Weight	Height: 53 – 70 in (1355-1780mm) Width: 23 in (585mm) Depth: 36.6 in (930mm) Weight: 111 Kg(no peripherals) (Note 4)	Height: 3 in (77mm) Width: 16 in (407mm) Depth: 15.3 in (388mm) Weight: 9.1Kg(with rechargeable battery, without power adaptor or transducers.)	Height. max (in operational use) 157.5cm (62in) Height. min (in operational use) 128cm (50.5in) Height min (displayed lower for transport) 104cm (41in) Width: 51cm (21.1in) Depth: 72cm(28.2) Weight: 65.3kg (144lb)
Power Requirements	100-240V, 50/60Hz, 2.5A max	Same	100-240V options, ~50-60Hz, 6A max

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 LX8 Ultrasound Imaging System complies with:

- (1) IEC 60601-1 Electrical Safety
- (2) IEC 60601-1-2 Electromagnetic Compatibility
- (3) IEC 60601-2-37 Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- (4) NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- (5) NEMA UD 3 Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment.
- (6) 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, ISO 10993-10 and 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 LX8 Ultrasound Imaging System. This premarket notification submission demonstrates that Acclarix LX8 Ultrasound Imaging System is substantially equivalent to the predicate devices.