



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

July 18, 2017

Re: K171824

Trade/Device Name: Acclarix AX8 Diagnostic Ultrasound System, Acclarix LX8
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: June 12, 2017

Received: June 19, 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,

 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

Indications for Use

510(k) Number (if known)

K171824

Device Name

Acclarix AX8 Diagnostic Ultrasound System/Acclarix LX8 Diagnostic Ultrasound System

Indications for Use (Describe)

The Acclarix AX8 Diagnostic Ultrasound system/Acclarix LX8 Diagnostic 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.

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

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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:

General	Clinical Application	Mode of Operation						
		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	N	N	N		N	N	N
	Small Organ (Specify) *	P	P	P		P	P	P
	Neonatal Cephalic	N	N	N		N	N	N
	Adult Cephalic	N	N	N	N	N	N	N
	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 AX8 with C5-2Q 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) ^[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)	N	N	N		N	N	N
	Musculo-skeletal (Superficial)	N	N	N		N	N	N
	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 L12-5Q 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) ^[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 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) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Specify) *							
	Neonatal Cephalic	N	N	N		N	N	N
	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) **	N	N	N		N	N	N	
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 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) ^[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) **								
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:

General	Clinical Application	Mode of Operation						
		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) **								
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:

General	Clinical Application	Mode of Operation						
		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) **								
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:

General	Clinical Application	Mode of Operation						
		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)	N	N	N		N	N	N
	Musculo-skeletal (Superficial)	N	N	N		N	N	N
	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) ^[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	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	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:

General	Clinical Application	Mode of Operation						
		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	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 C5-2MQ 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) ^[1]	Other (Specify) ^{[2][3][4]}
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(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)

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) ^[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	N	N	N	N	N	N	N
	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, B+CW, B+Color+CW, B+PDI/DPDI +CW,

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology and 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.

[4]: 3D/4D

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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 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) ^[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) **								
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 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) ^[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) **								
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) ^[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) **								
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 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) ^[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.

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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 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) ^[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	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	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, 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.

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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 L17-7SD 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) ^[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	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 C5-2MD 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) ^[1]	Other (Specify) _{[2][3][4]}
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							
	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)

Diagnostic Ultrasound Indications for Use Form

Acclarix LX8 with C5-2D 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) ^[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 LX8 with L12-5D 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) ^[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 LX8 with MC8-4D 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) ^[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)

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) 26859216 Fax: +1 (408) 418-4059

Contact Person: Alice Yang

Date prepared: June 12, 2017

2. Device name **Device Name:** Diagnostic Ultrasound System

and **Model:** Acclarix AX8, Acclarix LX8

classification:

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):

1. Edan Instruments, Inc., Acclarix LX8 Diagnostic Ultrasound System cleared under K162055 (Primary)

2. Edan Instruments, Inc., Acclarix AX8 Diagnostic Ultrasound System cleared under K161300 (Reference)

3. Shenzhen Mindray Bio-Medical Electronics Co., Ltd. DC60 Diagnostic Ultrasound System cleared under K152545 (Reference)

4. Shenzhen Mindray Bio-Medical Electronics Co., Ltd., M9 Diagnostic Ultrasound System cleared under K152543 (Reference)

5. Reason for
Submission

By submission of the Traditional 510(k), Edan Instruments is requesting clearance for an updated version of both the Acclarix AX8 and the Acclarix LX8 Diagnostic Ultrasound Systems, known as the 1.3 release.

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

7. Device Description: The Acclarix series contains the Acclarix AX8 and Acclarix LX8 Diagnostic Ultrasound Systems sharing a software platform (Edan Ultrasound Software Platform, also abbreviated as EUP) and the most parts of hardware platform from Edan Instruments. The Acclarix AX8 is a portable laptop diagnostic ultrasound system. A simple way to summarize the difference is that the Acclarix LX8 is a cart based version of the Acclarix AX8.

8. Intended Use: The Acclarix AX8 Diagnostic Ultrasound system/Acclarix LX8 Diagnostic 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 R1.3 and Acclarix LX8 R1.21

Item	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Acclarix LX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Acclarix LX8 R1.21 Diagnostic Ultrasound System (Edan Instruments)	Comparison Result
510(k) Number	Current Submission	Current Submission	(K160790 &) K162055	-
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	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 Acclarix AX8 Diagnostic Ultrasound System is intended for use by a qualified physician or sonographer for	The Acclarix LX8 Diagnostic Ultrasound System is intended for use by a qualified physician or sonographer	The Acclarix LX8 Diagnostic Ultrasound System is intended for use by a qualified physician or sonographer	Difference

	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 (including abdominal and cephalic), and Adult cephalic.	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 (including abdominal and cephalic), and Adult cephalic.	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 (including abdominal and cephalic).	
Installation and Use	Portable (laptop) Mobile Equipment	Trolley Mobile Equipment	Trolley Mobile Equipment	Refer to Table 9-2
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	Same
Patient Contact Materials	Complies with ISO 10993	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	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	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	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	Track 3: MI, TIS, TIC, TIB (TI Range 0-6.0) Derated I_{SPTA} : 720	Track 3: MI, TIS, TIC, TIB (TI Range 0-6.0) Derated I_{SPTA} : 720	Same

	W/cm ² maximum, Mechanic Index ≤1.9 maximum or Derated I _{SPPA} 190 W/cm ² max	W/cm ² maximum, Mechanic Index ≤1.9 maximum or Derated I _{SPPA} 190 W/cm ² max	W/cm ² maximum, Mechanic Index ≤1.9 maximum or Derated I _{SPPA} 190 W/cm ² max	
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	Convex Array Linear Array Endocavity-Micro Convex Array Phased Array Micro Convex Array	Same
Transducer Frequency	1-17.0 MHz	1-17.0 MHz	1-17.0 MHz	Same
Primary Display	Primary Screen:15.1 inch (1920 x 1080)	Primary Screen: 21.5 inch (1920 x 1080)	Primary Screen: 21.5 inch (1920 x 1080)	Refer to Table 9-2
Transducer Ports	Single -Transducer Port (Extendable with Multi-Transducer Connector to Three Ports)	Multi-Transducer Port (Four)	Multi-Transducer Port (Four)	Refer to Table 9-2
Dimensions/ Weight	407mm(W) x388mm(L) x77mm(H) Weight: 9.1Kg (With rechargeable battery, without power adaptor or transducers.)	Height: 53 – 70 in(1355-1780mm) Width: 23 in (585mm) Depth: 36.6 in (930mm) Weight: 111 Kg (no peripherals)	Height: 53 – 70 in (1355-1780mm) Width: 23 in (585mm) Depth: 36.6 in (930mm) Weight: 111 Kg (no peripherals)	Refer to Table 9-2
Power Requirements	00-240V, 50/60Hz, 2.5A max	00-240V, 50/60Hz, 2.5A max	100-240V, 50/60Hz, 2.5A max	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	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

Table 9-2 Comparison between the subject Acclarix AX8 R1.3 and Acclarix AX8 R1.2

Item	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Acclarix AX8 R1.2 Diagnostic Ultrasound System (Edan Instruments)	Comparison Result
510(k) Number	Current Submission	K161300 (Reference, as AX8 is portable compared to LX8 and this AX8 submission is an SW update to	-

Item	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Acclarix AX8 R1.2 Diagnostic Ultrasound System (Edan Instruments)	Comparison Result
		previous AX8.)	
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 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 (including abdominal and cephalic), and Adult cephalic.	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.	Difference
Installation and Use	Portable (laptop) Mobile Equipment	Portable (laptop) Mobile Equipment	Same
Design	128 channels	128 channels	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, 3D/4D	B-Mode, M-Mode, Color, PDI/DPDI, PW, CW	Difference
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} : 720W/cm ² maximum,	Track 3: MI, TIS, TIC, TIB (TI Range 0-6.0) Derated I_{SPTA} : 720W/cm ² maximum,	Same

Item	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Acclarix AX8 R1.2 Diagnostic Ultrasound System (Edan Instruments)	Comparison Result
	Mechanic Index ≤ 1.9 maximum or Derated I_{SPPA} 190 W/cm ² max Ophthalmic use: TI = Max (TIS _{as} , TIC) ≤ 1 ; ISPTA.3 ≤ 50 m/W/cm ² ; and MI ≤ 0.23	Mechanic Index ≤ 1.9 maximum or Derated I_{SPPA} 190 W/cm ² max Ophthalmic use: TI = Max (TIS _{as} , TIC) ≤ 1 ; ISPTA.3 ≤ 50 m/W/cm ² ; and MI ≤ 0.23	
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 9-3 Comparison between the subject Acclarix R1.3and DC60 (K152545)

Item	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Acclarix LX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	DC-60 Diagnostic Ultrasound System (Shenzhen Mindray Bio-Medical Electronics)	Comparison Result
510(k) Number	Current Submission	Current Submission	K152545 (Reference, for Adult Cephalic)	-
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound System applicable for adults, pregnant women, pediatric patients and neonates.	Same
Indications for Use	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,	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,	The DC-60DiagnosticUltrasound System is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, muscular-skeletal (conventional, superficial), adult and pediatric cardiac, peripheral vessel and urology exams.	Same (for Adult Cephalic)

	Small parts (Breast, Testes, Thyroid, etc.), Urology, Musculoskeletal, Peripheral vascular, Intra-operative, Pediatric and Neonatal (including abdominal and cephalic), and Adult cephalic.	Small parts (Breast, Testes, Thyroid, etc.), Urology, Musculoskeletal, Peripheral vascular, Intra-operative, Pediatric and Neonatal (including abdominal and cephalic), and Adult cephalic.		
Installation and Use	Portable (laptop) Mobile Equipment	Trolley Mobile Equipment	Trolley Mobile Equipment	Refer to Table 9-2
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	Same
Patient Contact Materials	Complies with ISO 10993	Complies with ISO 10993	Complies with ISO 10993	Same

Table 9-4 Comparison between the subject Acclarix R1.3 and M9 (K152543)

Item	Acclarix AX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	Acclarix LX8 R1.3 Diagnostic Ultrasound System (Edan Instruments)	M9 Diagnostic Ultrasound System (Shenzhen MindrayBio-Medical Electronics)	Comparison Result
510(k) Number	Current Submission	Current Submission	K152543 (Reference, for Measurement in Panorama, PW one-key optimization, Acoustic Power Control and Wireless network connection)	-
Intended Use	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound System applicable for adults, pregnant women, pediatric patients and neonates.	Same
Indications for Use	The Acclarix AX8 Diagnostic Ultrasound System is intended for use by a qualified physician or	The Acclarix LX8 Diagnostic Ultrasound System is intended for use	The M9 Diagnostic Ultrasound System is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid,	

	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 (including abdominal and cephalic), and Adult cephalic.	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 (including abdominal and cephalic), and Adult cephalic.	testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, muscular-skeletal (conventional, superficial), adult and pediatric cardiac, trans-esoph. (Cardiac), peripheral vessel, urology exams.	
Installation and Use	Portable (laptop) Mobile Equipment	Trolley Mobile Equipment	Portable Mobile Equipment	Refer to Table 9-2
Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-37 ISO 10993-1, -5, -10, -12 AIUM, NEMA UD 2, UD3	Same
Patient Contact Materials	Complies with ISO 10993	Complies with ISO 10993	Complies with ISO 10993	Same
Features	PW one-key optimization with a continuous adjustment on PW gain, DR, baseline and PRF scale Acoustic Power Control based on previous power management	PW one-key optimization with a continuous adjustment on PW gain, DR, baseline and PRF scale Acoustic Power Control based on	iTouch auto adjusts PW mode image with gain, scale, PRF and wall filter. Acoustic Power Setting and Acoustic Power Control	Difference (PW one-key optimization and Acoustic Power Control)

		previous power management		
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	B-Mode, M-Mode, PW-Mode, Color-Mode, Power/Dirpower Mode, THI, iScape mode, Color M, Elastography, LVO or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color).	Same (for Measurement in Panorama)
Wireless network connection	Complies with FCC Rules Part 15 (FCC ID: SMQAX8EDAN) Frequency Range: 2.400-2.483 GHz (2.4GHz IMS band) Module Type: OFDM, CCK Output Power: ≤17dbm	Complies with FCC Rules Part 15 (FCC ID: SMQLX8EDAN) Frequency Range: 2.412-2.472 GHz, (2.4GHz IMS band) Module Type: OFDM, CCK Output Power: ≤17dbm	Complies with FCC Rules Part 15 Operating Frequency: 2.412-2.472 GHz, 2.484 GHz (2.4GHz& 5GHz IMS band) Module Type: DSSS, OFDM Output Power: ≤17dbm	Difference (for Wireless)

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 AX8 and Acclarix LX8 Diagnostic Ultrasound Systems comply 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 AX8 and Acclarix LX8 Diagnostic Ultrasound Systems. This premarket notification submission demonstrates that Acclarix AX8 and Acclarix LX8 Diagnostic Ultrasound Systems are substantially equivalent to the predicate devices.