Edan Instruments, Inc.
% Ms. Melody Huang
Regulatory Engineer
#15 Jinhui Road, Jinsha Community,
Kengzi Sub-District Pingshan District
Shenzhen, 518122 Guangdong
CHINA

March 28, 2019

Re: K190186
Trade/Device Name: Acclarix AX4 Diagnostic Ultrasound System / Acclarix LX4 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: Class II
Product Code: IYO, ITX, IYN
Dated: January 29, 2019
Received: February 1, 2019

Dear Ms. Huang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal

statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K190186

Device Name

Acclarix AX4 Diagnostic Ultrasound System/Acclarix LX4 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The 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.**

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix AX4 Diagnostic Ultrasound System**

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

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

** 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

[5]: TDI

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix AX4 with C5-2Q Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix AX4 with L12-5Q Transducer**

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

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

** Other use includes Urology, Gynecology.

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

[2]: Biopsy Guidance

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix AX4 with MC8-4Q Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast.

** Other use includes Neonatal abdominal.

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

[2]: Biopsy Guidance

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix AX4 with E8-4Q Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix AX4 with L17-7SQ Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix AX4 with C5-2MQ Transducer**

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

| | Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General | Specific | B | M | PW | CW | Color | Combined (Specify) [1] | Other (Specify) [2][3][4] |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal / Obstetrics | P | P | P | | P | P | P |
| | Abdominal | 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**) | | | | | | | |
| | Musculo-skeletal (**Superficial**) | | | | | | | |
| | Intravascular | | | | | | | |
| | Other (Specify) ** | P | 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 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 AX4 with P5-1Q Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

[4]: TDI.

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix AX4 with MC9-3TQ Transducer**

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

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

(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 LX4 Diagnostic Ultrasound System**

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

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

** 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

[5]: TDI

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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 LX4 with C5-2D Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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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 LX4 with L12-5D Transducer**

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

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

** 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 LX4 with MC8-4D Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast.

** Other use includes Neonatal abdominal.

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

[2]: Biopsy Guidance

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

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Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**Acclarix LX4 with E8-4D Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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Concurrence of 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 LX4 with L17-7SD Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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Concurrence of 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 LX4 with C5-2MD Transducer**

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

| | Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General | Specific | B | M | PW | CW | Color | Combined (Specify) [1] | Other (Specify) [2][3][4] |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal / Obstetrics | P | P | P | | P | P | P |
| | Abdominal | 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**) | | | | | | | |
| | Musculo-skeletal (**Superficial**) | | | | | | | |
| | Intravascular | | | | | | | |
| | Other (Specify) ** | P | P | P | | P | P | P |
| Cardiac | Adult Cardiac | | | | | | | |
| | Pediatric Cardiac | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | |
| | Intra- cardiac | | | | | | | |
| Peripheral vascular | Peripheral vascular | | | | | | | |
| | Other (Specify) | | | | | | | |

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes 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 LX4 with P5-1D Transducer**

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

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

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

[4]: TDI.

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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 LX4 with MC9-3TD Transducer**

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

| | Clinical Application | Mode of Operation | | | | | | |
|---|---|---|---|---|---|---|---|---|
| General | Specific | B | M | PW | CW | Color | Combined (Specify) [1] | Other (Specify) [2][3] |
| Ophthalmic | Ophthalmic | | | | | | | |
| Fetal Imaging & Other | Fetal / Obstetrics | | | | | | | |
| | Abdominal | P | P | P | | P | P | P |
| | 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** K190186

**Prepared in accordance with the requirements of 21 CFR Part 807.92**

| | |
|---|---|
| **1. Submitter:** | Edan Instruments, Inc.<br>#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District, Shenzhen, 518122 P.R.China.<br>Tel: +86-755-2685 8736 Fax: +86-755-2689 8330 |
| **Contact person:** | Melody Huang |
| **Preparing date:** | Jan. 29, 2019 |
| **2. Device name and classification:** | **Device Name:** Acclarix AX4 Diagnostic Ultrasound System / Acclarix LX4 Diagnostic Ultrasound System<br>**Model:** Acclarix AX4, Acclarix LX4<br>**Classification Name/ Product code:**<br>21 CFR 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic / IYN<br>21 CFR 892.1560, Ultrasonic, Pulsed echo, Imaging / IYO<br>21 CFR 892.1570, Transducer, Ultrasonic, Diagnostic / ITX<br>**Regulatory Class:** Class II |
| **3.Premarket Notification Class III Certification and Summary** | Not applicable, the subject device is Class II. |
| **4. Predicate Device(s):** | 1) Edan Instruments, Acclarix AX8 Diagnostic Ultrasound System, cleared under K180862 (Primary)<br>2) Edan Instruments, Acclarix LX8 Diagnostic Ultrasound System, cleared under K180862 (Primary)<br>3) Edan Instruments, Acclarix AX4 Diagnostic Ultrasound System, cleared under K171900 (Reference) |
| **5. Reason for Submission** | By submission of the Traditional 510(k), Edan Instruments is requesting clearance for an updated version of the Acclarix AX4 Diagnostic Ultrasound Systems and the Acclarix LX4 (new model) Diagnostic Ultrasound Systems. |
| **6.Pre-Submission, IDE** | Not applicable, there is no pre-submission. |

**7. Device Description:** Acclarix AX4/ Acclarix LX4 is a software controlled Diagnostic Ultrasound System, which consists of a main unit along with associated transducers. It is intended for use by a qualified physician or allied health professional for ultrasound evaluations. This system is a Track 3 device to acquire and display ultrasound data in various imaging modes.

**8. Indication for Use** The Acclarix AX4 Diagnostic Ultrasound System/Acclarix LX4 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**

Edan Instruments' Acclarix AX4 and Acclarix LX4 Diagnostic Ultrasound System are comparable to the following legally marketed devices in the table below:

| No. | Device Name & Model | K Number | Manufacture |
|---|---|---|---|
| 1 | Acclarix AX8 Diagnostic Ultrasound System (Primary) | K180862 | Edan Instruments, Inc. |
| 2 | Acclarix LX8 Diagnostic Ultrasound System (Primary) | K180862 | Edan Instruments, Inc. |
| 3 | Acclarix AX4 Diagnostic Ultrasound System (Reference) | K171900 | Edan Instruments, Inc. |

The subject device Acclarix AX4/ Acclarix LX4 is same as the primary predicated device Acclarix AX8/

Acclarix LX8 (K180862) in items such as:

1) Intended Use/ Indications for Use;
2) Mode of Operations;
3) Transducer Types
4) Acoustic Output, which are below the limits of FDA;
5) The materials of transducers and needle-guided brackets;

The differences of subject device Acclarix AX4/ Acclarix LX4 with the primary predicated device Acclarix AX8/ Acclarix LX8 (K180862) are described as below:

1) The number of channels of the subject device is different with the primary predicated devices Acclarix AX8/ Acclarix LX8 (K180862), but same with the reference predicated devices Acclarix AX4 (K171900).
2) The subject device does not support five transducers that are already cleared in the primary predicated device Acclarix AX8/ Acclarix LX8 (K180862).
3) Safety standards that the subject device is designed in compliance with do not include UD3 standard because it has not been recognized by FDA, while the safety standards of primary predicated device Acclarix AX8/ Acclarix LX8 (K180862) include UD3 standard.
4) IEC 60601-1-2 and IEC 60601-2-37 standards have been updated to the latest version.

The subject and predicate devices have similar design features and performance specifications. The technological differences between the subject and predicate devices do not raise different questions of safety or effectiveness.

**10. Performance Data:**

**Clinical test:**

Clinical testing is not required.

**Non-clinical test:**

The Acclarix AX4 and Acclarix LX4 Diagnostic Ultrasound Systems comply with:

(1) ANSI/AAMI ES60601-1 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) Acoustic output testing as per the guideline “Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” dated September 9, 2008

(5) NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3

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.

The non-clinical performance testing showed that the subject devices are as safe and as effective as the predicate devices.

## 11. Conclusion

Verification and validation testing has been conducted on the Acclarix AX4 and Acclarix LX4 Diagnostic Ultrasound Systems. This premarket notification submission demonstrates that Acclarix AX4 and Acclarix LX4 Diagnostic Ultrasound Systems are substantially equivalent to the predicate devices.