DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 29, 2017

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

Re: K172380
Trade/Device Name: U2 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 1, 2017
Received: August 7, 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K172380

Device Name
U2 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The diagnostic ultrasound system (U2) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), endovaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.

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

U2 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]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / Obstetrics	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric	N	N	N		N	N	N
	Small Organ (Specify) *	N	N	N		N	N	N
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	N	N	N		N	N	N
	Trans-urethral							
	Musculo-skeletal(**Conventional**)	N	N	N		N	N	N
	Musculo-skeletal (**Superficial**)	N	N	N		N	N	N
	Intravascular							
	Other (Specify) **	N	N	N		N	N	N
Cardiac	Adult Cardiac	N	N	N	N	N	N	N
	Pediatric Cardiac	N	N	N		N	N	N
	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.

(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

U2 with C352UB 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	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **	N	N	N		N	N	N
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

U2 with L1042UB 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) *	N	N	N		N	N	N
	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) **							
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

U2 with L742UB 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) *	N	N	N		N	N	N
	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) **							
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

U2 with E612UB 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	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	N	N	N		N	N	N
	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

U2 with C612UB 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	N	N	N		N	N	N
	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	N	N	N		N	N	N
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

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

Additional comments: Combined mode: B+M, B+PW, B+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

U2 with C6152UB 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	N	N	N		N	N	N
	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	N	N	N		N	N	N
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

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

Additional comments: Combined mode: B+M, B+PW, B+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

U2 with C422UB Transducer

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

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

U2 with L552UB 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	N	N	N		N	N	N
	Small Organ (Specify) *	N	N	N		N	N	N
	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) **							
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

U2 with C5-2b 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	N	N	N		N	N	N
	Abdominal	N	N	N		N	N	N
	Intra-operative (Specify)							
	Intra-operative (Neuro logical)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **	N	N	N		N	N	N
Cardiac	Adult Cardiac							
	Pediatric Cardiac							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular							
	Other (Specify)							

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

U2 with P5-1b 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) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify) **							
Cardiac	Adult Cardiac	N	N	N	N	N	N	N
	Pediatric Cardiac							
	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

U2 with L15-7b 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) *	N	N	N		N	N	N
	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) **							
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.

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

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

Prescription Use (Per 21 CFR 801.109)

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:	Edan Instruments, Inc. #15 Jinhui Road,Jinsha Community, Kengzi Sub-District, Pingshan District, Shenzhen, 518122 P.R.China. Tel.: (0755) 26856469 Fax: +1 (408) 418-4059
Contact Person:	Alice Yang
Date prepared:	August 1,2017
2. Device name and classification:	**Device Name: U2** Diagnostic Ultrasound System **Model:** U2 **Classification Name:** 892.1550 System, Imaging, Pulsed Doppler, Ultrasonic Product code: IYN 892.1560 Ultrasonic, Pulsed echo, Imaging Product code: IYO 892.1570 Transducer, Ultrasonic, Diagnostic Product code: ITX **Regulatory Class:** Class II
3.Premarket Notification Class III Certification and Summary	Not applicable, the subject device is Class II.
4. Predicate Device(s):	Edan Instruments, Inc., U50 Diagnostic Ultrasound System cleared under K142511.
5. Reason for Submission	By submission of the Traditional 510(k), Edan Instruments is requesting clearance for new device U2 Diagnostic Ultrasound System.
6. Pre-Submission, IDE	Not applicable, there is no prior submission.

7. Device Description:

U2 is a cart based diagnostic ultrasound system. U2 has the same intended use, similar product design, same performance effectiveness as the previous cleared U50 (K142511).

8. Intended Use:

The diagnostic ultrasound system (U2) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), endovaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.

9. Predicate Device Comparison

Comparison to the predicate devices, U2 has the same intended use, similar product design, same performance effectiveness as the previous cleared U50 (K142511). The primary difference between the U2 and U50 is the operating system, the form factor of the system, an extra transducer and the number of probe sockets. The operating system of the U2 has been changed to utilize Linux; the U2 is a cart based system, where as the U50 is a tabletop system, and the U2 has 4 probe socket while the U50 has 2.

Item	U2 Diagnostic Ultrasound System (Edan Instruments)	U50 Diagnostic Ultrasound System (Edan Instruments)	Comparison Result
510(k) Number	Current Submission	K142511	
Manufacturer	EDAN Instruments	EDAN Instruments	Same
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 diagnostic ultrasound system (U2) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), endovaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.	The diagnostic ultrasound system (U50) is applicable for adults, pregnant women, pediatric patients' ultrasound evaluation in hospitals and clinics. It is intended for use in abdominal, obstetrics, gynecology, pediatric, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial), endovaginal and cardiac clinical applications, by or on the order of a physician or similarly qualified health care professional.	Same
Installation and Use	Trolley Mobile Equipment	a. Portable Equipment b. Mobile Equipment (when the system is installed on the mobile trolley)	Difference
Safety Standards	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Same

	IEC 60601-2-37 ISO 10993-1, -5, -10 AIUM, NEMA UD 2, UD3	IEC 60601-2-37 ISO 10993-1, -5, -10 AIUM, NEMA UD 2, UD3	
Patient Contact Materials	Complies with ISO 10993	Complies with ISO 10993	Same
Software life cycle processes	Complies with the standard: IEC 62304	Complies with the standard: IEC 62304	Same
Mode of Operations	Continuous operation	Continuous operation	Same
General Imaging mode	B-Mode, M-Mode, Color, PDI/DPDI, PW, CW	B-Mode, M-Mode, Color, PDI/DPDI, PW, CW	Same
Measurements	B-Mode: Distance, Area, Volume, Ratio, Histogram and Angle M-Mode: Distance, Time, Slope, and Heart Rate D-Mode: Time, Heart Rate, Velocity, Acceleration, RI, PI and Auto (auto trace)	B-Mode: Distance, Area, Volume, Ratio, Histogram and Angle M-Mode: Distance, Time, Slope, and Heart Rate D-Mode: Time, Heart Rate, Velocity, Acceleration, RI, PI and Auto (auto trace)	Same
Scanning method	Electronic convex Electronic linear with slant scanning	Electronic convex Electronic linear with slant scanning	Same
Cine loop	1227 frames	1227 frames	Same
Focus Number	Max=4	Max=4	Same
Software Packages	Abdomen, obstetric, small parts, gynecology, cardiology, urology, vascular and Pediatrics.	Abdomen, obstetric, small parts, gynecology, cardiology, urology, vascular and Pediatrics.	Same
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect reflected echo to construct diagnostic image	Applying high voltage burst to the Piezoelectric material in the transducer and detect reflected echo to construct diagnostic image	Same
Acoustic Output	Track 3: MI, TIS, TIC, TIB(TI Range 0-6.0) Derated I_{SPTA}: 720 W/cm^2 maximum, Mechanic Index ≤1.9 maximum or Derated I_{SPPA} 190 W/cm^2 max	Track 3: MI, TIS, TIC, TIB(TI Range 0-6.0) Derated I_{SPTA}: 720 W/cm^2 maximum, Mechanic Index ≤1.9 maximum or Derated I_{SPPA} 190 W/cm^2 max	Same
Transducer Types	Convex Array Linear Array Micro Convex Array Phased Array	Convex Array Linear Array Micro Convex Array Phased Array	Same
Transducer Frequency	2.0-15.0 MHz	2.0-15.0 MHz	Same
Primary Display	Primary Screen: 15 or 19 inch(1024*768)	Primary Screen: 12.1inch(1024*768)	Difference
Transducer Ports	Multi-Transducer Port (Four)	Multi-Transducer Port (Two)	Difference
Dimensions/ Weight	920 mm (L) × 650 mm (W) × 1400 mm (H) (with 15 inch monitor) 920 mm (L) × 650 mm (W) × 1480 mm (H) (with 19 inch monitor) net weight 60 kg	330 mm (W) × 320 mm (L) × 220 mm (H) net weight 7.8kg	Difference
Printer	B/W video thermal printer	B/W video thermal printer	Same

	Color video thermal printer Graph/text laser jet printer	Color video thermal printer Graph/text laser jet printer	
Temperature	Operating: 5°C ~40°C Transport/ Storage: -20~55°C	Operating: 5°C ~40°C Transport/ Storage: -20~55°C	Same
Relative humidity	Operating: 25% ~ 80%RH (no condensation) Transport/ Storage: 25% ~ 93%RH (no condensation)	Operating: 25% ~ 80%RH (no condensation) Transport/ Storage: 25% ~ 93%RH (no condensation)	Same
Atmospheric pressure	Operating: 860hPa ~1060hPa Transport/ Storage: 700hPa ~1060hPa	Operating: 860hPa ~1060hPa Transport/ Storage: 700hPa ~1060hPa	Same
Power Requirements	AC: 100-240V 50/60Hz	AC: 100-240V 50/60Hz	Same
Operation System	Linux	μCosII	Difference
Safety Classifications			
Type of protection against electric shock	Class I	Class I	Same
The degree of protection against electric shock	Type BF.	Type BF.	Same
The degree of protection against harmful ingress of liquid	The main unit : IPX0, probes : IPX7 Footswitch: IP68	The main unit : IPX0, probes : IPX7 Footswitch: IP68	Same
The degree of safety of application in the presence of a flammable gas	Equipment not suitable for use in the presence of a flammable gas	Equipment not suitable for use in the presence of a flammable gas	Same
The degree of RF	Group 1, Class A	Group 1, Class A	Same
Disinfection			
Disinfection	Probe: 2.4%Glutaraldehyde, 0.55%Ortho-Phthalaldehyde. Needle guide: 75% medical alcohol, 2.4%Glutaraldehyde.	Probe: 2.4%Glutaraldehyde, 0.55%Ortho-Phthalaldehyde. Needle guide: 75% medical alcohol, 2.4%Glutaraldehyde.	Same
Performance			
Displayed depth	20-320mm（Probe Dependent ）	20-320mm（Probe Dependent ）	Same
Gray Scales	256	256	Same
Dynamic range	150dB	150dB	Same
TGC	8 segments	8 segments	Same

Zoom	Up to 400%	Up to 400%	Same
Image Adjustments			
B Mode Parameters	Image type	Image type	Same
	Gain	Gain	
	Depth	Depth	
	TGC	TGC	
	Freq(Frequency)	Freq(Frequency)	
	Gray Map	Gray Map	
	Dynamic Range	Dynamic Range	
	Rejection	Rejection	
	Focus Position	Focus Position	
	Focus Number	Focus Number	
	eSRI(Spackle Rejection Imaging)	eSRI(Spackle Rejection Imaging)	
	Pseudo color	Pseudo color	
	Spatial Compound	Spatial Compound	
	GAO(Gain Auto Optimization)	GAO(Gain Auto Optimization)	
	Scan Angle	Scan Angle	
	Scan Mode	Scan Mode	
	Frame Persist	Frame Persist	
	H Reverse(horizontal)	H Reverse(horizontal)	
	V Reverse(vertical)	V Reverse(vertical)	
	90°Rotate	90°Rotate	
	B/W Invert	B/W Invert	
M Mode Parameters	Freq	Freq	Same
	Sweep Speed	Sweep Speed	
	Display Layout	Display Layout	
	Gray Map	Gray Map	
	Focus Position	Focus Position	
	Dynamic Range	Dynamic Range	
	Pseudo Color	Pseudo Color	
	Line Average	Line Average	
Color Mode & Power Doppler Mode & Directional Power Mode Parameters	Flow type	Flow type	Same
	Gain	Gain	
	Freq	Freq	
	Wallfilter	Wallfilter	
	PRF(Pulsed Repetition Frequency)	PRF(Pulsed Repetition Frequency)	
	Base Line	Base Line	
	Invert	Invert	
	Dual Live	Dual Live	
	Angle Steer	Angle Steer	
	Color Map	Color Map	
	Packet size	Packet size	
	Persist	Persist	
	Threshold	Threshold	
	Smooth Filter	Smooth Filter	
	ROI box position and size adjustment	ROI box position and size adjustment	
PW Mode Parameters	Flow type	Flow type	Same
	Gain	Gain	
	PRF	PRF	
	Invert	Invert	
	Angle steer	Angle steer	

	Correction Angle	Correction Angle	
	Quick Angle	Quick Angle	
	Base Line	Base Line	
	Sample Volume	Sample Volume	
	Wallfilter	Wallfilter	
	Freq	Freq	
	Duplex and Triplex	Duplex and Triplex	
	Pseudo Color	Pseudo Color	
	Dyn Rng	Dyn Rng	
	Volume	Volume	
	Sweep Speed	Sweep Speed	
	HPRF	HPRF	
CW Mode Parameters	Flow type	Flow type	Same
	Gain	Gain	
	PRF	PRF	
	Invert	Invert	
	Angle steer	Angle steer	
	Correction Angle	Correction Angle	
	Quick Angle	Quick Angle	
	Base Line	Base Line	
	Wallfilter	Wallfilter	
	Pseudo Color	Pseudo Color	
	Dynamic Range	Dynamic Range	
	Volume	Volume	
	Sweep Speed	Sweep Speed	
B-Mode Measurement Accuracy			
Range of Depth/ Distance	Maximum 324 mm	Maximum 324 mm	Same
Accuracy of Depth/ Distance	≤±5%	≤±5%	Same
Range of Area	Maximum 1126 cm^2	Maximum 1126 cm^2	Same
Accuracy of Area	≤±10%	≤±10%	Same
Range of Angle	0-180°	0-180°	Same
Accuracy of Angle	≤±3%	≤±3%	Same
Range of Ratio	Maximum 1.0	Maximum 1.0	Same
Accuracy of Ratio	≤±10%	≤±10%	Same
Range of Volume	Maximum 999 cm^3	Maximum 999 cm^3	Same
Accuracy of Volume	≤±15%	≤±15%	Same
M-mode Measurement Accuracy			
Range of Depth	Maximum 324mm	Maximum 324mm	Same
Accuracy of Depth	≤±5%	≤±5%	Same

Range of Time	Maximum 13s	Maximum 13s	Same
Accuracy of Time	≤±5%	≤±5%	Same
Range of Heart rate	Maximum 999bpm	Maximum 999bpm	Same
Accuracy of Heart rate	≤±5%	≤±5%	Same
Range of Slope	Maximum 999mm/s	Maximum 999mm/s	Same
Accuracy of Slope	≤±10%	≤±10%	Same
PW mode velocity Measurement Accuracy			
Range	0.5-2.5m/s	0.5-2.5m/s	Same
Accuracy	≤±10%	≤±10%	Same
CW mode velocity Measurement Accuracy			
Range	0.5-2.5m/s	0.5-2.5m/s	Same
Accuracy	≤±10%	≤±10%	Same

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 U2 Ultrasound Imaging System complies with:

(1) IEC 60601-1:2005/A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
(2) IEC 60601-1-2 Edition 3:2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.
(3) IEC 60601-2-37 Edition 2.0 2007, medical electrical equipment - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
(4) NEMA UD 3, Edition 2004 Standard for real-time display of thermal and mechanical acoustic output Indies 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.
(6) NEMA, UD2, Edition 2004 for acoustic output measurement methodology.

The following biocompatibility standards are conducted on the subject device:
(1) ISO 10993-1:2009, ISO 10993-5:2009 and ISO 10993-10:2010

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 U2 Ultrasound Imaging System. This premarket notification submission demonstrates that U2 Ultrasound Imaging System is substantially equivalent to the predicate devices.