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

Edan Instruments, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

February 20, 2015

Re: K142511
Trade/Device Name: U50 Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 27, 2015
Received: January 30, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142511

Device Name
U50 Diagnostic Ultrasound System

Indications for Use *(Describe)*

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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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

FOR FDA USE ONLY

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

Diagnostic Ultrasound Indications for Use Form

U50 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	P	P	P		P	P	P
	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) *	P	P	P		P	P	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	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	N	P	P	P
	Pediatric Cardiac	P	P	P		P	P	P
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra- cardiac							
Peripheral vascular	Peripheral vascular	P	P	P		P	P	P
	Other (Specify)							

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

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

Note * Small Organ includes Thyroid, Testes, Breast

** Other use includes Urology, Gynecology

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

[2]: Biopsy Guidance

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

U50 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	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 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

U50 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) *	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

U50 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) *	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

U50 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	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

U50 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	P	P	P		P	P	P
	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	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+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

U50 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	P	P	P		P	P	P
	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	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+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

U50 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	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) **							
Cardiac	Adult Cardiac	P	P	P		P	P	P
	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

U50 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	P	P	P		P	P	P
	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

U50 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 Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

U50 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 Center for Devices and Radiological Health (CDRH)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

U50 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.

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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:

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Contact Person: Cherry Sun

Date prepared: August 18, 2014

2. Device name and classification:

Device Name: Diagnostic Ultrasound System

Model: U50

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. Predicate Device(s):

U50 Diagnostic ultrasound system/ K123249/ Shenzhen EDAN Instruments CO., Ltd

DC-6 Diagnostic Ultrasound System/ K072164/ Shenzhen Mindray Bio-medical Electronics Co., Ltd.

GE LOGIQ E9 Diagnostic Ultrasound System/K082185/General Electric Co., Ltd.

4. Device Description:

The modifications are listed as below:

- Addition of CW mode – the basic system architecture previously supported CW mode.
- 3 new transducers C5-2b, P5-1b and L15-7b – The C5-2b and the L15-7b are new transducers. The P5-1b is the initial offering of a phased array device on this system..
- Addition of HPRF to PW mode
- Minor changes to the user interface

5. Intended Use:

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.

6. 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:

Item	DC-6	U50 1.0	U50 2.0	Comparison U50 2.0 with 1.0 and DC-6
Manufacturer/ K#	Mindray Instruments	EDAN Instruments	EDAN Instruments	
Indication for Use	DC-6 Diagnostic Ultrasound System is a general purpose, mobile, software controlled, Ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, CW mode, Color-Mode, Color M-Mode, Power/Dirpower Mode or the combined mode (i.e. B/M-Mode).This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.5MHz to	The U50 is a portable Diagnostic Ultrasound System, which applies advanced technologies such as Phased Inversion Harmonic Compound Imaging (eHCI), Spatial Compounding Imaging, Multi-Beam-Forming , Speckle Resistance Imaging (eSRI), etc. Its function is to acquire and display Ultrasound images in B-mode, M-mode, PW-mode, Color-mode, PDI/DPDI mode. This system provides a series of probes that include linear array, convex array, micro-convex array with a frequency range of approximately 2.5MHz to 11MHz.	The U50 is a portable Diagnostic Ultrasound System, which applies advanced technologies such as Phased Inversion Harmonic Compound Imaging (eHCI), Spatial Compounding Imaging, Multi-Beam-Forming , Speckle Resistance Imaging (eSRI), etc. Its function is to acquire and display Ultrasound images in B-mode, M-mode, PW-mode, CW-mode Color-mode, PDI/DPDI mode. This system provides a series of probes that include linear array, convex array, micro-convex array and phased array with a frequency range of approximately 2.0MHz to 15MHz.	Add CW-mode; (DC-6 includes CW mode and is therefore predicate) Add a phased array transducer; Frequency range is changed to 2.0 MHz to 15 MHz

	10.0MHz.			
Intended Use	abdominal, cardiac, small parts (breast, testes, thyroid, etc.), peripheral vascular, fetal, transrectal, transvaginal, pediatric, neonatal cephalic, musculoskeletal (general and superficial), and intraoperative (liver, gallbladder, pancreas)exams.	Abdominal, Obstetrics, Gynecology, Pediatric, Small Parts, Urology, Peripheral Vascular, Musculoskeletal (conventional and superficial),Transvaginal, and Cardiac clinical applications	Abdominal, Obstetrics, Gynecology, Pediatric, Small Parts, Urology, Peripheral Vascular, Musculoskeletal (conventional and superficial),Transvaginal, and Cardiac clinical applications	No change
Dimensions	1390 mm (H) × 480 mm (W) × 790 mm (D)	330 mm (W) × 320 mm (L) × 220 mm (H)	330 mm (W) × 320 mm (L) × 220 mm (H)	No change
Weight	Net weight 132 Kg	Net weight 7.8 Kg	Net weight 7.8 Kg	No change
General Imaging mode	B, M, Color, Power/DirPower, PW, CW,	B, M, Color, PDI/DPDI, PW	B, M, Color, PDI/DPDI, PW, CW	Add CW imaging mode (see DC-6)
Special Imaging mode	Smart 3D, iScape, Free Xros M	None	None	No change
B Mode General Measurements	Depth, Distance, Area, Volume, Trace Length, Ratio, B Histogram , Angle, Cross Line, Parallel Line, B Profile	Distance, Area, Volume, Ratio, Histogram and Angle	Distance, Area, Volume, Ratio, Histogram and Angle	No change
M Mode General Measurements	Distance, Time, Slope, and Heart Rate	Distance, Time, Slope, and Heart Rate	Distance, Time, Slope, and Heart Rate	No change
D Mode General Measurements	Time, Heart Rate, Velocity, Acceleration, RI, PI and Spectrum Trace	Time, Heart Rate, Velocity, Acceleration, RI, PI and Auto (auto trace)	Time, Heart Rate, Velocity, Acceleration, RI, PI and Auto (auto trace)	No change
Performance				
Displayed depth	26-263mm （Probe Dependent ）	20-320mm （Probe Dependent ）	20-320mm （Probe Dependent ）	No change
Gray Scales	256	256	256	No change
Dynamic range	192 dB	150dB	150dB	No change
TGC	8 segments	8 segments	8 segments	No change
Zoom	Up to 400%	Up to 400%	Up to 400%	No change

The differences between the subject device and predicate devices 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.

7. Effectiveness and Safety Considerations:

Clinical test:
Clinical testing is not required.

Non-clinical test:
The following safety standards are conducted on the subject device:
(1) IEC 60601-1 Electrical Safety
(2) IEC 60601-1-2 Electromagnetic Compatibility
(3) Acoustic output testing as per the guideline "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" dated September 9, 2008.
(4) ISO 10993-1, ISO 10993-5 and ISO 10993-10

The subject device passed all testing. The tests were selected to show substantial equivalence between the subject device and the predicate, and since the testing passed, substantial equivalence is shown.

8. Substantially Equivalent Determination

Verification and validation testing was conducted, and passed prespecified criteria, on the U50 Diagnostic Ultrasonic System. This premarket notification submission demonstrates that U50 Diagnostic Ultrasonic System is substantially equivalent to the predicate devices.