K091680

510(k) Summary of Safety and Effectiveness

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Edan Instruments, Inc.

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Contact Person: Jiang yucai

JUN 19 2009

Prepare date: April 2, 2009

2. Device name and classification:

Device name: DUS 3/DUS 6 Digital Ultrasonic Diagnostic Imaging System

Classification Name: 892.1560 System, Imaging, Pulsed echo, Ultrasonic
Product code: IYO

892.1570 Transducer, Ultrasonic, Diagnostic
Product code: ITX

Regulatory Class: II

3. Predicate Device:

DP-6600 Digital Ultrasonic Diagnostic Imaging System. K052113
Manufacturer: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD
DP-6600 Digital Ultrasonic Diagnostic Imaging System. K060949
Manufacturer: SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD

4. Device Description:

DUS 3/DUS 6 Digital Ultrasound Diagnostic Imaging System is a portable digital ultrasonic diagnostic B/W system applied in ultrasound diagnostic examination of abdominal, obstetrical, small parts, gynecological, orthopedic, cardiac, and urological applications.

It is designed to produce ultrasound waves into body tissue and to present the returned echo information on the monitor, the resulting information is displayed in five display modes: B-Mode, 2B-Mode, 4B-Mode, M-Mode or the combined mode (i.e. B/M-Mode). This system controlled by software is a Track 1 device that employs an array of probes that include linear array, convex linear array, microconvex linear array, transrectal and transvaginal with a frequency range of approximately 2.5MHz-10.0MHz.

The system consists of a main unit, a display and transducers.

5. Intended Use:

The DUS 6/DUS 3 Digital Ultrasonic Diagnostic Imaging System is intended for diagnostic ultrasound imaging analysis in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms. The DUS 6/DUS 3 is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus; Abdomen; Pediatrics; Small Organ; Neonatal Cephalic; Cardiology; Peripheral Vessel; Musculo-skeleton (both Conventional and Superficial); Urology (including prostate); Transrecta and Transvagina.

6. 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

7.Comparison to the predicate device

Comparison to the predicate device, the subject device has the similar technology characteristics and has the same intended use, same design principle, same electrical classification, same measurement mode and same accuracy. The different between the subject device and predicate device primarily includes physical specifications, environment specifications, scanning angle, printer, display frame rate, Image depth range, all the above differences do not affect the usage, safety and effectiveness, and no new question is raised regarding the safety and effectiveness.

8. Substantially Equivalent Determination

Verification and validation testing was done on the DUS 3/DUS 6 Digital Ultrasonic Diagnostic Imaging System. This premarket notification submission demonstrates that DUS 3/DUS 6 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

Edan Instruments, Inc.
% Mr. Marc M. Mouser
Manager & FDA Office Coordinator, Program Reviewer
Underwriters Laboratories, Inc.
2600 NW Lake Road
CAMAS WA 98607

Re: K091680
Trade/Device Name: Digital Ultrasonic Diagnostic Imaging Systems
(Models DUS3 and DUS6)
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: May 27, 2009
Received: June 10, 2009

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Digital Ultrasonic Diagnostic Imaging Systems (Models DUS3 and DUS6), as described in your premarket notification:

Transducer Model Number

DUS 3 Digital Ultrasonic Diagnostic Imaging System

C361-1 / C341
C321-1
L741
E741
E611-1

DUS 6 Digital Ultrasonic Diagnostic Imaging System

C363-1 / C343-1
C321
L743
E743
E613

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Paul Hardy at (240) 276-3666.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indication for Use

510(k) Number (if known): K091680

Device Name: Digital Ultrasonic Diagnostic Imaging System (Models DUS3 and DUS6)

The DUS 3 & DUS 6 Digital Ultrasonic Diagnostic Imaging System is intended for diagnostic ultrasound imaging analysis in gynecology rooms, obstetrics rooms, examination rooms, intensive care units, and emergency rooms.

The DUS 3/ DUS 6 Digital Ultrasonic Diagnostic Imaging System is intended for use by or on the order of a physician or similarly qualified health care professional for ultrasound evaluation of Fetus; Abdomen; Pediatrics; Small Organ; Neonatal Cephalic; Cardiology; Peripheral Vessel; Musculo-skeleton (both Conventional and Superficial); Urology (including prostate); Transrecta and Transvagina.

Prescription Use ___X___ Or Over the Counter Use _____

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 3 Digital Ultrasonic Diagnostic Imaging System

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N				N	
Abdominal	N	N				N	
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N				N	
Small Organ (Specify)	N	N				N	
Neonatal Cephalic	N	N				N	
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal	N	N				N	
Transurethral							
Musculo-skeletal (Conventional)	N	N				N	
Musculo-skeletal (Superficial)	N	N				N	
Intravascular							
Other (Specify)							
Cardiac	N	N				N	
Intravascular							
Peripheral vascular	N	N				N	
Other (Specify)							

N = new indication; P = previously cleared by FDA; E added under this appendix

Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 3 with C361-1 / C341 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N				N	
Abdominal	N	N				N	
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)							
Musculo-skeletal (**Superficial**)							
Intravascular							
Other (Specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Specify)							

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Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 3 with C321-1 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal	N	N				N	
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N				N	
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Other (Specify)							
Cardiac	N	N				N	
Intravascular							
Peripheral vascular							
Other (Specify)							

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Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 3 with L741 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)	N	N				N	
Neonatal Cephalic	N	N				N	
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (**Conventional**)	N	N				N	
Musculo-skeletal (**Superficial**)	N	N				N	
Intravascular							
Other (Specify)							
Cardiac							
Intravascular							
Peripheral vascular	N	N				N	
Other (Specify)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 3 with E741 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal							
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Other (Specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Specify)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 3 with E611-1 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal	N	N				N	
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Other (Specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Specify)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 6 Digital Ultrasonic Diagnostic Imaging System

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N				N	
Abdominal	N	N				N	
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N				N	
Small Organ (Specify)	N	N				N	
Neonatal Cephalic	N	N				N	
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal	N	N				N	
Transurethral							
Musculo-skeletal (Conventional)	N	N				N	
Musculo-skeletal (Superficial)	N	N				N	
Intravascular							
Other (Specify)							
Cardiac	N	N				N	
Intravascular							
Peripheral vascular	N	N				N	
Other (Specify)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 6 with C363-1 / C343-1 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics	N	N				N	
Abdominal	N	N				N	
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Other (Specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Specify)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 6 with C321 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal	N	N				N	
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric	N	N				N	
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Other (Specify)							
Cardiac	N	N				N	
Intravascular							
Peripheral vascular							
Other (Specify)							

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Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 6 with L743 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)	N	N				N	
Neonatal Cephalic	N	N				N	
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (Conventional)	N	N				N	
Musculo-skeletal (Superficial)	N	N				N	
Intravascular							
Other (Specify)							
Cardiac							
Intravascular							
Peripheral vascular	N	N				N	
Other (Specify)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 6 with E743 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal							
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Other (Specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Specify)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K091680

Diagnostic Ultrasound Indications for Use Form

DUS 6 with E613 Transducer

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

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics							
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal	N	N				N	
Transvaginal	N	N				N	
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Other (Specify)							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Specify)							

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Prescription Use (Per 21 CFR 801.109)

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