December 1, 2017

Advanced Instrumentations, Inc.
℅ Jorge Millan, Ph.D.
Regulatory Affairs Manager
6800 NW 77th Ct.
MIAMI FL 33166

Re: K172931
Trade/Device Name: DUS-6000 Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: October 3, 2017
Received: October 6, 2017

Dear Dr. Millan:

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.

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.

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

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172931

Device Name

DUS-6000 Digital Ultrasonic Diagnostic Imaging System

Indications for Use *(Describe)*

The DUS-6000 Digital Ultrasonic Diagnostic Imaging System is applicable for ultrasound evaluation in hospitals and clinics. It is intended for use in Abdominal, obstetric, gynecology, pediatrics, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial) and cardiac 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Diagnostic Ultrasound Indications for Use Form
DUS-6000 Digital Ultrasonic Diagnostic Imaging System

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics	P	P	P			P	Note 1,2
	Abdominal	P	P	P			P	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric	P	P	P			P	Note 1,2
	Small Organ (Specify) *	P	P	P			P	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P			P	Note 1,2
	Trans-vaginal	P	P	P			P	Note 1,2
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)	P	P	P			P	Note 1,2
	Musculo-skeletal (**Superficial**)	P	P	P			P	Note 1,2
	Intravascular							
	Other (Specify)**	P	P	P			P	Note 1,2
Cardiac	Cardiac	P	P	P			P	Note 1,2
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular	P	P	P			P	Note 1,2
	Other (Urology)							

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

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

*Small Organ includes thyroid

**Other use includes Urology

Note 1: Biopsy guidance

Note 2: Harmonic Imaging, This feature does not use contrast agents

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with C361-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics	P	P	P			P	Note 1,2
	Abdominal	P	P	P			P	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)**	P	P	P			P	Note 1,2
Cardiac	Cardiac							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Urology)							

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

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

*Small Organ includes thyroid

**Other use includes Urology

Note 1: Biopsy guidance

Note 2: Harmonic Imaging, This feature does not use contrast agents

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with C363-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics	P	P	P			P	Note 1,2
	Abdominal	P	P	P			P	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)**	P	P	P			P	Note 1,2
Cardiac	Cardiac							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Urology)							

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

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

*Small Organ includes thyroid

**Other use includes Urology

Note 1: Biopsy guidance

Note 2: Harmonic Imaging, This feature does not use contrast agents

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with C341-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics	P	P	P			P	Note 1,2
	Abdominal	P	P	P			P	Note 1,2
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)**	P	P	P			P	Note 1,2
Cardiac	Cardiac							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Urology)							

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

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

*Small Organ includes thyroid

**Other use includes Urology

Note 1: Biopsy guidance

Note 2: Harmonic Imaging, This feature does not use contrast agents

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with L741-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	P	P	P			P	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)	P	P	P			P	Note 1,2
	Musculo-skeletal (**Superficial**)	P	P	P			P	Note 1,2
	Intravascular							
	Other (Specify)**							
Cardiac	Cardiac							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular	P	P	P			P	Note 1,2
	Other (Urology)							

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

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

*Small Organ includes thyroid

**Other use includes Urology

Note 1: Biopsy guidance

Note 2: Harmonic Imaging, This feature does not use contrast agents

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with L743-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	P	P	P			P	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)	P	P	P			P	Note 1,2
	Musculo-skeletal (**Superficial**)	P	P	P			P	Note 1,2
	Intravascular							
	Other (Specify)**							
Cardiac	Cardiac Adult							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vascular	Peripheral vascular	P	P	P			P	Note 1,2
	Other (Urology)							

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

*Small Organ includes thyroid

**Other use includes Urology

Note 1: Biopsy guidance

Note 2: Harmonic Imaging, This feature does not use contrast agents

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with L761-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *	P	P	P			P	Note 1,2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)	P	P	P			P	Note 1,2
	Musculo-skeletal (**Superficial**)	P	P	P			P	Note 1,2
	Intravascular							
	Other (Specify)**							
Cardiac	Cardiac							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular	P	P	P			P	Note 1,2
	Other (Urology)							

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

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

*Small Organ includes thyroid

**Other use includes Urology

Note 1: Biopsy guidance

Note 2: Harmonic Imaging, This feature does not use contrast agents

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with C611-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric	P	P	P			P	Note 1,2
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)**							
Cardiac	Cardiac	P	P	P			P	Note 1,2
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Urology)							

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

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Note 1: Biopsy guidance

Note 2: Harmonic Imaging, This feature does not use contrast agents

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with E741-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P			P	Note 1,2
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)**							
Cardiac	Cardiac							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Urology)							

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-6000 with E611-2 Transducer

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

Clinical Application								
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging and Other	Fetal/Obstetrics							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neurological)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify) *							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P			P	Note 1,2
	Trans-vaginal	P	P	P			P	Note 1,2
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal(**Conventional**)							
	Musculo-skeletal (**Superficial**)							
	Intravascular							
	Other (Specify)**							
Cardiac	Cardiac Adult							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral vascular	Peripheral vascular							
	Other (Urology)							

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510K SUMMARY

DUS-6000 Digital Ultrasonic Diagnostic Imaging System

SUBMITTER ADVANCED INSTRUMENTATIONS, INC
6800 NW 77th Ct, Miami, FL 33166
Phone: (305) 477-6331

US AGENT JORGE MILLAN, PHD
REGULATORY AFFAIRS MANAGER
Email: sigmabiomedical@gmail.com
Web: https://www.sigmabiomedical.com

DEVICE NAME AND CLASSIFICATION

TRADE NAME: DUS-6000 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: *Class II*
PANEL IDENTIFICATION *Radiology*

DEVICE DESCRIPTION

The DUS-6000 Digital Ultrasonic Diagnostic Imaging System is a portable diagnostic ultrasound system, which applies advanced technologies such as Phased Inversion Harmonic Compound Imaging (eHCI), Double-Beam-Forming (D Beam), Speckle Resistance Imaging (eSRI), scan receiving aperture (SRA) and Spatial Compounding Imaging. Various image parameter adjustments, 12.1 inch LCD and diverse probes are configured to provide clear and stable images. It is intended for diagnostic ultrasound imaging analysis in hospitals and clinics.

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 the following display modes: BB/2B/4B-Mode, M-Mode, B+M Mode or PW Mode. Supported probe types include convex, linear, micro-convex, endocavity (transvaginal, endorectal) probes. The device can detect the probe automatically.

The system consists of 7 major functional blocks, including a main unit, a display subsystem, a transducer and transceiver subsystem, digital beamformer, keyboard and power subsystem.

Predicate Devices: The proposed system model is substantially equivalent to diagnostic ultrasound systems cleared for marketing in the US. The DUS-6000 Ultrasound system is equivalent to the DUS 60 ultrasound system (K131830), manufactured by EDAN Instruments Inc.

Indications for Use: The DUS-6000 Digital Ultrasonic Diagnostic Imaging System is applicable for ultrasound evaluation in hospitals and clinics. It is intended for use in Abdominal, obstetric, gynecology, pediatrics, small parts, urology, peripheral vascular, musculoskeletal (conventional and superficial) and cardiac applications by or on the order of a physician or similarly qualified health care professional.

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) IEC 60601-2-37 Particular 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.
(4) ISO 10993-1, ISO 10993-5 and ISO 10993-10 Biological Evaluation of medical devices

Comparison to the predicate device
The subject device has similar technology characteristics and has the same intended use, same design principle, same electrical classification and same accuracy. There are no differences between the devices that affect the usage, safety and effectiveness. The subject device has the same needle-guide bracket material, property, and sterilization methods as those of the predicate device DUS 60, therefore, the needle-guide bracket will not cause any safety and effectiveness issues.

Substantially Equivalent Determination
This premarket notification submission demonstrates that the DUS-6000 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent to the predicate devices.