



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

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

August 31, 2017

Re: K172055
Trade/Device Name: DUS-7000 Digital Color Doppler Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: June 20, 2017
Received: July 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.

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,

A handwritten signature in blue ink that reads "Robert D. O'Hara". The signature is written over a large, light blue "FDA" watermark. To the right of the signature, the word "For" is printed in black.

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

Enclosure

Indications for Use

510(k) Number (if known)

K172055

Device Name

DUS-7000 Digital Color Doppler Ultrasound System

Indications for Use (Describe)

The DUS-7000 Digital Color Doppler Ultrasound System is a general purpose ultrasonic imaging instruments intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

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.

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Diagnostic Ultrasound Indications for Use Form
DUS-7000 Ultrasonic Diagnostic Imaging System

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2],[3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Note 2,4,5
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Note 2,4
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Note 2,4,6
	Neonatal Cephalic	P	P	P		P	P	Note 1	Note 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Note 2,3,4
	Trans-rectal	P	P	P		P	P	Note 1	Note 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Note 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Note 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Note 2,4
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4,5
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2, 4
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Note 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Note 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	Note 1	Note 2,3,4
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ: breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
DUS-7000 with 2P1 Phase Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2, 4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other(Urology)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
DUS-7000 with 5P1 Phase Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other(Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with C613 Micro-curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	Small Organ (Specify) *								
	Neonatal Cephalic	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	P	P	P	P	Note 1	Notes 2,3,4
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form DUS-7000 with 6V1 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with 6V3 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic	P	P	P		P	P	Note 1	Notes 2,4
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with EC9-5 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form DUS-7000 with BCC9-5 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with BCL10-5 Biplane (Micro-curved + Linear Array) Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-vaginal	P	P	P		P	P	Note 1	Notes 2,4
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form DUS-7000 with C344 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	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 (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form DUS-7000 with C353 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	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 (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

(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-7000 with C542 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	Note 1	Notes 2,4
	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 (Ob/GYN)								
	Other (Urology)	P	P	P		P	P	Note 1	Notes 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form DUS-7000 with C354 Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Note 2,4
	Abdominal	P	P	P		P	P	Note 1	Note 2,4
	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 (Ob/GYN)	P	P	P		P	P	Note 1	Note 2,4
	Other (Urology)	P	P	P		P	P	Note 1	Note 2,4
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with C322 Micro-Curved Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4
	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 (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Diagnostic Ultrasound Indications for Use Form
DUS-7000 with VC6-2 Curved Array Transducer**

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal	P	P	P		P	P	Note 1	Notes 2,4,5
	Abdominal	P	P	P		P	P	Note 1	Notes 2,4,5
	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 (Ob/GYN)	P	P	P		P	P	Note 1	Notes 2,4,5
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with L741 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P	P	P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form DUS-7000 with L742 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with L752 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with 10L1 Linear Array Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	Intra-operative (Specify)								
	Intra-operative (Neurological)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify) *	P	P	P		P	P	Note 1	Notes 2,4,6
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal(Conventional)	P	P	P		P	P	Note 1	Notes 2,4
	Musculo-skeletal (Superficial)	P	P	P		P	P	Note 1	Notes 2,4
	Intravascular								
	Other (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	Notes 2,4
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with MPTEE Phased Array (Multi-Plane) Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	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 (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	P	P	P		P	P	Note 1	Notes 2,3,4
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI Note 4: 3D Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form
DUS-7000 with MPTEE mini Phased Array (Multi-plane) Transducer

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

Clinical Application		Mode of Operation							
General (Track 1 only)	Specific (Tracks 1&3)	B	M	PW	CW	Color	Power	Combined (Specify) ^[1]	Other (Specify) ^{[2][3]}
Ophthalmic	Ophthalmic								
Fetal Imaging and Other	Fetal								
	Abdominal								
	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 (Ob/GYN)								
	Other (Urology)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	P	P	P		P	P	Note 1	Notes 2,3,4
	Intra-cardiac								
	Other (Specify)								
Peripheral Vessel	Peripheral vessel								
	Other (Urology)								

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

Additional comments: Combined mode: B+M

Note 1: Other Combined includes: B/M; B/THI; B/Color Doppler; B/Color Doppler/PWD; B/Power Doppler/PWD

Note 2: Tissue Harmonics, The feature does not use contrast agents

Note 3: TDI

Note 4: 3D

Note 5: 4D

Note 6: Small Organ breast, thyroid, testes

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510K SUMMARY

DUS-7000 Digital Color Doppler Ultrasound 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
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DEVICE NAME AND CLASSIFICATION

TRADE NAME: DUS-7000 Digital Color Doppler Ultrasound System

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
PANEL IDENTIFICATION Radiology

DEVICE DESCRIPTION

The **DUS-7000 Digital Color Doppler Ultrasound System** is an integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The basic principle is that system transmits ultrasonic energy into patient body and implements post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. This system is a Track 3 device that employs a wide array of probes that include linear array, convex array and phased array with a frequency range of 2.0 MHz to 15.0 MHz. This system consists of a mobile console with keyboard control panel, power supply module, color LCD monitor and optional probes. This system is a mobile, general purpose, software controlled, color diagnostic ultrasound system. Its basic function is to acquire ultrasound data and to display the image in B-Mode (including Tissue Harmonic Image), M-Mode, TDI, Color-Flow Doppler, Pulsed Wave Doppler, Continued Wave Doppler and Power Doppler, or the combination of these modes, Elastography, 3D/4D.

Indications for Use: The DUS-7000 Digital Color Doppler Ultrasound System is a general purpose ultrasonic imaging instruments intended for use by a qualified physician for evaluation of Fetal, Abdominal, Pediatric, Small Organ (breast, testes, thyroid), Cephalic (neonatal and adult), Trans-rectal, Trans-vaginal, Peripheral Vascular, Musculo-skeletal (Conventional and Superficial), Cardiac (neonatal and adult), OB/Gyn and Urology.

Predicate Devices: The proposed system is equivalent to the Sonoscape S22 ultrasound system (K142815).

Comparison with the Predicate Devices [21 CFR 807.92(a) (6)]

The DUS-7000 Digital Color Doppler Ultrasound System is comparable with and substantially equivalent to the Sonoscape S22 Digital Color Doppler Ultrasound System. Compared with the Sonoscape S22, the Subject Device DUS-7000 has the same intended uses.

Technical Characteristics Comparison:

The basic and main technical features of the subject device DUS-7000 are the same as the predicated device S22 including Design, Operation Controls, Display Modes, Measurement Items, Cine Loop and Operating and Storage Condition.

Probes Comparison:

Subject device DUS-7000 has the similar probes as the predicated device Sonoscape S22.

Table 1 Probes Comparison

DUS-7000	SONOSCAPE S22	REMARK
C322 Micro-curved Array C344 Curved Array C353 Curved Array C354 Curved Array C542 Curved Array	C322 Micro-curved Array C344 Curved Array C353 Curved Array C354 Curved Array C542 Curved Array	SAME
VC6-2 Curved Array	VC6-2 Curved Array	SAME
C613 Micro-curved Array	C613 Micro-curved Array	SAME
2P1 Phased Array 5P1 Phased Array	2P1 Phased Array 5P1 Phased Array	SAME
L741 Linear Array L742 Linear Array L752 Linear Array 10L1 Linear Array	L741 Linear Array L742 Linear Array L752 Linear Array 10L1 Linear Array	SAME
6V1 Micro-curved Array 6V3 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array)	6V1 Micro-curved Array 6V3 Micro-curved Array EC9-5 Micro-curved Array BCC9-5 Micro-curved Array BCL10-5 Biplane (Micro-curved + Linear Array)	SAME

MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane)	MPTEE Phased Array (Multi-plane) MPTEE mini Phased Array (Multi-plane)	SAME
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EFFECTIVENESS AND SAFETY CONSIDERATIONS

Clinical Test:

Clinical testing is not required.

Non-clinical Test:

The DUS-7000 Digital Color Doppler Ultrasound System has been evaluated for electrical, mechanical, thermal and electromagnetic compatibility safety, biocompatibility and acoustic output. Laboratory tests were conducted to verify that the DUS-7000 system met all design specifications and the DUS-7000 system conformed to applicable medical device standards. Phantom test was conducted to verify that the strain Elastography function was effective and Elastography performance met design specifications, including accuracy and repeatability of strain ratio measurement and etc. The DUS-7000 system has been designed and manufactured to meet the following standards: IEC 60601-1, IEC 60601-1-2, IEC 60601-2-37, ISO 10993-5, ISO10993-10, UD2, and UD3.

Substantially Equivalent Determination

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, thus no new question is raised regarding the safety and effectiveness. In accordance with the 21 CFR Part 807 and based on the information provided in this premarket notification, Advanced Instrumentations concludes that the DUS-7000 Digital Color Doppler Ultrasound System is substantially equivalent to the predicate devices with regards to safety and effectiveness.