APR 1 2 2013

510(k) Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92

Section a):

1. Submitter: Hitachi Aloka Medical Co., Ltd., 10 Fairfield Boulevard, Wallingford, CT 06492

   Contact Person: Angela Van Arsdale, RA/QA Mngr.,
   Tel: (203)269-5088 Ext. 346, Fax: 203-269-6075
   Date Prepared: 7/10/12

2. Device Name: Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System
   Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550 , 90 IYN
   Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90 ITX
   Ultrasonic Pulsed Echo Imaging System., 21 CFR 892.1560, 90 IYO

3. Substantially Equivalent devices: Aloka SSD- Alpha 7 Diagnostic Ultrasound System K072285 for probes and system. Aloka SSD-5500 (K032875), Aloka Prosound F75 (K110207), and Aloka SSD-5000 (K012080) for expanded indications.

4. Device Description: The Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System is a full feature imaging and analysis system. It consist of a mobile console that provides acquisition, processing and display capability. The user interface includes a computer type keyboard, specialized controls and a display.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal, Abdominal, Intra-operative, Intra-operative (Neuro), Laparoscopic, Pediatric, Neonatal Cephalic, Trans-rectal & vaginal, Musculo-skeletal, Gynecological, Cardiac-(Adult, Neonatal, Pediatric), TEE & Peripheral Vascular.
   The device is not indicated for Ophthalmic applications.

6. Comparison w/ Predicate Device:
   The Prosound Alpha 7 Ver. 6.0 is technically comparable and substantially equivalent to the current Aloka SSD- Alpha 7 -(K072285). It has the same technological characteristics, key safety and effectiveness features, and has the same uses and basic operating modes as the predicate device.

Section b):

1. Non-clinical Tests: The device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform with applicable medical device safety standards.

2. Clinical Tests: None Required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer conforms to 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effectiveness performance. Therefore, it is the opinion of Hitachi Aloka Medical, Ltd. that the Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System and its transducers are equivalent with respect to safety and effectiveness to its predicate and other currently cleared Hitachi Aloka Medical systems.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

April 12, 2013

Hitachi Aloka Medical, Ltd. (Hitachi Aloka Medical AMERICA)
% Mr. Michael S. Ogunleye
510(k) Program Manager/Medical Lead Auditor
TUV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

Re: K122537
Trade/Device Name: Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 4, 2013
Received: March 13, 2013

Dear Mr. Ogunleye:

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 Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

UST-533	UST-534
UST-536	UST-547
UST-567	UST-675
UST677P (L&T)	UST-678 (C&L)
UST-984-5	ASU-1010

ASU-1012	ASU-1013
UST-2265-2	UST-2266-5
UST-5045P-3.5	UST-5293-5
UST-5296	UST-5411
UST-5412	UST-5534T-7.5
UST-5536-7.5	UST-5543
UST-5548	UST-5550
UST-5712	UST-5713T
UST-9101-7.5	UST-9104-5
UST-9115-5	UST-9118
UST-9120	UST-9128
UST-9130	UST-9132 I/T
UST-9133	UST-9135P
UST-9136U	UST-9146 I/T
UST-52101	UST-52105
UST-52108	UST-52109
UST-52110S	UST-52114P
UST-52119S	UST-52120S
UST-52121S	UST-52124

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 895. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21

CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K122537

Device Name: Prosound Alpha 7 Ver. 6.0 Diagnostic Ultrasound System

Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal. Abdominal. Intra-operative (Neuro). Laparoscopic. Pediatric. Neonatal Cephalic. Trans-rectal & vaginal. Musculoskeletal. Gynecological. Cardiac (Adult. Neonatal. Pediatric). TEE & Peripheral Vascular.

The device is not intended for ophthalmic applications.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

1.3.1

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	Note 2
	Abdominal	P	P	P		P	Note 1	Note 2
	Intra-operative (Specify)	P	P	P		P	Note 1	
	Intra-operative (Neuro), Burr Hole	N	N	N		N	Note 1	
	Inter-operative, Laparoscopic	N	N	N		N	Note 1	
	Pediatric	N	N	N		N	Note 1	
	Small Organ (Specify)	P	P	P		P	Note 1	Note 2
	Neonatal Cephalic	P	P	P		P	Note 1	Note 2
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal	P	P	P		P	Note 1	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	P	P	P		P	Note 1	Note 2
	Musculo-skeletal (Superfical)							
	Other : Gynecological	P	P	P		P	Note 1	Note 2
Cardiac	Cardiac Adult	P	P	P		P	Note 1	Note 2
	Cardiac Adult, TEE	N	N	N		N	Note 1	Note 2
	Cardiac Pediatric, TEE	N	N	N		N	Note 1	Note 2
	Cardiac Neonatal, TEE	N	N	N		N	Note 1	Note 2
	Cardiac, Pediatric	N	N	N		N	Note 1	Note 2
	Cardiac, Neonatal	N	N	N		N	Note 1	Note 2
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	P	P	P		P	Note 1	Note 2
	Other (Specify)							

N = new indication for system; P= Previously cleared K072285, E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-533

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...),

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-534

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-536

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-547

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic	E	E	E		E	Note 1	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E.= added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-567

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	E	E	E		E	Note 1	
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-675

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

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal	P	P	P		P	Note 1	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared K072285

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST677P (L&T)

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E	Note 1	
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-678 (C&L)

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E	Note 1	
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-984-5

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	Note 1	
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	E	E	E		E	Note 1	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	E	E	E		E	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: ASU-1010

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: ASU-1012

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	Note 1	
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	E	E	E		E	Note 1	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	E	E	E		E	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: ASU-1013

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	E	E	E		E	Note 1	
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-2265-2

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult				E			
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-2266-5

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult				E			
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular				E			
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5045P-3.5

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	E		E	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	E	E	E		E	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5293-5

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**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE	N	N	N		N	Note 1	Note 2
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared-K032875

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD , Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5296

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal	N	N	N		N	Note 1	Note 2
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD , Note 2: B/CWD, B/CD/CWD

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Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5411

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	E	E	E		E	Note 1	
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5412

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	P	P	P		P	Note 1	Note 2
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	P	P	P		P	Note 1	Note 2
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	P	P	P		P	Note 1	Note 2
	Other (Specify)							

P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5534T-7.5

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5536-7.5

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**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic	N	N	N		N	Note 1	
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared-K 032875

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Application: Intra-operative: (liver, pancreas, gall bladder,....)

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Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5543

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	E	E	E		E	Note 1	
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5548

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5550

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic	N	N	N		N	Note 1	
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system;

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Small Organ- (breast, testes, thyroid....).

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Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer; UST-5712

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)	E	E	E		E	Note 1	
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-5713T

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9101-7.5

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric	N	N	N		N	Note 1	
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared K072285, E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9104-5

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic	E	E	E		E	Note 1	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9115-5

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	E		E	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric, Abdominal							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	E	E	E		E	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system;

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9118

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note 1	
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9120

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	P	P	P		P	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic	P	P	P		P	Note 1	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

P= Previously cleared K072285,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9128

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	E		E	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric, Abdominal							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system;

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9130

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P		P	Note 1	Note 2
	Abdominal	P	P	P		P	Note 1	Note 2
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	P	P	P		P	Note 1	Note 2
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

P= Previously cleared K072285

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9132 I/T

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular	E	E	E		E	Note 1	
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9133

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	E	E	E		E	Note 1	
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9135P

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	Note 1	
	Abdominal	E	E	E		E	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	E	E	E		E	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9136U

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	E	E	E		E	Note 1	
	Abdominal	E	E	E		E	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E		E	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological	E	E	E		E	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-9146 I/T

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)	E	E	E		E	Note 1	
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52101

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult	P	P	P		P	Note 1	Note 2
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

P= Previously cleared K072285

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52105

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult	E	E	E	E	E	Note 1	Note 2
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52108

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**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric	N	N	N	N	N	Note 1	Note 2
	Cardiac, Neonatal	N	N	N	N	N	Note 1	Note 2
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared K032875

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...), Small Organ- (breast, testes, thyroid....).

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52109

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic	N	N	N		N	Note 1	
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared-K032875

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Applications:- Intra-operative- (liver, pancreas, gall bladder, ...)

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52110S

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE	N	N	N	N	N	Note 1	Note 2
	Cardiac Neonatal, TEE	N	N	N	N	N	Note 1	Note 2
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system;

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD , Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52114P

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**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole	N	N	N		N	Note 1	
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52119S

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE	N	N	N	N	N	Note 1	Note 2
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system , P= Previously cleared-K110207

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD , Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52120S

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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal	N	N	N		N	Note 1	Note 2
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared K032875, E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD , Note: 2 : B/CWD, B/CD/CWD

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Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound Alpha 7 Ver. 6.0
Transducer: UST-52121S

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**	**PWD**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric							
	Cardiac, Neonatal	N	N	N		N	Note 1	Note 2
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared K110207, E = added to Alpha 7 under Appendix E,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD , Note 2: B/CWD, B/CD/CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: **Prosound Alpha 7 Ver. 6.0**
Transducer: UST-52124

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 D**	**CWD**	**Color Doppler**	**Combined (Specify)**	**Other (Specify)**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro), Burr Hole							
	Inter-operative, Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superfical)							
	Other : Gynecological							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac Pediatric, TEE							
	Cardiac Neonatal, TEE							
	Cardiac, Pediatric	N	N	N		N	Note 1	Note 2
	Cardiac, Neonatal							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vascular							
	Other (Specify)							

N = new indication for system; P= Previously cleared K110207,

Combined: Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)
Prescription Use (Per 21 CFR 801.109)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

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Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health