K 123828

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

JAN 18 2013

Section a):

1. Submitter's contact name, address, telephone/fax number

Angela Van Arsdale
RA/QA Manager
Hitachi Aloka Medical, Ltd.,
10 Fairfield Boulevard
Wallingford, CT 06492
Tel: (203)269-5088 Ext. 346
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Date Prepared: 12/10/2012

2. Device Name: Prosound F75 Diagnostic Ultrasound System

90 IYN - Ultrasonic Pulsed Doppler Imaging System	21 CFR 892.1550
90 ITX - Transducer Ultrasonic, Diagnostic	21 CFR 892.1570
90 IYO - Ultrasonic Pulsed Echo Imaging System	21 CFR 892.1560

3. Substantially Equivalent Devices:

Aloka Prosound F75 Diagnostic Ultrasound System, (K110207), for system & probes.
Aloka SSD-5000 V 5.0 Ultrasound System, (K033311), for expanded indications.
Aloka SSD-5500 V6.0 Diagnostic Ultrasound System, (K032875), for expanded indications.

4. Device Description:

The Prosound F75, formerly named Aloka Prosound F75, 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. The changes made to the Prosound F75 are the expanded indications: Adult/ Pediatric Cardiac- TEE, Neonatal/Pediatric, Cardiac, Intra-operative Neurosurgery, and Trans-esoph (non-cardiac).

5. Indications for Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Intra-operative; Intra-operative (Neurosurgery); Pediatric; Small Organ; Neonatal Cephalic; Trans-rectal; Trans-vaginal; TEE (non-cardiac); Musculo-skeletal; Cardiac Adult; Cardiac, Adult -TEE; Cardiac - Neonatal; Cardiac - Pediatric; Cardiac Pediatric, TEE; Peripheral Vascular; and Gynecological applications. The device is not indicated for Ophthalmic applications.

6. Comparison w/ Predicate Device:

The Prosound F75 with expanded indications is technically comparable and substantially equivalent to the current Aloka Prosound F75 (K110207) and to the above mentioned predicates. They are Track 3 systems that employ the same fundamental and scientific technology.

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Section b):

1. Non-clinical Tests:

No new hazards were identified with the addition of the added Indications. The clinical safety and effectiveness of the system and transducers have been identified in the previous Aloka Prosound F75 submission (K110207), with the above predicates as well as this submission. The clinical safety and effectiveness of the added indications are well accepted for use with ultrasound systems including the predicate device, Aloka Prosound F75 (K110207).

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:

The Hitachi-Aloka Medical, Ltd.'s Prosound F75 with expanded indications is substantially equivalent in safety and effectiveness to the predicates identified above;

- The predicate device(s) and the Prosound F75 with expanded indications are indicated for diagnostic ultrasound imaging and fluid flow analysis,
- The predicate device(s) and the Prosound F75 with expanded indications have the same gray scale and Doppler capabilities,
- The predicate device(s) and the Prosound F75 with expanded indications use essentially the same technologies for imaging, Doppler functions and signal processing,
- The predicate device(s) and the Prosound F75 with expanded indications have acoustic output levels below the Track 3 FDA limits,
- The predicate device(s) and the Prosound F75 with expanded indications are manufactured under equivalent quality and manufacturing systems,
- The predicate device(s) and the Prosound F75 with expanded indications are manufactured of materials equivalent bio safety. The materials have been evaluated and found to be safe for this application,
- The predicate device(s) and the Prosound F75 with expanded indications are designed and manufactured to the same electrical and physical safety standards.

Note: The Hitachi-Aloka Medical, Ltd. Ultra-Sound System naming convention for this device can be identified as Aloka Prosound F75 or Prosound F75; both trade names reference the same device. The trade name, Aloka Prosound F75, listed within K110207 was modified to Prosound F75 prior to this premarket 510(K) submission and may be identified as "Prosound F75, formerly named Aloka Prosound F75" within the text of this submission. All the device instruction and operator manuals, advertisement and promotional materials, and labeling will identify the device as Prosound F75. The naming convention change is simply a marketing decision and not indicative of a separate device or any design modifications other than the modifications described with the body of this submission.

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

January 18, 2013

Hitachi Aloka Medical, Ltd.
c/o Ms. Angela Van Arsdale
RA/QA Manager
10 Fairfield Blvd.
WALLINGFORD CT 06492

Re: K123828
Trade/Device Name: Prosound F75
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, ITX, and IYO
Dated: December 10, 2012
Received: December 12, 2012

Dear Ms. Arsdale:

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.

This determination of substantial equivalence applies to the Prosound F75 and the following transducers intended for use with the Prosound F75 Ultrasonic pulsed Doppler Imaging System, as described in your premarket notification:

Transducer Model Number			
UST-567	UST-5293-5	UST-9130	UST-52114P
UST-675P	UST-5411	UST-9132 I & T	UST-52119S
UST-677P	UST-5415	UST-9133	UST-52121S
UST-678	UST-5417	UST-9135P	UST-52124
ASU-1010	UST-5419	UST-9146 I & T	GF-UE160 AL5
ASU-1012	UST-5713T	UST-9147	GF-UCT180
ASU-1013	UST-9115-5	UST-52105	BF-UC180F
UST-2265-2	UST-9118	UST-52110S	TGF-UC180
UST-2266-5	UST-9120	UST-52120S	

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 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.

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

Sincerely yours,

Sean M. Boyd -S for

Janine Morris
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):

Device Name: Prosound F75

Indications For Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Intra-operative; Intra-operative (Neurosurgery); Pediatric; Small Organ; Neonatal Cephalic; Trans-rectal; Trans-vaginal; TEE (non-cardiac); Musculo-skeletal; Cardiac Adult; Cardiac, Adult –TEE; Cardiac - Neonatal; Cardiac - Pediatric; Cardiac Pediatric, TEE; Peripheral Vascular; and Gynecological applications. The device is not indicated for Ophthalmic applications.

Prescription Use ___√___ **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 Device Evaluation

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75

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)*	P	P	P		P	Note 1	
	Intra-operative (Neurosurgery)	N	N	N		N	Note 1	
	Laparoscopic							
	Pediatric	N	N	N		N		
	Small Organ (Specify)*	P	P	P	N	P	Note 1,2	
	Neonatal Cephalic	P	P	P		P	Note 1	
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note 1	
	Trans-vaginal	P	P	P		P	Note 1	
	TEE (non cardiac)	N	N	N		N	Note 1	
	Musculo-skeletal (Convent.)	P	P	P		P	Note 1	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac, Adult	P	P	P	P	P	Note 1, 2	
	Cardiac Adult, TEE	N	N	N	N	N	Note 1, 2	
	Cardiac- Neonatal	N	N	N	N	N	Note 1, 2	
	Cardiac- Pediatric	N	N	N	N	N	Note 1, 2	
	Cardiac Pediatric, TEE	N	N	N	N	N	Note 1, 2	
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P	N	P	Note 1,2	
	Other: Gynecological	P	P	P		P	Note 1	

N = new indication; P= previously cleared by FDA-(K110207); E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Note 3: Specification for "Other" Airways, Tracheobronchial tree, Gastrointestinal Tract and Surrounding Organs
***Applications: Small Parts – (breast, testes, & thyroid…), Intra-operative – (liver, pancreas, gall bladder…)**
Other:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	P	P	P		P	See note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)	P	P	P		P	See note 1	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	See note 1	
	Other: Gynecological							

P= previously cleared by FDA-(K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
***Applications: Small Parts – (breast, testes, & thyroid…), Intra-operative – (liver, pancreas, gall bladder…)**
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
Transducer: UST-675P

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	See note 1	
	Trans-vaginal	P	P	P		P	See note 1	
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
Transducer: UST-677P

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E		
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Prescription Use (Per 21 CFR 801.109)

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
Transducer: UST-678

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	E	E	E		E		
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological	P	P	P		P	Note 1	

P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123528

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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				
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	E	E	E				
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological	E	E	E				

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)	E	E	E				
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult				P			
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other :Gynecological							

N = new indication; P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult				P			
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular				P			
	Other :Gynecological							

P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other :

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1, 2	
	Cardiac Adult, TEE	N	N	N	N	N	Note 1, 2	
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication; P = previously cleared by FDA -(K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	P	P	P		P	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)	P	P	P		P	Note 1	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	Note 1	
	Other :Gynecological							

N = new indication; P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
*Applications: Small Parts: (breast, testes, & thyroid…)
Other:

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Prescription Use (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
Transducer: UST-5415

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	P	P	P		P	Note 1	
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)	P	P	P		P	Note 1	
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	P	P	P		P	Note 1	
	Other: Gynecological							

P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
***Applications: Small Parts – (breast, testes, & thyroid…), Intra-operative – (liver, pancreas, gall bladder…)**
Other:

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
Transducer: UST-5417

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)*	E	E	E				
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	E	E	E				
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
***Applications: Small Parts – (breast, testes, & thyroid…), Intra-operative – (liver, pancreas, gall bladder…)**
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
Transducer: UST-5419

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				
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular	E	E	E				
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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				
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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				
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological	E	E	E				

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note 1	
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological	P	P	P		P	Note 1	

P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)	E	E	E				
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic	E	E	E				
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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	
	Abdominal	P	P	P		P	Note 1	
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological	P	P	P		P	Note 1	

N = new indication; P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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				
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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							
	Intra-operative (Specify)*	P	P	P		P	Note 1	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic	P	P	P		P	Note 1	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

P= Previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
*Applications: Intra-operative – (liver, pancreas, gall bladder…)
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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							
	Abdominal	E	E	E				
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Prescription Use (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)	P	P	P	P		Note 1	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD . Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
Transducer: UST-9147

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological	P	P	P		P	Note 1	

P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult	P	P	P	P	P	Note 1 & 2	
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Prescription Use (Per 21 CFR 801.109)

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal	N	N	N				
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal	E	E	E	E	E	Note 1 & 2	
	Cardiac Pediatric	E	E	E	E	E	Note 1 & 2	
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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 (Neurosurgery)	N	N	N				
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE	N	N	N	N		Note 1, 2, 3	
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Note 3: Cardiac, Pediatric cleared by FDA – (K110287)
Other:

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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 (Neurosurgery))							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE	N	N	N	N	N	Note 1,2, 3	
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Note 3: Cardiac, Pediatric cleared by FDA – (K110287)
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
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	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic	P	P	P	P	P	Note 1, 2	
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)							
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal	P	P	P	P	P	Note 1, 2	
	Cardiac-Pediatric	N	N	N	N	N	Note 1, 2	
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication; P= previously cleared by FDA- (K110207)
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2: B/CWD, B/CD/CWD
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Prosound F75
Transducer: GF-UE160 AL5

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)	P	P	P		P	Note 1	
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)	P	P	P		P	Note 1	
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
	Others (Specify) Note 2	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication; P= previously cleared by FDA via K051541; E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD Note 2:
Specification for "Other" Airways, Tracheobronchial tree, Gastrointestinal Tract and Surrounding
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123528

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus Endoscope for use with Aloka Ultrasound System
Transducer: GF-UCT180

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)	P	P	P		P	Note 1	
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
	Others (Specify) Note 2	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication; P= previously cleared by FDA K093395; E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Note 2: Specification for "Other" Gastrointestinal Tract and Surrounding Organs
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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Office of In Vitro Diagnostics and Radiological Health

510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus Endoscope for use with Aloka Ultrasound System
Transducer: BF-UC180F

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)	P	P	P		P	Note 1	
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
	Others (Specify) Note 2	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication; P= previously cleared by FDA K070983; E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, B/CD/PWD;
Note 2: Specification for "Other" Airways, Tracheobronchial tree
Other:

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510(k) K123828

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: Olympus Endoscope for use with Aloka Ultrasound System
Transducer: TGF-UC180J

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)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	TEE (non-Cardiac)	P	P	P		P	Note 1	
	Musculo-skeletal (Convent.)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Intra-luminal							
	Other (Specify) Note 2	P	P	P		P	Note 1	
Cardiac	Cardiac Adult							
	Cardiac Adult, TEE							
	Cardiac- Neonatal							
	Cardiac Pediatric, TEE							
	Intravascular (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral Vascular							
	Other: Gynecological							

N = new indication; P= previously cleared by FDA K093395; E=added under Appendix E
Combination of each operating mode includes: Note 1: B/M, B/PWD, M/CD, B/CD/PWD
Note 2: Specification for "Other" Gastrointestinal Tract and Surrounding Organs
Other:

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Concurrence of CDRH, Office of Device Evaluation (ODE)
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