

K110267

FEB 17 2011

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

Section a):

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

Contact Person: Richard J. Cehovsky, RA/QA Mngr.,
Tel: (203)269-5088 Ext. 346, Fax: 203-269-6075

Date Prepared: 11/24/2010

2. Device Name: Aloka Prosound F75 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. Marketed Device: Aloka Alpha 10 Diagnostic Ultrasound System, K043196, (90-IYN, ITX, IYO)
(A device currently in commercial distribution)

4. Device Description: The 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.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Small Parts, Abdominal, Cardiac, Peripheral Vascular, Fetal, Intra-operative, Trans-vaginal, Trans-rectal, Gynecological, Musculo-skeletal and Neonatal Cephalic applications. The device is not indicated for Ophthalmic applications.

6. Comparison w/ Predicate Device:

The Aloka Prosound F75 is technically comparable and substantially equivalent to the current Aloka Alpha 10-(K043196). It has the same technological characteristics, key safety and effectiveness features, and has the same intended 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 confirms with 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 Aloka Co., Ltd. that the Aloka Prosound F75 Diagnostic Ultrasound System and its transducers are substantially equivalent with respect to safety and effectiveness to its predicate and other currently cleared Aloka systems.

1.3.2 New Indications for Use: There are no new indications for use.

1.3.3 Previously Cleared Indications for Use:

The Prosound F75 diagnostic ultrasound system and its transducers are intended for use in diagnostic ultrasound examinations. These ultrasound applications and indications for use include: Small Parts, Intra-operative, Abdominal, Gynecological, Cardiac, Musculo-skeletal, Transrectal, Transvaginal, Neonatal Cephalic, Fetal & Peripheral Vascular.

The Prosound F75 has the same indications for use as its predicate – Aloka Alpha 10- (K043196) and other market cleared systems and transducers manufactured by Aloka.

Promotional information for the Prosound F75 is provided in Appendix D of this submission.



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

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

FEB 17 2011

Re: K110207
Trade/Device Name: Aloka Prosound F75
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: January 14, 2011
Received: January 25, 2011

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 the Aloka Prosound F75, as described in your premarket notification:

Transducer Model Number

UST-567
UST-675P
ASU-1010
UST-2265-2
UST-2266-5
UST-5293-5

UST-5411
UST-5415
UST-9118
UST-9130
UST-9133
UST-9146I

UST-9146T
UST-9147
UST-52105
UST-52119S
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.

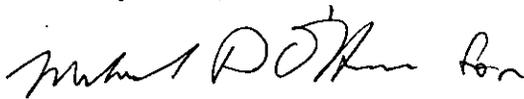
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Lauren Hefner at (301) 796-6881.

Sincerely Yours,



Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(K) Number (if known):

Device Name:

Aloka Prosound F75

Indications For Use:

The device is intended for use by a qualified physician for ultrasound evaluation of Small Parts, Abdominal, Cardiac, Peripheral Vascular, Fetal, Intra-operative, Trans-vaginal, Trans-rectal, Musculo-skeletal, Gynecological and Neonatal Cephalic applications.

The device is not indicated for Ophthalmic applications.

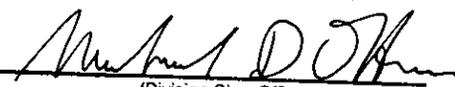
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

Page 1 of 1

510K K110207

1.3.1

**Diagnostic Ultrasound Indications for Use Form
Prosound F75**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N			See Note 1	
Abdominal		N	N	N		N			See Note 1	
Intra-operative (specify)		N	N	N		N			See Note 1	
Intra-operative Neurological										
Pediatric										
Small Organ (specify)		N	N	N		N			See Note 1	
Neonatal Cephalic		N	N	N		N			See Note 1	
Adult Cephalic										
Cardiac		N	N	N	N	N			See Note 1, 2	
Transesophageal										
Transrectal		N	N	N		N			See Note 1	
Transvaginal		N	N	N		N			See Note 1	
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N			See Note 1	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N				
Musculo-skeletal Superficial										
Other: Gynecological		N	N	N		N			See Note 1	

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

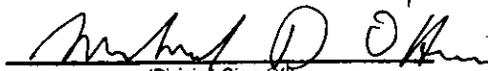
Additional Comments: Mixed mode operation includes: Note 1- B/M, B/PWD, M/CD, B/CD/PWD, Note 2- B/CWD, B/CD/CWD

Applications: Small Parts-(breast, testes & thyroid..), Intra-operative- (liver, pancreas, gall bladder..)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110207

**Diagnostic Ultrasound Indications for Use Form
UST-567
(K041916)**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		N	N	N		N			See Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N			See Note 1	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N			See Note 1	
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications: Small Parts: (breasts, testes, thyroid....)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)


(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110207

**Diagnostic Ultrasound Indications for Use Form
UST-675P
(K992663)**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		P	P	P		P			See Note 1	
Transvaginal		P	P	P		P			See Note 1	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological										

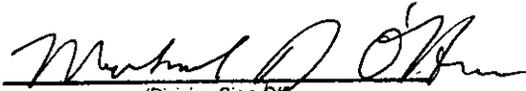
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Prescription Use (Per 21 CFR 801.109)



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Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110207

Diagnostic Ultrasound Indications for Use Form
ASU-1010
(K043196)

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P			See Note 1	
Abdominal		P	P	P		P			See Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal-										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P		P			See Note 1	

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

Additional Comments: Combined includes Note 1: B/M, B/PWD, M/CD, B/CD/PWD

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Prescription Use (Per 21 CFR 801.109)

[Signature]
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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110227

**Diagnostic Ultrasound Indications for Use Form
UST-2265-2
(K012080)**

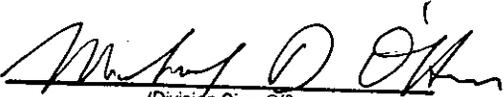
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					P					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

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

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


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510K K110207

Diagnostic Ultrasound Indications for Use Form
UST-2266-5
(K963616)

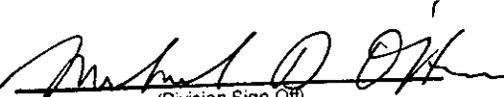
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac					N					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

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

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


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510K K110207

**Diagnostic Ultrasound Indications for Use Form
UST-5293-5
(K003739)**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P			See Note 1, 2	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes 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)


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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110207

Diagnostic Ultrasound Indications for Use Form
UST-5411
(K043196)

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	P		P			See Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P			See Note 1	
Laparoscopic										
Musculo-skeletal Conventional		P	P	P		P			See Note 1	
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications: Small Parts: (breasts, testes, thyroid....)

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Prescription Use (Per 21 CFR 801.109)


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 Office of In Vitro Diagnostic Device Evaluation and Safety

**Diagnostic Ultrasound Indications for Use Form
UST-5415
(K043196)**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		N	N	N		N			See Note 1	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N	N		N			See Note 1	
Laparoscopic										
Musculo-skeletal Conventional		N	N	N		N			See Note 1	
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes Note 1: B/M, B/PWD, M/CD, B/CD/PWD

Applications: Small Parts: (breasts, testes, thyroid....)

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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 Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

510K

K110207

**Diagnostic Ultrasound Indications for Use Form
UST-9118
(K992663)**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P			See Note 1	
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal		P	P	P		P			See Note 1	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P		P			See Note 1	

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

Additional Comments: Combined includes: 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)


(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110207

**Diagnostic Ultrasound Indications for Use Form
UST-9130
(K043196)**

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

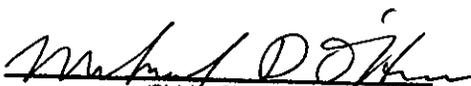
Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P		P			See Note 1	
Abdominal		P	P	P		P			See Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		P	P	P		P			See Note 1	

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

Additional Comments: Combined includes: 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)


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 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

**Diagnostic Ultrasound Indications for Use Form
UST-9133
(K060059)**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		P	P	P		P			See Note 1	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		P	P	P		P			See Note 1	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes-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)


(Division Sign-Off)

Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K: K110207

Diagnostic Ultrasound Indications for Use Form
UST-9146I
(K963616)

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		N	N	N		N			See Note 1	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes-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)


 (Division Sign-Off)

Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

**Diagnostic Ultrasound Indications for Use Form
UST-9146T
(K963616)**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		N	N	N		N			See Note 1	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes 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)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110207

Diagnostic Ultrasound Indications for Use Form
UST-9147
(K043196)

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N	N		N			See Note 1	
Abdominal		N	N	N		N			See Note 1	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other: Gynecological		N	N	N		N			See Note 1	

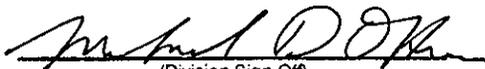
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Combined includes: 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)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

Diagnostic Ultrasound Indications for Use Form
UST-52105
(K032875)

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N	N	N			See Note 1, 2	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes 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)


 (Division Sign-Off)

Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K 15110207

**Diagnostic Ultrasound Indications for Use Form
UST-52124
(K032875)**

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

Clinical Application	Modes of operation									
	A	B	M	PWD	CWD	Color Doppler (CD)	Amplitude Velocity	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		N	N	N	N	N			Note 1, 2	
Adult Cephalic										
Cardiac (Neonatal)		N	N	N	N	N			Note 1, 2	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other:										

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

Additional Comments: Combined includes 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)


 (Division Sign-Off)
 Division of Radiological Devices
 Office of In Vitro Diagnostic Device Evaluation and Safety

510K K110207