

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

DEC 8 - 2003

Mr. Richard J. Cehovsky
RA/QA Coordinator
Aloka Co., Ltd.
10 Fairfield Boulevard
WALLINGFORD CT 06492-7502

Re: K033311

Trade/Device Name: Aloka SSD-5000 V5.0 Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.1560

Regulation Name: Ultrasonic pulsed echo imaging system

Regulation Number: 21 CFR 892.1570

Regulation Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: November 11, 2003 Received: November 17, 2003

Dear Mr. Cehovsky:

This letter corrects our substantially equivalent letter of October 29, 2003 regarding the Aloka SSD-5000 V5.0 Ultrasound System. Transducer Model Number: UST-52109 located on page 69 of the original 510(k) was inadvertently omitted from the list below and is now being added.

Transducer Model Numbers

ASU-67-10/7.5	<u>UST-5281-5</u>	UST-5712
UC140P-AL5	UST-5284-2.5	UST-5713T
<u>UCT140-AL-5</u>	UST-5285-3.5	UST-9101-7.5
<u>UST-533</u>	UST-5293-5	UST-9102-3.5
<u>UST-547</u>	UST-5294-5	UST-9104-5
UST-672-5/7.5	UST-5296	UST-9114-3.5
UST-675P	UST-5297	UST-9115-5
UST-995-7.5	UST-5524-5	UST-9118
UST-987-7.5	UST-5524-7.5	UST-9119
ASU-1000C-3.5	UST-5526L-7.5	UST-9120
ASU-1001	UST-5531	UST-9121
ASU-1002	UST-5534T-7.5	UST-9126
ASU-1005	UST-5536-7.5	UST-9128
UST-2265-2	UST-5539-7.5	UST-52104
UST-5268P-5	UST-5543	UST-52104
UST-5271S-5	UST-5545	UST-52109
UST-5280-5	UST-5548	UST-MC11-8731
	337 33 10	<u>051-141C11-0/31</u>

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 (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.

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 <u>Federal Register</u>.

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 continue marketing your device as described in your Section 510(k) 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 the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for <u>in vitro</u> diagnostic devices), please contact the Office of Compliance at (301) 594-4654. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mancy C Brogdon
Nancy C. Brogdon

Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

4.3.1

Diagnostic Ultrasound Indications for Use Form

SSD-5000 V5.0

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

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

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWDIntraoperative applications: include liver, pancreas and gall bladder. Small parts applications include breast testes and thyroid.

David a. Legen	Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)	Prescription Use (Per 21 CFR 801.109)
Division of Reproductive, Abdominal,	
and Radiological Devices is MA n O.	\\\ 19
510(k) Number)//

ASU-67-10/7.5

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

	Modes of operation										
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify	
Opthalmic											
Fetal .											
Abdominal											
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal											
Transrectal		P	P	P		P	P		See Below		
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

David a Segrapm	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	
Division of Reproductive, Abdomi	nal,
and Radiological Devices KO2	03311

UC140P-AL5

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

	Modes of operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify	
Opthalmic											
Fetal .										,	
Abdominal		· P	P	. P		P	Р.		See Below		
Intraoperative (specify)		P	P	P		P	Р		See Below		
Intraoperative Neurological											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Transesophageal		Р	P	P		Р	Р		See Below		
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Intraoperative applications: liver, pancreas and gall bladder

David a. Legum	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off) Division of Reproductive, Abdomin	nal
and Radiological Devices 1200/ 510(k) Number	3311

UCT140-AL-5

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

	Modes of operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Opthalmic											
Fetal _											
Abdominal		P	P	P		P	P		See Below		
Intraoperative (specify)		P	P	P		P	Р		See Below		
Intraoperative Neurological								/			
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac					,						
Transesophageal		P	P	P		P	P		See Below		
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Intraoperative applications: include liver, pancreas and gall bladder.

David de Symm	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Olyloid Sidu-Off)	
Division - (D	nal
and Radiological Devices	idi,
and Radiological Devices, Abdomic 510(k) Number	311

UST-533

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

	Modes of operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify
Opthalmic										
Fetal .						 				
Abdominal										
Intraoperative (specify)		Е	E	Е		E	E		See Below	
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: Mixed mode operation includes B/M, B/PWD,B/Bflow?PWD

Intraoperative applications: liver, pancreas and gall bladder.

(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 Reproductive, Abdominal, and Radiological Devices 10(k) Number	Division of Day	/		11

UST-547

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

	Modes of operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify	
Opthalmic											
Fetal .											
Abdominal											
Intraoperative (specify)		E	Е	Е		Е	Е		See Below		
Intraoperative Neurological											
Pediatric						-					
Small Organ (specify)		Е	Е	Е		Е	Е		See Below		
Neonatal Cephalic		Е	Е	Е		Е	Е		See Below		
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD. Intraoperative applications: include liver, pancreas and gall bladder. Small Organ applications: breast, testes, thyroid

Earin a Segonn	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off) Division of Reproductive, Abdom and Radiological Devices 510(k) Number	

UST-672-5/7.5

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

	Modes of operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)		Р	P	P		P	P		See Below			
Intraoperative Neurological												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic				-								
Cardiac												
Transesophageal												
Transrectal		P	Р	Р		Р	Р		See Below			
Transvaginal										1		
Transurethral												
Intravascular								ANADOS CONTRACTOR CONT				
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Intraoperative applications: abdominal, bladder, pancreas and gall bladder.

Said a Segmon	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	AND
Division of Poproductive At 4	าลไ
and Radiological Devices 510(k) Number	
510(k) Number KD	55511 25

UST-675P

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal _												
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal		P	P	P		Р	P		See Below			
Transvaginal		P	. Р	P		Р	Р		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

KO33311

UST-995-7.5

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

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic 2													
Fetal .													
Abdominal													
Intraoperative (specify)		P	P	P		P	P	******************	See Below				
Intraoperative Neurological													
Pediatric													
Small Organ (specify)		P	P	P		P	P		See Below				
Neonatal Cephalic													
Adult Cephalic													
Cardiac										· · · · · · · · · · · · · · · · · · ·			
Transesophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral Vascular		P	P	P		P	Р		See Below				
Laparoscopic					1			***************************************					
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other													

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD.

Applications: Intraoperative: liver, pancreas and gall bladder. Small Organ: breast, testes, thyroid. (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Janil a Sym	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
Division Sign-Off) Division of Reproductive Abd	
and Radiological Devices KO	32311

UST-987-7.5

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify		
Opthalmic									-			
Fetal												
Abdominal												
Intraoperative (specify)		Р	P	P		P	Р		See Below			
Intraoperative Neurological												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic		P	P	P		P	Р		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Intraoperative applications: include liver, pancreas and gall bladder.

David G. Legum	Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)	Prescription Use (Per 21 CFR 801.109)
Division of Reproductive, Abdomin	nal,
and Radiological Devices K 0 (510(k) Number	33311

ASU-1000C-3.5

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify		
Opthalmic												
Fetal .		P	P.	P		P	P		See Below			
Abdominal		P	P	P		P	P		See Below	·		
Intraoperative (specify)												
Intraoperative Neurological								-				
Pediatric												
Small Organ (specify)												
Neonatal Cephalic				<u> </u>								
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

(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)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

ASU-1001

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

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify			
Opthalmic													
Fetal -		Р	P	P		P	P		See Below				
Abdominal		P	P	Р		Р	P		See Below				
Intraoperative (specify)													
Intraoperative Neurological													
Pediatric													
Small Organ (specify)			<u> </u>		\								
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

(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)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

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

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify			
Opthalmic													
Fetal .		Р	P	P		P	P		See Below				
Abdominal													
Intraoperative (specify)													
Intraoperative Neurological			-										
Pediatric										`			
Small Organ (specify)													
Neonatal Cephalic													
Adult Cephalic													
Cardiac													
Transesophageal													
Transrectal													
Transvaginal		P	P	Р		Р	P		See Below				
Transurethral													
Intravascular													
Peripheral Vascular					,			(
Laparoscopic		-											
Musculo-skeletal Conventional									,				
Musculo-skeletal Superficial		1											
Other	,												

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

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

	Concurrence of CDRH, Office of Device Evaluation (ODE)
1/2:10	Prescription Use (Per 21 CFR 801.109)
David a Seyonn	
(Division Sign-Off)	
Division of Reproductive Abdom	t

and Radiological Devices KO

ASU-1005

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

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

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

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

Λ	Concurrence of CDRH, Office of Device Evaluation (OD
6/10/	Prescription Use (Per 21 CFR 801.109)
Division Sign Off	**** - '
(Division Sign-Off)	

Division of Reproductive, Abdominal, and Radiological Devices

510(k) Number ____ K033311

UST-2265-2

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

Clinical Application	Modes of operation												
	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal													
Abdominal													
Intraoperative (specify)								4					
Intraoperative Neurological													
Pediatric													
Small Organ (specify)													
Neonatal Cephalic								,					
Adult Cephalic													
Cardiac					P				See Below				
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

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

	Concurrence of CDRH, Office of Device Evaluation (ODE)
David a Segonn	
(Division Sign-Off)	
Division of Reproductive, Abdomir	nal,

and Radiological Devices 103331

UST-5268P-5

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

					N	lodes of ope	eration			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify
Opthalmic										
Fetal .										
Abdominal						,		***************************************		
Intraoperative (specify)		P	P	P	, ' '	P	Р		See Below	
Intraoperative Neurological		P	P	Р		P	P		See Below	
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		P	P	P		P	P		See Below	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal							·			
Transurethral							-			,
Intravascular				,						
Peripheral Vascular							`			`.
Laparoscopic					3					
Musculo-skeletal Conventional										
Musculo-skeletal Superficial	,									
Other										

in- new indication; P- previously cleared by FDA; E= added under	Appendix E
Additional Comments: Mixed mode operation includes B/M, B/PWD	, B/Bflow/PWD

Applications: Neurological burr hole, Intraoperative: liver, pancreas, gall bladder.

	The state of the s
David a Segum	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	(
Division of Reproductive, Abdomina	al,
and Radiological Devices 100 2	53311

UST-5271S-5

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

Clinical Application	Modes of operation											
	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Othe (specif		
Opthalmic												
Fetal												
Abdominal	-											
Intraoperative (specify)												
Intraoperative Neurological	-											
Pediatric		P	P	Р		P	P		See Below			
Small Organ (specify)	-											
Neonatal Cephalic												
Adult Cephalic												
Cardiac		P	P	P		P	P		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

David Q Sens	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off) Division of Reproductive, A and Radiological Devices 510(k) Number	bdominal, (V.03331)

UST-5280-5

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

			LIL		N	lodes of ope	eration			·
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify
Opthalmic									· ·	
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P		P	P		See Below	
Transesophageal		P	P	P		P	P		See Below	
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal,
and Radiological Devices (10000)
510(k) Number

UST-5281-5

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify		
Opthalmic												
Fetal												
Abdominal			1									
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic		P	P	P		Р	P		See Below	,		
Adult Cephalic							-					
Cardiac		P	P	P		P	P		See Below			
Transesophageal								1				
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

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David a begom	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	
Division of Reproductive, Abdomi	nal.
and Radiological Devices 1/10	2021
510(k) Number	37

UST-5284-2.5

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (specify)										-		
Neonatal Cephalic												
Adult Cephalic												
Cardiac		P	P	P	P	P	P		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

	Concurrence of CDRH, Office of Device Evaluation (ODE)
David a Segom	` ,
Dam 18 Aldren	
(Division Sign-Off)	
Division of Reproductive, Abdomi	nal,
and Radiological Devices U	88311
E10/6/ Number	30

Diagnostic Ultrasound Indications for Use Form UST-5285-3.5

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal .												
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic		,		,				The state of the s				
Adult Cephalic												
Cardiac		P	P	P	P	P	P	· P. S. I Sec. And Approximately	See Below			
Trausesophageal												
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

(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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mod A Somm	

Division Sign-Off) Division of Reproductive, Abdominal, and Radiological Devices KD333

510(k) Number __

UST-5293-5

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac		P	P	P		P	P		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

//	oncurrence of CDRH, Office of Device Evaluation (ODE)
Downed a Segmen	Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	
Division of Reproductive, Abdominal,	
and Radiological Devices K0333	40

UST-5294-5

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

	Modes of operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify		
Opthalmic 2												
Fetal ·												
Abdominal												
Intraoperative (specify)									×			
Intraoperative Neurological												
Pediatric						, , , , , , , , , , , , , , , , , , ,						
Small Organ (specify)												
Neonatal Cephalic		P	P	P		P	P		See Below			
Adult Cephalic												
Cardiac		P	P	P		P	P		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Neonatal

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

David a. Segum	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
Prinsion Sign-Off)	Memoralization of the gas constructed for the construction of the production of the construction of the co
Division of Reproductive, Abdominal	

and Radiological Devices KD33311
510(k) Number

UST-5296

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

					N	lodes of ope	eration			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify
Opthalmic										
Fetal .										
Abdominal										,
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		P	Р	P		P	P		See Below	
Adult Cephalic										
Cardiac		P	P	P		P	P		See Below	
Transesophageal										
Transrectal										-
Transvaginal								-		
Transurethral										
Intravascular										
Peripheral Vascular						i				
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Neonatal

510(k) Number ____

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

	Concurrence of CDRH, Office of Device Evaluation (ODE)
David a Segmon	Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	
Division of Reproductive, Abdomin	le
and Radiological Dovings	idi _e

UST-5297

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic						,						
Fetal												
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (specify)				-								
Neonatal Cephalic												
Adult Cephalic												
Cardiac		Р	P	P	P	P	P		See Below			
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular					ί.		•					
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

	Concurrence of CDRH, Office of Device Evaluation (ODE)
(d) 10 1	Prescription Use (Per 21 CFR 801.109)
David a byom	
thusion Sign-Off) 7	
Division of Reproductive, Abdomin	nal.
and Radiological Devices	2011
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UST-5524-5

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

	Modes of operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal -												
Abdominal												
Intraoperative (specify)												
Intraoperative Neurological			1.									
Pediatric												
Small Organ (specify)		P	P	P		P	P		See Below			
Neonatal Cephalic												
Adult Cephalic												
Cardiac							,			· · · · · · · · · · · · · · · · · · ·		
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular		P	P	P	,	P	P		See Below			
Laparoscopic					•			,				
Musculo-skeletal Conventional		-										
Musculo-skeletal Superficial												
Other .												

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Small Organ applications: breasts, testes and thyroid

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

David of from	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
Davision Sign-Off)	
Ivision of Reproductive Abdomic	nal

and Radiological Devices (403331)
510(k) Number

UST-5524-7.5

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

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify			
Opthalmic .								,					
Fetal													
Abdominal													
Intraoperative (specify)													
Intraoperative Neurological								7711-17-10-20-20-20-20-20-20-20-20-20-20-20-20-20					
Pediatric													
Small Organ (specify)		P	P	P		P	P		See Below				
Neonatal Cephalic													
Adult Cephalic													
Cardiac													
Transesophageal													
Transrectal													
Transvaginal													
Transurethral													
Intravascular													
Peripheral Vascular		P	P	P		P	P		See Below				
Laparoscopic						-			500 20.011				
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other													

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Small Organ applications: Breasts, testes and thyroid

(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) Prescription Use (Per 21 CFR 801.109)
	2 Draw Of the grown
•	
	ean of Reproductive, Abdominal,
	Padiological Devices K 023311
;	U(k) Number 45

5 EU(k) Number ____

UST-5526L-7.5

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal .												
Abdominal												
Intraoperative (specify)		P	P	P		P	Р		See Below			
Intraoperative Neurological												
Pediatric								***************************************				
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral							·					
Intravascular						-						
Peripheral Vascular												
Laparoscopic		P	P	P		·P	ņ	***************************************	See Below			
Musculo-skeletal Conventional							,					
Musculo-skeletal Superficial								-				
Other								1.				

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Intraoperative: Liver, pancreas, gall bladder

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

	Concurrence of CDRH, Office of Device Evaluation (ODE)
David a Segram	Prescription Use (Per 21 CFR 801.109)
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(Division Sign-Off)	
0	

Division of Reproductive, Abdominal, and Radiological Devices 10,533

UST-5531

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

	Modes of operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)		P	P	P		P	P		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Intraoperative applications: include liver, pancreas and gall bladder.

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

	Concurrence of CDRH, Office of Device Evaluation (ODE)
Shird a legenm	Prescription Use (Per 21 CFR 801.109)
June Ca Valum	
Division Sign-Off)	
Division of Reproductive, Abdomin	nal

and Radiological Devices (023)

UST-5534T-7.5

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

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal .													
Abdominal													
Intraoperative (specify)	-	P	P	P		P	P		See Below				
Intraoperative Neurological													
Pediatric							-						
Small Organ (specify)		P	P	P		P	P		See Below				
Neonatal Cephalic													
Adult Cephalic													
Cardiac													
Transesophageal													
Transrectal								·					
Transvaginal													
Transurethral													
Intravascular													
Peripheral Vascular		P	Р	P		P	P		See Below				
Laparoscopic								7					
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other													

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Intraoperative- liver, pancreas and gall bladder. Small parts: breast, testes and thyroid (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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

and Sign-Off)

sign of Reproductive, Abdominal,

Radiological Devices

510(k) Number _

Diagnostic Ultrasound Indications for Use Form UST-5536-7.5

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

	Modes of operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specif		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)		Р	P	Р		P	Р		See Below			
Intraoperative Neurological												
Pediatric							·					
Small Organ (specify)												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular										`		
Laparoscopic		Р	Р	Р		Р	Р		See Below			
Musculo-skeletal Conventional	,					·						
Musculo-skeletal Superficial									,			
Other												

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Intraoperative-liver, pancreas and gall bladder.

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

Daniela Lynn	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

UST-5539-7.5

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

Clinical Application	Modes of operation									
	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify
Opthalmic	,									
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		P	P	Р		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										,
Transvaginal			-							
Transurethral										
Intravascular						٠ '	,			
Peripheral Vascular		P	P	P		P	P		See Below	
Laparoscopic					,					
Musculo-skeletal Conventional										
Musculo-skeletal Superficial		P	Р	P	·	Р	Р		See Below	
Other								4		

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Small parts: breast, testes and thyroid

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

6/ 10	1	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
David A.	Symm	
(Division Sign-Off)	Abdomin	al

Division of Reproductive, Abdominal,

and Radiological Devices (03331)

UST-5543

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

Clinical Application	Modes of operation									
	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal .										
Abdominal										
Intraoperative (specify)						-				
Intraoperative Neurological					7					
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		P	P P		See Below	
Laparoscopic					. '					
Musculo-skeletal Conventional		P	Р	P		Р.	P		See Below	
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Small parts: breast, testes and thyroid

David a. Sayoum	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
, Division Sign-Offi	
Division of Reproductive, Abdominand Radiological Doving	nal,
and Radiological Devices 510(k) Number	3331

UST-5545

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

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

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Small parts: breast, testes and thyroid

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	Oncurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
David A. Segum	\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \
Division Sign-Off) Division of Reproductive Abdomin	

and Radiological Devices 1603931

UST-5548

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

Y					N	lodes of ope	eration	•		
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic						-				
Fetal _										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)		Е	Е	Е		E	Е		See Below	
Neonatal Cephalic										
Adult Cephalic										
Cardiac						-				
Transesophageal				-					1	
Transrectal										,
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		E	Е	Е		Е	E		See Below	
Laparoscopic					1					
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications- Small parts: breast, testes and thyroid

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

Daniel Q. Leyron	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	
Division of Reproductive, Abdomi	
and Radiological Devices // Ork	3211
510(k) Number	53

UST-5712

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

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

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications- Small parts: breast, testes and thyroid

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David a bearm	Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use (Per 21 CFR 801.109)
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hvision of Reproductive, Abdomir	nal,

and Radiological Devices K 033311 510(k) Number ______

UST-5713T

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

					N	lodes of ope	eration			
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic		,								
Fetal .										
Abdominal										
Intraoperative (specify)		P	P	P		P	P		See Below	
Intraoperative Neurological				,						
Pediatric										
Small Organ (specify)		P	P	P		P	P		See Below	
Neonatal Cephalic										
Adult Cephalic								-		
Cardiac										
Transesophageal										
Transrectal								-		
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P		Р'	P		See Below	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial Other										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Intraoperative- liver, pancreas and gall bladder. Small parts: breast, testes and thyroid (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

	Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

311
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UST-9101-7.5

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic 2												
Fetal .												
Abdominal		P	P	P		P	P		See Below			
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric		P	P	P		P	P		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

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Danis q. Le	Concurrence of CDRH, Office of Device Evaluation (ODE Prescription Use (Per 21 CFR 801.109)
(Division Sign-Off)	

Givision of Reproductive, Abdominal, and Radiological Devices 1/020

Diagnostic Ultrasound Indications for Use Form UST-9102-3.5

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

Clinical Application	Modes of operation										
	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)	
Opthalmic										-	
Fetal .											
Abdominal		Е	Е	Е		Е	Е		See Below		
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									_		

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic 2												
Fetal .												
Abdominal												
Intraoperative (specify)		P	P	P		P	P		See Below			
Intraoperative Neurological												
Pediatric												
Small Organ (specify)								,				
Neonatal Cephalic		P	P	P		P	P		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Intraoperative-liver, pancreas and gall bladder.

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Division of Reproductive Abdomin	-1

and Radiological Devices K033311

Diagnostic Ultrasound Indications for Use Form UST-9114-3.5

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

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal .		P	P	P		P	P		See Below				
Abdominal		P	P	P		P	P		See Below				
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													

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

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

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal													
Abdominal		P	P	P		P	P		See Below				
Intraoperative (specify)													
Intraoperative Neurological													
Pediatric		Р	P	P		P	P		See Below				
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal,

and Radiological Devices

Number ___ KO33311

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

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic							,						
Fetal .		P	P	P		P	P		See Below				
Abdominal													
Intraoperative (specify)													
Intraoperative Neurological					` .								
Pediatric									1				
Small Organ (specify)													
Neonatal Cephalic													
Adult Cephalic													
Cardiac									,				
Transesophageal													
Transrectal													
Transvaginal		P	P	P		Р	Р		See Below				
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

K033311

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

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal _		P	P	Р		P	P		See Below				
Abdominal		P	P	P		P	P		See Below				
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													

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal, and Radiological Devices

510(k) Number _

UST-9120

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic												
Fetal												
Abdominal												
Intraoperative (specify)		Е	Е	Е		Е	Е		See Below			
Intraoperative Neurological												
Pediatric												
Small Organ (specify)												
Neonatal Cephalic		E	Е	Е		Е	Е		See Below			
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal										7		
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Intraoperative-liver, pancreas, gall bladder

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

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wision of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

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

					N	Todes of ope	eration	•		
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal .										
Abdominal		P	P	P		P	P		See Below	
Intraoperative (specify)			 							
Intraoperative Neurological										
Pediatric					,					
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic	1	***************************************								
Cardiac									,	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral		-								
Intravascular							-			
Peripheral Vascular										
Laparoscopic		-			•			-,		
Musculo-skeletal								-		
Conventional										
Musculo-skeletal Superficial										
Other					1					

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal,

and Radiological Devices

510(k) Number __

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UST-9126

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

	Modes of operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal .		Е	Е	Е		Е	Е		See Below				
Abdominal		Е	Е	Е		Е	Е		See Below				
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													

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Abdominal and Gynecological, fetal

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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 Reproductive, Abdominal,

and Radiological Devices

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UST-9128

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

	Modes of operation											
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)		
Opthalmic 2												
Fetal												
Abdominal		Е	Е	Е		Е	Е		See Below			
Intraoperative (specify)												
Intraoperative Neurological												
Pediatric		E	Е	E		E	E		See Below			
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/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 Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

K033311

UST-52104

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

•					N	lodes of ope	ration			
Clinical Application	A	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N	N		N	N		See Below	
Transesophageal		N	N	N		N	N		See Below	
Transrectal										
Transvaginal										
Transurethral										,
Intravascular										
Peripheral Vascular					,					
Laparoscopic					, 1					
Musculo-skeletal Conventional								•		•
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD (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 Sign-Off) 4 Division of Reproductive, Abdo	
and Radiological Devices 510(k) Number	033311 67

UST-52108

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

	Modes of operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)			
Opthalmic													
Fetal										-			
Abdominal													
Intraoperative (specify)													
Intraoperative Neurological									^				
Pediatric													
Small Organ (specify)								,					
Neonatal Cephalic		Е	Е	Е		Е	Е		See Below				
Adult Cephalic													
Cardiac		Е	Е	Е		Е	Е		See Below				
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Applications: Neonatal

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

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

K033311

UST-52109

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

Clinical Application	Modes of operation									
	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify
Opthalmic										
Fetal										
Abdominal										
Intraoperative (specify)		E	Е	Е		Е	E		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic		Е	Е	Е		Е	Е		See Below	
Musculo-skeletal Conventional									200 BOIOW	
Musculo-skeletal Superficial										
Other										

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

Additional Comments: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Intraoperative applications: Liver, pancreas, gall bladder

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(Division Sign-Off) Division of Reproductive, Abdorand Radiological Devices 510(k) Number	ninal, 0311
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Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Modes of operation									
	A	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Opthalmic										
Fetal										-
Abdominal										
Intraoperative (specify)		Е	Е	Е		· E	E		See Below	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic		Е	Е	Е		Е	Е		See Below	
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: Mixed mode operation includes B/M, B/PWD, B/Bflow/PWD

Intraoperative applications: Liver, pancreas, gall bladder

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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 Reproductive, Abdominal,

and Radiological Devices

510(k) Number 2005