D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

510(K) Summary Of Safety And Effectiveness APR 0 7 2003

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

Submitter's name, address, telephone number, contact person:

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Date prepared:

March 6, 2003

Name of the device, including the trade or proprietary name if applicable, 2) the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite TITAN™ high-resolution ultrasound system (subject to change)

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Picture Archiving And Communications System	892.2050	90-LLZ

Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that the System described in this Submission is substantially equivalent to a combination of the Philips Ultrasound HDI® 5000 Ultrasound System (K011224), the GE LOGIQ 9 Diagnostic Ultrasound System (K011188) and the Siemens OMNIA X/XS Diagnostic Ultrasound System (K020353).

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4) Device Description:

The SonoSite TITAN™ high-resolution ultrasound systemis a highly portable, software controlled ultrasound system used to acquire and display high-resolution, real-time ultrasound data in 2D, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, Color Power Doppler, Velocity Color Doppler (VCD) and Directional Color Power Doppler, or in a combination of these modes.

The System has an electrocardiography (ECG) display feature and supports a 3-lead ECG cable assembly to collect data for M-mode measurements. The System provides measurement capabilities for anatomical structures and fetal biometry that provide information used for clinical diagnostic purposes. The System has a PW and CW Doppler audio output feature and cine review, image zoom, labeling, biopsy, measurements and calculations, image storage and review, printing, and recording capabilities. The system includes Digital Imaging and Communications (DICOM) to capabilities to provide the acceptance, transfer, display, storage, and digital processing of ultrasound images.

The SonoSite TITAN™ high-resolution ultrasound system is designed to accept curved or linear transducers of the types and frequency listed in the table below. All actions affecting the performance of the transducer are activated from the main system control panel.

Frequency Range:	2.0 - 10.0 MHz
Transducer Types:	Linear array
	Curved array
	Intracavitary array
	Static probes

The SonoSite TITAN™ high-resolution ultrasound system is designed to comply with the standards listed below.

- a. ANSI/AAMI EC 53: 1995 + Amendments, ECG Cables and Electrodes <u>except</u> for sections 4.4 and 4.5.9.
- b. CAN/CSA-C22.2, No. 601.1:1998, Canadian Standards Association, Medical Electrical Equipment-Part 1. General Requirements for Safety
- c. EN 60529, European Norm, Degrees of Protection Provided by Enclosures (I.P. Code)
- d. EN 60601-1:1997, European Norm, Medical Electrical Equipment-Part 1. General Requirements for Safety
- e. EN 60601-1-1:1993, European Norm, Medical Electrical Equipment Part 1. General Requirements for Safety-Section 1-1. Collateral Standard. Safety Requirements for Medical Electrical Systems

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- f. EN 60601-1-2:2001, European Norm, Medical Electrical Equipment. General Requirements for Safety-Collateral Standard. Electromagnetic Compatibility. Requirements and Tests, Second Edition
- g. EN 60601-2-25:1996, European Norm, Medical Electrical Equipment-Part 2. Particular Requirements for Safety-Section 25. Specification for Electrocardiographs
- h. IEC 61157:1992, International Electrotechnical Commission, Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment
- i. ISO 10993 Biological Evaluation of Medical Devices and Related Tests
- j. JIS-T-100x Series, Japanese Standards for Medical Electrical Equipment
- k. Medical Ultrasound Safety, American Institute of Ultrasound in Medicine (AIUM), 1994
- I. NEMA PS3.15 2000, Digital Imaging and Communications in Medicine (DICOM) Part 15: Security Profile.
- m. NEMA UD2-1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- n. NEMA UD3-1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- o. RTCA/DO160D:1997, Radio Technical Commission for Aeronautics, Environmental Conditions and Test Procedures for Airborne Equipment, Section 21.0 Emission of Radio Frequency Energy, Category B
- p. UL 2601-1:1999, Underwriters Laboratories, Inc., Medical Electrical Equipment-Part 1: General Requirements for Safety
- q. UL 94, Fifth Edition, Underwriters Laboratory, Inc., Tests for Flammability of Plastic Materials for Parts in Devices and Appliances

5) Intended Use:

The intended uses of the SonoSite TITAN™ high-resolution ultrasound system as defined by FDA guidance documents, are:

Fetal - OB/GYN	Trans-rectal
Abdominal	Trans-vaginal
Intra-operative	
(Abdominal organs and vascular)	Trans-urethral
Laparoscopic	Musculo-skel. (Conventional)
Pediatric	Musculo-skel. (Superficial)
Small Organ	
(breast, thyroid, testicles.)	Cardiac Adult
Neonatal Cephalic	Cardiac Pediatric
Adult Cephalic	Peripheral vessel

Typical examinations performed using the SonoSite TITAN™ high-resolution ultrasound system are:

Abdominal Imaging Applications:

This system transmits ultrasound energy into the abdomen of patients using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), Tissue Harmonic Imaging (THI), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler to obtain ultrasound images. The liver, kidneys, pancreas, spleen, gallbladder, bile ducts, transplanted organs, abdominal vessels, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally.

Cardiac Imaging Applications:

This system transmits ultrasound energy into the thorax of patients using 2D, M-mode, directional color power Doppler (DCPD), velocity color Doppler (VCD), color Doppler, Tissue Harmonic Imaging (THI), pulsed wave (PW) Doppler, and continuous wave (CW) Doppler to obtain ultrasound images. The heart, cardiac valves, great vessels, surrounding anatomical structures, overall cardiac performance, and heart size can be assessed for the presence or absence of pathology. The heart can be imaged transthoracic. The patient's electrocardiogram (ECG) may be obtained and is used for accurate timing of diastolic and systolic function.

Warning: The ECG is not used to diagnose cardiac arrhythmias and is not designed for long term cardiac rhythm monitoring.

Cephalic Imaging Applications:

This system transmits ultrasound energy into the heads of adults and neonates using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), and pulsed wave (PW) Doppler to obtain ultrasound images. The patient's blood flow can be evaluated transcranially.

Gynecology and Infertility Imaging Applications:

This system transmits ultrasound energy in the pelvis and lower abdomen using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The uterus, ovaries, adnexa, and surrounding anatomical structures can be assessed for the presence or absence of pathology transabdominally or transvaginally.

Interventional and Intraoperative Imaging Applications:

This system transmit ultrasound energy into the various parts of the body using 2D, color power Doppler (CPD), directional color power Doppler (DCPD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images that provide guidance during interventional and intraoperative procedures. This system can be used to provide ultrasound guidance for biopsy and drainage procedures, vascular line placement, ova harvesting, amniocentesis and other obstetrical procedures, and provide assistance during abdominal and vascular intraoperative procedures.

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Obstetrical Imaging Applications:

This system transmits ultrasound energy into the pelvis of pregnant women using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), color Doppler, Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The fetal anatomy, viability, estimated fetal weight, gestational age, amniotic fluid, and surrounding anatomical structures can be assessed for the presence or absence of pathology trans-abdominally or transvaginally. CPD and DCPD imaging is intended for high-risk pregnant women. High-risk pregnancy indications include, but are not limited to, multiple pregnancy, fetal hydrops, placental abnormalities, as well as maternal hypertension, diabetes, and lupus.

Warning:	CPD or DCPD images can be used as an adjunctive method, not as a screening tool,
	for the detection of structural anomalies of the fetal heart and as an adjunctive
	method, not as a screening tool for the diagnosis of Intrauterine Growth Retardation
	(IUGR).

Pediatric and Neonatal Imaging Applications:

This system transmits ultrasound energy into the pediatric or neonatal patients using 2D, M-mode, color power Doppler (CPD), directional color power Doppler (DCPD), velocity color Doppler (VCD), pulsed wave (PW) and continuous wave (CW) Doppler to obtain ultrasound images. The pediatric abdominal, pelvic and cardiac anatomy, pediatric hips, neonatal heads, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Prostate Imaging Applications:

This system transmits ultrasound energy into the prostate of an adult male using 2D, M-mode, color power Doppler (CPD), velocity color Doppler (VCD), and pulsed wave (PW) Doppler to obtain ultrasound images. The prostate gland can be assessed for the presence or absence of pathology transrectally.

Superficial Imaging Applications:

This system transmits ultrasound energy into various parts of the body using 2D, M-mode, color power Doppler (CPD), velocity color Doppler (VCD), and pulsed wave (PW) Doppler to obtain ultrasound images. The breast, thyroid, testicle, lymph nodes, hernias, musculoskeletal structures, soft tissue structures, and surrounding anatomical structures can be assessed for the presence or absence of pathology.

Vascular Imaging Applications:

This system transmits ultrasound energy into the various parts of the body using 2D, M-mode, color power Doppler (CPD), velocity color Doppler (VCD), Tissue Harmonic Imaging (THI), and pulsed wave (PW) Doppler to obtain ultrasound images. The carotid arteries, deep veins in the arms and legs, superficial veins in the arms and legs, great vessels in the abdomen, and various small vessels feeding organs can be assessed for the presence or absence of pathology.

6) Technological Characteristics:

This device operates identically to the predicate devices in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as 2D or M-mode images. Doppler shift caused by blood flow is displayed as Color Flow, or as spectrum analysis. The modes of this device (2D, PW Doppler, CW Doppler, velocity color Doppler, Color Power Doppler, and directional color power Doppler, and duplex imaging) are the same as a combination of the predicate devices identified in item 3. Transducer patient contact materials are biocompatible.

This device conforms to the Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment (AIUM/NEMA, 1998) for an on-screen display feature that provides information on potential thermal and cavitation bioeffect mechanisms. A user education program provides additional information so users may moderate the system's acoustic output in accordance with the ALARA (as low as reasonably achievable) principle.

The device's acoustic output limits are:

All applications:

I _{SPTA} (d)	720 mW/cm² (Maximum)	
TIs/TIb/TIc	0.1 - 4.0 (Range)	
Mechanical Index (MI)	1.9 (Maximum)	
I _{SPPA} (d)	0 - 700 W/cm ² (Range)	

The limits are the same as predicate Track 3 devices.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

APR 0 7 2003

SonoSite, Inc. % Ms. Laura Danielson TUV Product Service 1775 Old Highway 8 NW Suite 104 NEW BRIGHTON MN 55112-1891

Re: K030949

Trade Name: TITAN™ High-Resolution Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: 90 IYN and LLZ

Dated: March 25, 2003 Received: March 26, 2003

Dear Ms. Danielson:

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 TITANTM High-Resolution Ultrasound System, as described in your premarket notification:

Transducer Model Number

C11/7-4 C11/8-5 C15/4-2 C60/5-2 HST/10-5 ICT/7-4 C8/8-5 ICT/8-5 L25/10-5 L38/10-5 L52/10-5 L52-S/10-5 2MHz Doppler Pencil

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 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 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 contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Wancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

D02576B-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 1 Diagnostic Ultrasound Indications for Use Form - TITAN System

System:		SonoSite TITA	V™ hiah	resolu	ition ul	trasour	nd syste	m	
Transducer	•	N/A		· · · · · · · · · · · · · · · · · · ·		·	<u> </u>		
Intended Us		Diagnostic ultra	sound in	naging	or flui	d flow a	analysis	of the human	hody as
michaea ea		follows:			,				
Clinica	Clinical Application					Mode d	of Opera		
General		Specific					Color	Combined	Other
(Track I only)		(Tracks I & III)	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)
Ophthalmic		Ophthalmic		ļ					
		F-4-1					l N	B+M; B+PWD;	Ninto d
ļ	ļ	Fetal	N	N	N	<u> </u>	N	B+CD B+M; B+PWD;	Note 1
<u> </u>								B+CWD;	
		Abdominal	N	N	N	N	N	B+CD	Note 1
		Intra-operative							
	(Ab	dominal organs and						B+M; B+PWD;	
		vascular)	N	N	N		N	B+CD	Note 1
	Intra	-operative (Neuro.)	N	N	N			B+M; B+PWD	Note 1
Fetal Imaging	ļ	Laparoscopic	IN	IN	IN.			B+M; B+PWD;	Note 1
	1				1	ļ		B+CWD;	
& Other	1	Pediatric	N	N	N	l N	N	B+CD	Note 1
	Sn	nall Organ (breast,						B+M; B+PWD;	
	ti	nyroid, testicles.)	N	N	N		N.	B+CD	Note 1
	١.					1	l	B+M; B+PWD;	A1-4- 4
	N	Neonatal Cephalic	N	N	N		N	B+CD B+M; B+PWD;	Note 1
		Adult Cephalic	N	N	N		N	B+CD	Note 1
		riduit Oopridiio		†				B+M; B+PWD;	
		Trans-rectal	N	N	N		N	B+CD	Note 1
								B+M; B+PWD;	
		Trans-vaginal	N	N	N		N	B+CD	Note 1
		Trans-urethral		 					
	I rans	s-esoph. (non-Card.) culo-skel. (Convent.)	N	N	N			B+M; B+PWD	Note 1
	ivius	Julo-skei. (Convent.)	IN	14	IN			B+M; B+PWD;	NOIG 1
	Muse	culo-skel. (Superfic.)	P	P	Ρ.		Р	B+CD	Note 1
	1	Intra-luminal							
		Other (spec.)		1					
								B+M; B+PWD;	
	1	_ ,, ,,,,,		1	l '			B+CWD;	N
		Cardiac Adult	N	N	N	N	N	B+CD B+M; B+PWD;	Note 1
	l			1				B+CWD;	
Cardiac	1	Cardiac Pediatric	N	N	N	N	N	B+CD	Note 1
Caraido		s-esophageal (card.)	.,	1					
		Other (spec.)							
								B+M; B+PWD;	
Peripheral	E	Peripheral vessel	<u>N</u>	N_	N.		N	B+CD	Note 1
Vessel	i	Other (spec.)		1					

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Musculo-skel. (Superfic.) imaging previously cleared in 510(k) K003399. Included with this 510(k) is picture archiving, communications and storage functionality previously cleared in 510(k) K023957.

Color Doppler includes Velocity Color Doppler (Division Sign-Off)

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25 of 961 pages

Prescription Use (Per 21 CFR 801.109) Indications for Use

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 2 Diagnostic Ultrasound Indications for Use Form - C11/7-4 Transducer

System:	SonoSite TITAN	l™ high	n-resolu	ution ult	rasoun	d systen	n			
Transducer:	C11/7-4 7.0 – 4.	0 MHz	Curve	d Array						
Intended Use	Diagnostic ultras follows:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinica	Clinical Application			1	Mode o	f Opera	tion			
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)		
Ophthalmic	Ophthalmic					•				
	Fetal									
	Abdominal Intra-operative (Abdominal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1		
	organs and vascular)				ļ					
Fetal Imaging	Intra-operative (Neuro.) Laparoscopic			ļ						
& Other	Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1		
u outei	Small Organ (breast, thyroid, testicles.)							140(6.1		
	Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1		
	Adult Cephalic Trans-rectal									
	Trans-vaginal					ļ				
	Trans-urethral			-	<u> </u>					
	Trans-esoph. (non-Card.) Musculo-skel. (Convent.) Musculo-skel. (Superfic.)									
	Intra-luminal Other (spec.)									
				 	-					
	Cardiac Adult				-	 	B+M; B+PWD;			
Cardiac	Cardiac Pediatric Trans-esophageal (card.)	N_	N	N	N	N	B+CWD; B+CD	Note 1		
	Other (spec.)			 		<u> </u>				
Peripheral	Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1		
Vessel	Other (spec.)	<u></u>		 ``		1		7,0,0		

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number.

Indications for Use

Table 4.3- 3 Diagnostic Ultrasound Indications for Use Form - C11/8-5 Transducer

System:	SonoSite TITAN				rasoun	d systen	n		
Transducer:	C11/8-5 8.0 - 5.	0 MHz	Curve	d Array					
Intended Use		sound i	maging	or fluid	flow a	nalvsis o	of the human b	odv as	
l interiora do	follows:	, , , , , , , , , , , , , , , , , , , ,		9 0				,	
		Mode of Operation							
Clinica	Clinical Application			l.	<u>node o</u>				
General	Specific					Color	Combined	Other	
(Track I only)	(Tracks I & III)	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)	
Ophthalmic	Ophthalmic								
	Fetal								
				1			B+M; B+PWD;		
	Abdominal	N	N	N	N	N	B+CWD; B+CD	Note 1	
	Intra-operative (Abdominal]		1				
	organs and vascular)								
Estables a sing	Intra-operative (Neuro.) Laparoscopic		ļ	 					
Fetal Imaging	Laparoscopic		l	 			B+M; B+PWD;		
& Other	Pediatric	N	N	N	N	N	B+CWD; B+CD	Note 1	
a Other	Small Organ (breast,			 		<u> </u>	<u> </u>		
	thyroid, testicles.)		[
							B+M; B+PWD;		
	Neonatal Cephalic	N	N	N		N	B+CD	Note 1	
	Adult Cephalic			<u> </u>					
L	Trans-rectal					<u> </u>			
	Trans-vaginal			ļ					
	Trans-urethral		ļ	ļ		ļ			
	Trans-esoph. (non-Card.)		ļ	 	 				
	Musculo-skel. (Convent.) Musculo-skel. (Superfic.)		 	+	-				
	Intra-luminal		<u> </u>	 	<u> </u>				
	Other (spec.)		 	-	 				
	Cardiac Adult		 	<u> </u>					
	Cardiac Addit			 	 	 	B+M; B+PWD;		
Cardiac	Cardiac Pediatric	N	N	N	N	N	B+CWD; B+CD	Note 1	
	Trans-esophageal (card.)		 			1			
	Other (spec.)								
							B+M; B+PWD;		
Peripheral	Peripheral vessel	N	N	N		N	B+CD	Note 1	
Vessel									

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 4 Diagnostic Ultrasound Indications for Use Form - C15/4-2 Transducer

System:		SonoSite TITAN				rasoun	d systen	<u> </u>		
Transducer:		C15/4-2 4.0 - 2.0	O MHz	Curve	d Array					
Intended Us	e:	Diagnostic ultras	sound imaging or fluid flow analysis of the human body as							
		follows:							·	
Clinic	al Ar	plication		-	l N	lode o	f Operat	ion		
General	<u> </u>	Specific					Color	Combined	Other	
(Track I only)		(Tracks I & III)	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)	
Ophthalmic		Ophthalmic								
	 	Fetal	N	N	N			B+M; B+PWD	Note 1	
								B+M; B+PWD;		
	1	Abdominal	N	N	N	N	N	B+CWD; B+CD	Note 1	
	Intra	-operative (Abdominal								
		rgans and vascular)	N	N	N			B+M; B+PWD	Note 1	
		ra-operative (Neuro.)								
Fetal Imaging		Laparoscopic								
& Other		Pediatric	N	N	N			B+M; B+PWD	Note 1	
		mall Organ (breast,		}			1			
		thyroid, testicles.)	<u>N</u>	N	N			B+M; B+PWD	Note 1	
	<u> </u>	Neonatal Cephalic	N	N	N		ļ	B+M; B+PWD	Note 1	
	1			l	.		1	B+M; B+PWD;	A1 - 1 - 4	
		Adult Cephalic	N	N	N	ļ	N N	B+CD	Note 1	
		Trans-rectal		ļ	 		-			
	.	Trans-vaginal		 		 	 			
	-	Trans-urethral		 	 				<u></u> _	
		ns-esoph. (non-Card.)	N	A1	 		 	B+M; B+PWD	Note 1	
		sculo-skel. (Convent.)	N	N_	N		 	DTIVI, DTEVVD	Note	
	Mu	sculo-skel. (Superfic.)		 		 	 			
	 	Intra-luminal	-	 	 			 		
	-	Other (spec.)		 	-		 	DAM DADIMO		
		0		.	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1	
		Cardiac Adult	N	N	N	IN IN	IN IN	B+M; B+PWD;	Note	
Cardina		Cardiac Pediatric	N	N	N	N	N	B+CWD; B+CD	Note 1	
Cardiac	1-T	ins-esophageal (card.)	IN	IN	IN .	14	IN	BACTED, BACD	INOIG	
	113	Other (spec.)		 	 	 	-			
	+	Outer (spec.)		+	-	1	+	B+M; B+PWD;	-	
Dorinhore!		Parinhaml vaccal	N	NI NI	N		N	B+M; B+PWU;	Note 1	
Peripheral Vessel		Peripheral vessel Other (spec.)	IN	N	+ !\	+	IN	D+00_	11016	
vessei	1	Outer (Spec.)		1	1	1	ı	1	1	

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 5 Diagnostic Ultrasound Indications for Use Form - C60/5-2 Transducer

System:	SonoSite TITA	V™ hig	h-resol	ution ull	trasoun	d systen	1	
Transducer:	C60/5-2 5.0-2.0	MHz (Curved	Array				
Intended Us		sound imaging or fluid flow analysis of the human body as						
Clinic	Clinical Application			F	Mode o	f Operat	tion	······································
General (Track I only)	Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic			<u> </u>			-	
	Fetal	N	N	N		N	B+M; B+PWD; B+CD B+M; B+PWD;	Note 1
	Abdominal	N	N	N		N	B+CD	Note 1
	Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Intra-operative (Neuro.)							
Fetal Imaging	Laparoscopic		ļ	ļ	ļ			
& Other	Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1
	Small Organ (breast, thyroid, testicles.)							
	Neonatal Cephalic							
	Adult Cephalic	├ ──	ļ	-	<u> </u>			
	Trans-rectal Trans-vaginal	 		ļ	 			
	Trans-vaginal Trans-urethral	1	<u> </u>	 	 			
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)							
	Musculo-skel. (Superfic.)							
·	Intra-luminal	ļ	ļ	<u> </u>		<u> </u>		
	Other (spec.)	<u> </u>		ļ	ļ			
	Cardiac Adult	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Cardiac	Cardiac Pediatric Trans-esophageal (card.)	N	N	N		N,	B+M; B+PWD; B+CD	Note 1
	Other (spec.)		1					
Peripheral	Peripheral vessel							
Vessel	Other (spec.)	i						

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 6 Diagnostic Ultrasound Indications for Use Form – HST/10-5 Transducer

System:	SonoSite TITAN						1			
Transducer:	HST/10-5 10.0-5	5.0 MH	lz Linea	ar Array	Transo	ducer				
Intended Use	e: Diagnostic ultras	sound	imagin	a or fluid	d flow a	nalvsis o	of the human b	odv as		
	follows:			J				,		
Clinic	Clinical Application			Mode of Operation						
General	Specific		i	T	1	Color	Combined	Other		
(Track I only)	(Tracks I & III)	В	М	PWD	CWD	Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic				02	Воррісі.		(0)00.7		
	Fetal	· · · · · · · · ·								
	Abdominal					1		-		
	Intra-operative (Abdominal		İ				B+M; B+PWD;			
	organs and vascular)	N	N	N		N	B+CD	Note 1		
	Intra-operative (Neuro.)									
Fetal Imaging	Laparoscopic									
							B+M; B+PWD;			
& Other	Pediatric	N	N	N		N	B+CD	Note 1		
	Small Organ (breast,						B+M; B+PWD;			
	thyroid, testicles.)	N	N	N N		N	B+CD	Note 1		
	Neonatal Cephalic		<u> </u>	ļ	ļ					
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)			 						
	Musculo-skel. (Convent.)	N	N	N	ļ		B+M; B+PWD	Note 1		
	Maranta aliat (Comansa)	P		Р		_	B+M; B+PWD;			
	Musculo-skel. (Superfic.)	Р	Р	P	<u> </u>	Р	B+CD	Note 1		
	Intra-luminal		ļ	 	-	 				
	Other (spec.)			 	 			[
	Cardiac Adult		<u> </u>	ļ	<u> </u>	 	~			
Cardiac	Cardiac Pediatric									
	Trans-esophageal (card.)		 	 						
	Other (spec.)		-				D.14 D. DU.			
Davishassi	Devinberet	3. 1	A1	l Ar			B+M; B+PWD;	Nat- 4		
Peripheral	Peripheral vessel	N	N	N	1	N	B+CD	Note 1		
Vessel	Other (spec.)		<u> </u>	<u> </u>	<u> </u>					

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Musculo-skel. (Superfic.) imaging previously cleared in 510(k) K003399.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices,

510(k) Number

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 7 Diagnostic Ultrasound Indications for Use Form – ICT/7-4 Transducer

System:		SonoSite TITAN	™ high	n-resol	ution ult	rasoun	d systen	1	
Transducer:		ICT/7-4 7.0-4.0 I	MHz In	tracavi	tary Tra	ansduc	er		
Intended Us	e:	Diagnostic ultras						of the human b	odv as
	•	follows:		····-g···,	, - · · · · · ·				,
Clinic	Clinical Application				N	Mode o	f Operat	tion	
General	<u> </u>	Specific					Color	Combined	Other
(Track I only)		(Tracks I & III)	B	М	PWD	CWD	Doppler	(Spec.)	(Spec.)
Ophthalmic		Ophthalmic							
								B+M; B+PWD;	
	<u> </u>	Fetal	N	N	N		N	B+CD	Note 1
	<u> </u>	Abdominal				ļ			
		operative (Abdominal		1					i
		gans and vascular)				ļ			
	Intr	a-operative (Neuro.)		ļ.	 	<u> </u>			
Fetal Imaging	L	Laparoscopic		ļ	ļ	ļ	 		
& Other	_	Pediatric		 	ļ	 			
		nall Organ (breast,							
		thyroid, testicles.)		 			 		
	<u> </u>	Neonatal Cephalic Adult Cephalic		 	 				
	I	Adult Cephalic			 	-	-	B+M; B+PWD;	
		Trans-rectal	N	N	N		N	B+CD	Note 1
	1	Halls-rectar	14		- '	-	· · · · · ·	B+M; B+PWD;	14010 1
	1	Trans-vaginal	N	N	N	Ì	N	B+CD	Note 1
	 	Trans-urethral		†					11010
	Tran	ns-esoph. (non-Card.)							
		culo-skel. (Convent.)			1				
		sculo-skel. (Superfic.)							
	1	Intra-luminal			1			• •	
	1	Other (spec.)							
		Cardiac Adult							
Cardiac		Cardiac Pediatric							
		ns-esophageal (card.)			1	<u> </u>			
		Other (spec.)	***************************************		1	1			
Peripheral		Peripheral vessel							
Vessel	1	Other (spec.)							

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number __

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 8 Diagnostic Ultrasound Indications for Use Form - C8/8-5 Transducer

System:	SonoSite TITA	SonoSite TITAN™ high-resolution ultrasound system								
Transducer:	C8/8-5 8.0- 5.0	MHz P	rostate	Transd	ucer					
Intended Use	P. Diagnostic ultra	sound imaging or fluid flow analysis of the human body as								
intenaca os	follows:	ioodi id		g 0a.	3 11011 0	in lary old	or and marrian b	cay ac		
		τ								
Clinica	al Application	ion Mode of Operation								
General	Specific					Color	Combined	Other		
(Track I only)	(Tracks I & III)	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
							B+M; B+PWD;			
	Fetal	N	N	N		N	B+CD	Note 1		
	Abdominal	<u> </u>								
	Intra-operative (Abdominal									
	organs and vascular)									
Cotal taxasina	Intra-operative (Neuro.)		 							
Fetal Imaging & Other	Laparoscopic Pediatric	1	<u> </u>	 	-	 				
a Other	Small Organ (breast,	 		 		†				
	thyroid, testicles.)	ł		1						
	Neonatal Cephalic	i -	 							
	Adult Cephalic			1						
	1						B+M; B+PWD;			
	Trans-rectal	N	N	N		N	B+CD	Note 1		
		i					B+M; B+PWD;			
	Trans-vaginal	N	N N	N		N	B+CD	Note 1		
	Trans-urethral	ļ		ļ						
	Trans-esoph. (non-Card.)	 		1						
	Musculo-skel. (Convent.)	 		 						
	Musculo-skel. (Superfic.) Intra-luminal		<u> </u>	 	1	1				
	Other (spec.)	1								
	Cardiac Adult	1		 	-					
Candia	Cardiac Addit Cardiac Pediatric	 		 						
Cardiac	Trans-esophageal (card.)	1	1	 	 					
	Other (spec.)	1			 					
Peripheral	Peripheral vessel	†								
Vessel	Other (spec.)	1	1					**		

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices, 02696

510(k) Number -

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 9 Diagnostic Ultrasound Indications for Use Form - ICT/8-5 Transducer

System:	SonoSite TITA	N™ higl	n-resol	ution ult	trasoun	d systen	1			
Transducer:	ICT/8-5 10.0- 5	5.0 MHz	Intraca	vitary T	ransdu	icer				
Intended Us	e. Diagnostic ultr	asound	sound imaging or fluid flow analysis of the human body as							
interiaca oc	follows:			9		,				
Clinic	Clinical Application Mode of Operation						tion			
General	Specific	 		T		Color	Combined	Other		
(Track I only)	(Tracks I & III)	В	_ M	PWD	CWD	Doppler	(Spec.)	(Spec.)		
Ophthalmic	Ophthalmic									
			ļ				B+M; B+PWD;			
	Fetal	N	N	N		N	B+CD	Note 1		
	Abdominal									
	Intra-operative (Abdomina									
<u> </u>	organs and vascular)			<u> </u>	ļ	ļ				
	Intra-operative (Neuro.)	<u> </u>								
Fetal Imaging	Laparoscopic		<u> </u>			ļ				
& Other	Pediatric		ļ			ļ				
1	Small Organ (breast,	1								
	thyroid, testicles.)			<u> </u>	ļ					
	Neonatal Cephalic		<u> </u>	<u> </u>	ļ					
	Adult Cephalic		<u> </u>	ļ	ļ	-	D.M. D.DMD.			
•			١.,	١,,			B+M; B+PWD;	Nata 4		
	Trans-rectal	N	N	N	-	N	B+CD	Note 1		
	- un atreat		N.	N	1	N	B+M; B+PWD; B+CD	Note 1		
	Trans-vaginal	N	N	N		14	עטיים	Note		
	Trans-urethral	_			 	-				
	Trans-esoph. (non-Card.)		 	 	 	 				
	Musculo-skel. (Convent.)		 	+	-	-				
	Musculo-skel. (Superfic.)		+	+	 	 		 		
	Intra-luminal			+		 				
	Other (spec.)			+	-	 				
	Cardiac Adult		 							
Cardiac	Cardiac Pediatric		 	 	 	 				
	Trans-esophageal (card.)	+	 	+	 					
	Other (spec.)		 		-					
Peripheral	Peripheral vessel			1		 				
Vessel	Other (spec.)	1	1	1	1					

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number_

Table 4.3- 10 Diagnostic Ultrasound Indications for Use Form – L25/10-5 Transducer

System:	Sono	Site TITAN	™ high	n-resol	ution ult	rasoun	d systen	1		
Transducer:	L25/1	L25/10-5 10.0-5.0 MHz Linear Array								
Intended Use	ınalysis d	of the human b	ody as							
Clinica	al Application	on			N	Mode o	f Operat	tion		
General (Track I only)	Spec (Tracks		В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)	
Ophthalmic	Ophtha	ılmic								
	Feta	al	N	N	N	•	1	B+M; B+PWD	Note 1	
	Abdom		N	N	N		N	B+M; B+PWD; B+CD	Note 1	
	Intra-operative organs and	vascular)	N	N	N			B+M; B+PWD	Note 1	
Cotol Incoming	Intra-operativ		N	N	N	-		D.M. D. DWD	Ninta d	
Fetal Imaging	Laparos	copic		IN	<u>IN</u>			B+M; B+PWD;	Note 1	
& Other	Pedia		N	N	N		N	B+CD	Note 1	
	Small Orgai thyroid, te		N	N	N		N	B+M; B+PWD; B+CD	Note 1	
	Neonatal (N	N	N		N	B+M; B+PWD; B+CD	Note 1	
	Adult Ce						<u> </u>			
	Trans-r									
		Trans-vaginal				ļ				
		Trans-urethral Frans-esoph. (non-Card.)			-		ļ			
			N	N	N		-	DIM DIDWD	N-1- 4	
	Musculo-skel.	(Convent.)	IN	IN .	IN			B+M; B+PWD;	Note 1	
	Musculo-skel.	(Superfic.)	Р	P	P		Р	B+CD	Note 1	
	Intra-lui				1					
· · · · · · · · · · · · · · · · · · ·	Other (s	spec.)			T					
	Cardiac									
Cardiac	Cardiac P	ediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1	
	Trans-esopha				-	ļ	ļ			
	Other (s	pec.)			ļ					
Peripheral	Periphera	l vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1	
Vessel	Other (s	spec.)								

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Musculo-skel. (Superfic.) imaging previously cleared in 510(k) K003399.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number ___

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 11 Diagnostic Ultrasound Indications for Use Form - L38/10-5 Transducer

System:	SonoSite TITAN	l™ high	n-resol	ution ult	trasoun	d systen	n					
Transducer:	L38/10-5 10.0- 5	5.0 MH	z Intrad	cavitary	Transo	lucer						
Intended Use		sound imaging or fluid flow analysis of the human body as										
	follows:											
Clinica	Clinical Application			Mode of Operation								
General	Specific	_				Color	Combined	Other				
(Track I only)	(Tracks I & III)	В	М	PWD	CWD	Doppler	(Spec.)	(Spec.)				
Ophthalmic	Ophthalmic											
	Fetal	2	N	N			B+M; B+PWD	Note 1				
							B+M; B+PWD;					
	Abdominal	N	N	N		N	B+CD	Note 1				
	Intra-operative (Abdominal											
	organs and vascular)	N	N	N	<u> </u>		B+M; B+PWD	Note 1				
	Intra-operative (Neuro.)											
Fetal Imaging	Laparoscopic	N	N	N			B+M; B+PWD	Note 1				
2.00	5 "			١			B+M; B+PWD;					
& Other	Pediatric	N	N	N		N	B+CD	Note 1				
	Small Organ (breast,						B+M; B+PWD;					
	thyroid, testicles.)	N	N	N	 	N	B+CD	Note 1				
	Na anatal Cambalia	N	N	N		N	B+M; B+PWD; B+CD	Ninta 4				
	Neonatal Cephalic	IN	IN	114	<u> </u>	IN	B+CD	Note 1				
	Adult Cephalic Trans-rectal											
	Trans-rectar Trans-vaginal				<u> </u>							
	Trans-vaginal Trans-urethral				ļ							
P1. 1. P1.	Trans-esoph. (non-Card.)			 								
	Musculo-skel. (Convent.)	N	N	N	 	 	B+M; B+PWD	Note 1				
	Musculo-skel. (Convent.)	iv .			 		B+M; B+PWD;	INOLE I				
	Musculo-skel. (Superfic.)	Р	Р	P		P	B+CD	Note 1				
	Intra-luminal	·'	•	†			5.05	- Auto I				
	Other (spec.)				1	 						
	Cardiac Adult					 						
	Caldiac Addit			 			B+M; B+PWD;					
Cardiac	Cardiac Pediatric	N	N	N		N	B+CD	Note 1				
- Carolao	Trans-esophageal (card.)	- ' '		 	 	 		110101				
	Other (spec.)			 	 	 		†				
							B+M; B+PWD;	1				
Peripheral	Peripheral vessel	N	N	N		N	B+CD	Note 1				
Vessel	Other (spec.)	· · · · · · · · · · · · · · · · · · ·	- '`			'*	D. 00	110.0				
A C29C1	Otner (spec.)							L				

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Musculo-skel. (Superfic.) imaging previously cleared in 510(k) K003399.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

Indications for Use

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 12 Diagnostic Ultrasound Indications for Use Form – L52/10-5 & L52-S/10-5 Transducers

System:		SonoSite TITAN	™ high	n-resol	ution ult	rasoun	d systen	1			
Transducer:		L52/10-5 and L5	2S/10-	5 10.0	-5.0 MH	Iz Line:	ar Array				
Intended Use	e:	Diagnostic ultras	sound imaging or fluid flow analysis of the human body as								
		follows:							•		
Clinica	Clinical Application			Mode of Operation							
General		Specific					Color	Combined	Other		
(Track I only)		(Tracks I & III)	В	M	PWD	CWD	Doppler	(Spec.)	(Spec.)		
Ophthalmic		Ophthalmic									
		Fetal	N	N	N			B+M; B+PWD	Note 1		
		Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1		
	org	operative (Abdominal gans and vascular)	N	N	N			B+M; B+PWD	Note 1		
	Intra	a-operative (Neuro.)			1						
Fetal Imaging	ļ	Laparoscopic	N	N	N			B+M; B+PWD	Note 1		
& Other		Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1		
		nall Organ (breast,						B+M; B+PWD;			
	t	hyroid, testicles.)	N	N	N		N	B+CD	Note 1		
	l,	Icanatal Caphalia	N	N	N		_N	B+M; B+PWD; B+CD	Note 1		
		leonatal Cephalic Adult Cephalic	IV	IN .	111	<u> </u>	1	BTCD	Note 1		
		Trans-rectal			 						
	-	Trans-vaginal			1						
		Trans-urethral	-		-		l				
	Tran	s-esoph. (non-Card.)									
		culo-skel. (Convent.)	N	N	N			B+M; B+PWD	Note 1		
	1							B+M; B+PWD;			
	Mus	culo-skel. (Superfic.)	<u>P</u>	Р	Р		Р	B+CD	Note 1		
		Intra-luminal									
	1	Other (spec.)									
		Cardiac Adult									
Cardiac		Cardiac Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1		
	Tran	s-esophageal (card.)									
		Other (spec.)									
Peripheral		Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1		
Vessel		Other (spec.)					,				

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

Additional Comments:

Note 1: Other includes Color Power Doppler, combined B and Color Power Doppler, combined B and Directional Color Power Doppler, 3-D Imaging, Tissue Harmonic Imaging, and imaging for guidance of biopsy. Included with this 510k are imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Musculo-skel. (Superfic.) imaging previously cleared in 510(k) K003399.

Color Doppler includes Velocity Color Doppler.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _

D02576A-510(K) Submission-SonoSite TITAN high-resolution ultrasound system 06-Mar-2003

Table 4.3- 13 Diagnostic Ultrasound Indications for Use Form - 2 MHz Doppler Pencil

System:		SonoSite TITAN™ high-resolution ultrasound system								
Transducer:		Doppler Pencil Tr						cular Array	-	
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body follows:										
Clinica	al Ap	Application Mode of Operation								
General (Track I only)		Specific (Tracks I & III)	В	М	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)	
Ophthalmic		Ophthalmic			}					
		Fetal	*							
		Abdominal								
		operative (Abdominal gans and vascular)								
	Intr	a-operative (Neuro.)								
Fetal Imaging		Laparoscopic			<u> </u>					
& Other		Pediatric								
	1	mall Organ (breast, thyroid, testicles.)								
		Neonatal Cephalic					ļ	<u>.</u>	ļ	
		Adult Cephalic			ļ					
		Trans-rectal			<u> </u>		ļ		1	
		Trans-vaginal					 			
	77	Trans-urethral			-				-	
		s-esoph. (non-Card.)		-	 			<u> </u>		
		sculo-skel. (Convent.)		-	-		 -	****	 	
	ivius	Intra-luminal		 	 				-	
		Other (spec.)		 	 				-	
		Cardiac Adult				N				
Cardiac		Cardiac Pediatric			 	N	 		 	
Oditilat		ns-esophageal (card.)			 	- ' -	 	 		
	- 1141	Other (spec.)		<u> </u>	1					
Peripheral		Peripheral vessel	***							
Vessel		Other (spec.)			1					

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

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal,

and Radiological Devices

510(k) Number _