KO41499

JUN 1 0 2004

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name:

Toshiba America Medical Systems, Inc.

Address:

PO Box 2068,2441 Michelle Drive Tustin, CA 92781-2068

Contact:

Paul Biggins, Sr. Manager of Regulatory Affairs

Telephone No.:

(714) 730-5000

Device Proprietary Name: SSA-770A, APLIO Version 5.5

Common Name:

Diagnostic Ultrasound System

Classification:

Regulatory Class:

II

Review Category:

Tier II

Ultrasonic Pulsed Doppler Imaging System - Product Code: 90-IYN

[Fed.Reg.No.:892.1550]

Ultrasonic Pulsed Echo Imaging System - Product Code: 90-IYO

[Fed.Reg.No.:892.1560]

Diagnostic Ultrasonic Transducer – Product Code: 90-ITX

[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

- 1) Toshiba SSA-770A, Aplio Version 4.0 Diagnostic Ultrasound; 510(k) control number k032281
- 2) Siemens Medical Solutions Sequoia 8.0 Diagnostic Ultrasound System; 510(k) control number k032281

Device Description:

The APLIO Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:

The APLIO is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular, musculo-skeletal (both conventional and superficial) and laparoscopic.

Safety Considerations:

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601 (applicable portions), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

JUN 1 0 2004

Toshiba America Medical Systems, Inc. % Mr. Mark Job Responsible Third Party Official Regulatory Technology Services LLC 1394 25th Street NW BUFFALO MN 55313

Re: K041499

Trade Name: APLIO Diagnostic Ultrasound System, Model SSA-770A

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

Regulatory Name: Diagnostic ultrasonic transducer

Regulatory Class: II

Product Code: 90 IYN, IYO, and ITX

Dated: June 4, 2004 Received: June 7, 2004

Dear Mr. Job:

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 APLIO Diagnostic Ultrasound System, Model SSA-770A, as described in your premarket notification:

Transducer Model Number

PST-25AT PVT-375AT PVT-661VT PLT-805AT	PLT-1204AX PC-20M PET-510MB PLT-1202S	<u>PST-37CT</u> <u>PST-30BT</u> <u>PLT-704AT</u> <u>PLT-1204AT</u> PVT-375AX
PST-20CT	PET-704LA	<u>PVT-375AX</u>

PST-65AT PLT-604AT PST-50AT PLT-308P PET-508MA PVT-770RT <u>PVT-375BT</u> <u>PVT-382BT</u>

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,

Nancy C. Brogdon

Director, Division of Reproductive, Abdominal and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System X Transducer	
Model SSA-770A	
510(k) Number(s)	

		Mode of Operation										
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic									P			
Fetal	P	P	P	P	P	P	P	P	P			
Abdominal	P	P	P	P	P	P	P	P	r		<u> </u>	
Intraoperative (Specify)**	P	P	P	ļ	P	P	P	P			1	├
Intraoperative Neurological												ļ
Pediatric	P	P	P	P	P	P	P	P	P		ļ	↓
Small Organ (Specify)***	P	P	P		P	P	P	P	P		ļ.—	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P			<u> </u>
Adult Cephalic	P	P	P	P	P	P	P	P	P		-	P
Cardiac	P	P	P	P	P	P	P	P	P	Ε'	P	
Transesophageal	P	P	P	P	P	P	P	P		E	ļ	P
Transrectal	P	P	P		P	P	P	P	P		<u> </u>	
Transvaginal	P	P	P		P	P	P	P	P		<u> </u>	<u> </u>
Transurethral								<u> </u>	ļ		ļ —	
Intravascular					<u> </u>						<u> </u>	—
Peripheral Vascular	P	P	P		P	P	P	P	P		 	—
Laparoscopic	P	1_	<u> </u>	1	P	P	P	P			ļ <u> </u>	
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P			
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Com	ments: Combined Modes: B/M; B/PWD;
BDF/PWD: BD	F/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;
CHI/2D: FEI/2	D; CHI/BDF; FEI/BDF
CHUZD, I DUZ	
E¹ - Adde	l via LTF against SSA-700A 510(k) control number K022400
Previous 5	10(k) for this device k013633
	odominal
*** Fo	r example: thyroid, parathyroid, breast, scrotum and penis

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON OTHER PAGES IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)11

System Transducer_X	
Model PST-25AT	
510(k) Number(s)	

		Mode of Operation										
Clinical Application	В	M	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI Q
Ophthalmic				\dashv				<u> </u>				-
Fetal							<u> </u>	<u> </u>			<u> </u>	
Abdominal		<u> </u>					 	<u> </u>	ļ		 	┼
Intraoperative (Specify)							<u> </u>	 	<u></u>		 	+
Intraoperative Neurological										_		<u> </u>
Pediatric	P	P	P	P	P	P	P	P	P		 	
Small Organ (Specify)				_			<u> </u>	<u> </u>	 		 	┼
Neonatal Cephalic											 	+
Adult Cephalic		_	_					P	P	E	-	├ P
Cardiac	P	P	P	P	P	P	P		· · · · · · · · · · · · · · · · · · ·		 	┤╌
Transesophageal		<u> </u>		_		<u> </u>					├	╁╌─
Transrectal		L	<u> </u>	1_		ļ			ļ			
Transvaginal				<u> </u>							+-	
Transurethral		↓_		L			<u> </u>		 	ļ. <u> </u>	-	-
Intravascular				<u> </u>					·			
Peripheral Vascular		1		<u> </u>			1					+
Laparoscopic		_	1	L				_			-	+
Musculo-skeletal												
Superficial		1	\downarrow	1_		 		 	 			+
Musculo-skeletal					1							
Conventional		_		_	<u> </u>			7.1. d d a		E (LTE)		

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF	
E' - Added via LTF against SSA-700A 510(k) control number K022400	
Previous 510(k) for this device k013633	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System Transducer \underline{X}	
Model PVT-375AT	
510(k) Number(s)	

		Mode of Operation										
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic								P	P		<u> </u>	
Fetal	P	P	P		P	P	P	<u> </u>				\vdash
Abdominal	P	P	P	_	P	P	P	P	P			—
Intraoperative (Specify)												—
Intraoperative Neurological		<u> </u>									 	
Pediatric	P	P	P	L	P	P	P	P	P	<u>-</u>		∤
Small Organ (Specify)			_				<u> </u>					╂
Neonatal Cephalic]_	ļ					ļ		<u> </u>			 -
Adult Cephalic		<u> </u>		_				<u> </u>				┼
Cardiac	\perp		L.	<u> </u>				<u> </u>	ļ. ——		 	
Transesophageal			L	_				<u> </u>				┼
Transrectal	\perp	<u> </u>		<u> </u>				<u> </u>	ļ		ļ	+
Transvaginal	_	_		↓				<u> </u>	<u> </u>			
Transurethral		1_	L	_				.	<u> </u>		-	
Intravascular	\perp	<u> </u>		↓_				ļ		<u> </u>		
Peripheral Vascular		1_	L	<u> </u>				.	<u> </u>			
Laparoscopic	_	1_	_	1.				<u> </u>	<u> </u>		 	+-
Musculo-skeletal Superficial		<u> </u>	L.	<u> </u> _	<u> </u>				ļ		 	+
Musculo-skeletal		1						1				
Conventional			1	1				.1	1	<u> </u>	<u> </u>	

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

	Combined Modes		
BDF/PWD; BDF/MDF; BDF	/MDF/PWD:B-TDI:	M-TDI; 2D/CWD; BD	F/CWD;
CHI/2D; FEI/2D; CHI/BDF;	LENDOL		
			-
Previous 510(k) for this dev	rice k013633		
=:			

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

							Mode o	f Operati	on		г	ı—
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI Q
Ophthalmic	1											
Fetal	1											<u> </u>
Abdominal	1											<u> </u>
Intraoperative (Specify)	1											├
Intraoperative Neurological												
Pediatric											 -	-
Small Organ (Specify)	T							ļ	<u> </u>		-	-
Neonatal Cephalic	Т						ļ	ļ			-	-
Adult Cephalic	T								ļ <u> </u>		-	
Cardiac		Γ									 	┼─-
Transesophageal		ĺ							P		 	-
Transrectal	P	P	P		P	Р	P	P			<u> </u>	┼
Transvaginal	P	P	P		P	P	P	P	P		 	
Transurethral]					<u> </u>		ļ			-
Intravascular	T							ļ				-}
Peripheral Vascular								<u> </u>			↓	-}
Laparoscopic	7		Γ								 	
Musculo-skeletal						1						
Superficial		\perp_{-}	L		ļ			<u> </u>		<u>'</u>	 	+-
				1								
Musculo-skeletal	1	1										

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System Transducer X	· •
Model PLT-805AT	·
510(k) Number(s)	

							Mode o	f Operati	on		т	
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic							<u></u>	<u> </u>			 	
Fetal								<u> </u>			 	┼
Abdominal				_			ļ		ļ		 	
Intraoperative (Specify)								ļ			 	
Intraoperative Neurological								ļ				
Pediatric							<u> </u>		<u> </u>		 	┼┈ ─
Small Organ (Specify)	P	P	P		P	P	P	P	P		<u> </u>	
Neonatal Cephalic				_					ļ		 	┼
Adult Cephalic						ļ			<u> </u>		 	 -
Cardiac		_	_			ļ		<u> </u>	ļ		-	
Transesophageal				_					 			-
Transrectal		<u></u>	ļ					ļ <u>.</u>	<u> </u>		 	+-
Transvaginal			<u> </u>	_							 	┼
Transurethral			<u> </u>						 		 	-
Intravascular		L.	_	_		<u> </u>	ļ <u> </u>	ļ <u>.</u> -	P	ļ .	┼	┼
Peripheral Vascular	P	P	P	<u>.</u>	P	P	P	P	P		 	
Laparoscopic		L	_				<u> </u>	ļ	P		 -	
Musculo-skeletal Superficial	P	P	P		P	P	P	P				<u> </u>
Musculo-skeletal Conventional	P	P	P		P	P	P	Ъ	P			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes	<u>: B/M; B/PWD;</u>	
BDF/PWD; BDF/MDF; BDI	F/MDF/PWD;B-TDI;	M-TDI; 2D/CWD; BDF	/CWD;
CHI/2D; FEI/2D; CHI/BDF			
CHUZD, I EUZD, CHUBDI	, , , , , , , , , , , , , , , , , , , ,		
Previous 510(k) for this de	vice k013633		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

							Mode o	f Operati	on	<u>.</u>		τ
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TD Q
Ophthalmic											ļ	-
etal	P	P	P	P	P	P	P	P	P			
Abdominal												
ntraoperative (Specify)											ļ	-
ntraoperative Neurological												<u> </u>
Pediatric								<u> </u>			ļ —	
Small Organ (Specify)											ļ.—	╁┈—
Veonatal Cephalic	P	P	P	P	P	P	P	P	P		 	↓_
Adult Cephalic											<u> </u>	-
Cardiac	P	P	P	P	P	P	P	P	P		ļ	
Fransesophageal		<u> </u>		_								<u> </u>
Fransrectal				L							<u> </u>	_
Transvaginal			<u> </u>								<u> </u>	-
[ransurethral				L							 	┼
ntravascular	$\prod_{i=1}^{n}$			<u> </u>							<u> </u>	+
Peripheral Vascular												_
Laparoscopic				L							<u> </u>	╄
Musculo-skeletal												
Superficial		<u> </u>	<u> </u>	┺			<u> </u>				 	+
Musculo-skeletal Conventional			1									
		1		l		1		1 .	ļ.,	E (LTF)	<u> </u>	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

System Transducer _X Model PLT-1204AX 510(k) Number(s)	

	1		_				Mode o	f Operati	on		,	т—
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic								ļ			-	┼—
Fetal											-	
Abdominal							<u> </u>	 				
Intraoperative (Specify)								ļ <u></u> -			 	┼
Intraoperative Neurological								ļ				
Pediatric	\top								P	<u> </u>		
Small Organ (Specify)	P	P	P		P	P	P	P	r		 	┼
Neonatal Cephalic			_								 	┼
Adult Cephalic						ļ		- 			 	
Cardiac			_	_				 			ļ —	┼
Transesophageal			_	<u> </u>			ļ	<u> </u>			 	┼
Transrectal			_	ļ <u>.</u>				ļ. ————			 	┼
Transvaginal			_	_			<u> </u>				┼ —	┼
Transurethral		_		<u> </u>			ļ—. —	<u></u>			 	╂
Intravascular	_ _	<u> </u>		_			ļ	P	P		 -	
Peripheral Vascular	P	P	P	_	Р	P	P	l r	I		+	+-
Laparoscopic		1_	ļ	\perp		ļ	P	P	P		-	+-
Musculo-skeletal Superficial	P	P	P		P	P					_	<u> </u>
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P			

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF	
Previous 510(k) for this device k013633	

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Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

	-							f Operati				1
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	Q Q
Ophthalmic												
Fetal												
Abdominal												ļ.—
Intraoperative (Specify)											ļ	├ ─
Intraoperative Neurological												
Pediatric	Т		-	P								
Small Organ (Specify)								<u> </u>				1
Neonatal Cephalic							ļ	ļ				<u> </u>
Adult Cephalic							<u> </u>				 	
Cardiac	1			P							<u> </u>	
Transesophageal												
Transrectal											<u> </u>	╄
Transvaginal				L								
Transurethral			Ī					<u> </u>			 	↓ _
Intravascular	T										<u> </u>	┼-
Peripheral Vascular							ļ				 	
Laparoscopic											 	-
Musculo-skeletal						1						
Superficial		1_	$oldsymbol{ol}}}}}}}}}}}}}}}}}}$	<u> </u>					 		-	-
Musculo-skeletal	ł						•					
Conventional N= new indication;			<u> </u>	<u> </u>		<u> </u>	<u> </u>	1		E (LTE)	l	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

							Mode o	f Operati	on			
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI Q
Ophthalmic								ļ	!		 	
Fetal											 	┼─
Abdominal						-		ļ			├	├─
Intraoperative (Specify)											 -	┼—
Intraoperative												
Neurological	丄										 	╁—-
Pediatric											<u> </u>	
Small Organ (Specify)									ļ. <u></u>		 	┼
Neonatal Cephalic		Γ										 -
Adult Cephalic								<u> </u>	ļ		 	┼
Cardiac	\neg										ļ	- n
Transesophageal	P	P	P	P	P	P	P	P	P	E		P
Transrectal	_ _								ļ		<u> </u>	↓
Transvaginal											-	
Transurethral		1						<u> </u>	ļ		 -	—
Intravascular	T							ļ	ļ			↓-
Peripheral Vascular		Ī										↓ —
Laparoscopic	\top						<u> </u>			<u></u>		
Musculo-skeletal	\top		1 -						1			
Superficial			_		<u> </u>					ļ	-	
Musculo-skeletal	T							1				
Conventional]	<u> </u>		<u> </u>		1	<u> </u>		
N= new indication: Additional Common BDF/PWD; BDF/N CHI/2D; FEI/2D; Previous 510(ents: MDF CHL	; <u>B</u>]	DF/)F;	MI FE	Combine DF/PWD I/BDF	d Modes: B	/M· B/PW	VD:		E(LIF)		

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Prescription Use (Per 21 CFR 801.109)

System Transducer X
Model PLT-1202S
510(k) Number(s)

							Mode of	f Operation	n			
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q
Ophthalmic				_								-
Fetal												
Abdominal				ļ			 	P	P		<u> </u>	┼
Intraoperative (Specify)	P	P	P		P	P	P	P	F		-	┼
Intraoperative Neurological	_			ļ			 		 	<u> </u>		┼
Pediatric				<u> </u>			<u> </u>	P	P			┼
Small Organ (Specify)	P	P	P	<u> </u>	P	P	P	r	r -	 	<u> </u>	┼
Neonatal Cephalic				<u> </u>						<u> </u>	 	┼
Adult Cephalic	1	ļ					<u> </u>		<u> </u>	<u> </u>	 	+-
Cardiac	ļ	<u> </u>	_	 					 	 -		+-
Transesophageal	<u> </u>	<u>L</u>		1_	<u> </u>	<u></u>	<u> </u>	<u> </u>			ļ <u> </u>	
Transrectal	<u> </u>	<u> </u>		ļ_			 		 	ļ	<u> </u>	+
Transvaginal	┷	_		<u> </u>					 			+
Transurethral	<u> </u>	_	ļ <u>.</u>	_		<u> </u>			ļ		┼	╂
Intravascular	1_	lacksquare	\downarrow _	上		<u> </u>	P	P	P -		-	
Peripheral Vascular	P	P	P	\perp	P	P	r	r	ļ [*]	 	-	+-
Laparoscopic	\perp	<u> _</u>	<u> </u>	<u> </u>		<u> </u>	P	P	P	<u> </u>	 	+
Musculo-skeletal Superficial	P		1	\perp	P	P		P	P	ļ	ļ	+
Musculo-skeletal	P	P	P	1	P	P	P	r	1			1
Conventional					<u> </u>		<u> </u>	1 1 1			<u> </u>	

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD;	
BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF	
Previous 510(k) for this device k013633	
	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

	1		_				Mode o	f Operati	on			
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI Q
Ophthalmic	† -			\exists					·			ļ
Fetal												<u> </u>
Abdominal			一									ļ
Intraoperative (Specify)	+-											
Intraoperative Neurological	1											
Pediatric	1											<u> </u>
Small Organ (Specify)												<u> </u>
Neonatal Cephalic											<u> </u>	<u> </u>
Adult Cephalic	\top											<u> </u>
Cardiac											ļ	<u> </u>
Transesophageal												1
Transrectal												ļ
Transvaginal												
Transurethral	_ _										ļ	
Intravascular			·									
Peripheral Vascular											<u> </u>	
Laparoscopic	P	P	P		P	P	P	P			<u> </u>	<u> </u>
Musculo-skeletal												
Superficial			<u> </u>				ļ				 	-
Musculo-skeletal			1									
Conventional					<u> </u>	1				E (Y TE)	<u> </u>	L
N= new indication;	P =	= Pt	evi	iou:	sly Clear	ed by FDA	E = Ad	lded under	Appendix	E(LIF)		
Additional Comme BDF/PWD; BDF/M	nts:			(<u>Combine</u>	d Modes: B	<u>5/M; B/PW</u>	<u>/D;</u>				
BDF/PWD; BDF/N	<u>IDF</u>	BI)F/	MI	<u> DF/PWD</u>	<u>;B-TDI; M</u>	<u>-TDI; 2D/</u>	CWD; BD	F/CWD;			
CHI/2D; FEI/2D; G	CHI/	<u>B</u> D	F;_	FE.	I/BDF							
Previous 510(1	() for	thic	devi	ا م	013633							
Previous 510()	O for	uns	uevi	LE K	01.00.5.7						_	
									· · · · · · · · · · · · · · · · · · ·	•		

Division of Reproductive, Abdominal, and Radiological Devices KOZIIIG

(Division Sign-Off)

Prescription Use (Per 21 CFR 801.109)

		_				· · · · · · · · · · · · · · · · · · ·	Mode of	Operation	on			
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic												├ ──
Fetal	E	E	E	E	E	E	E	E	E			
Abdominal	E	E	E	E	E	Е	E	E	E			· -
Intraoperative (Specify)	1 –											1
Intraoperative	1											
Neurological											ļ	
Pediatric	E	E	E	E	E	E	Е	E	E		ļ	
Small Organ (Specify)												
Neonatal Cephalic										ļ	ļ	
Adult Cephalic										-		
Cardiac		Г										
Transesophageal	1			1							ļ	
Transrectal								_			<u> </u>	
Transvaginal		T									ļ	
Transurethral		1									<u> </u>	<u> </u>
Intravascular		1		\Box							ļ	┸
Peripheral Vascular											<u> </u>	
Laparoscopic											<u> </u>	_
Musculo-skeletal	_	t	T	1								İ
Superficial				1							<u> </u>	
Musculo-skeletal		\top								ļ		
Conventional		_						<u> </u>			l	⊥
N= new indication; Additional Comme BDF/PWD; BDF/M CHI/2D; FEI/2D; C	nts: <u>IDF</u>	; <u>B</u> l	DF/	(MI	Combine OF/PWD	d Modes: B	/M; <u>B/P</u> W	/D;		L (LII		- - -

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

			_				Mode of	f Operation	on			
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
Ophthalmic	_											<u> </u>
Fetal												ļ
Abdominal	E	E	Е	E	Е	Е	E	E	E			<u> </u>
Intraoperative (Specify)									,			
Intraoperative												
Neurological												<u> </u>
Pediatric	E	E	Е	E	E	E	E	Е	Е			
Small Organ						1						
(Specify)								<u> </u>				
Neonatal Cephalic												<u> </u>
Adult Cephalic												
Cardiac	E	E	Е	E	E	E	Е	E	E	E	P	P
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												<u> </u>
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal												
Superficial												
Musculo-skeletal												
Conventional									1		<u> </u>	
N= new indication; Additional Commen		= Pr	evi			ed by FDA; d M <u>odes:</u> B			Appendix	E (LTF	⁷)	

Prescription Use (Per 21 CFR 801.109)

510(k) Number __

							Mode of	Operation	on			
inical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-
ohthalmic												ļ
tal			i									
odominal	1							<u> </u>				<u> </u>
traoperative (Specify)												
traoperative eurological												
diatric								<u> </u>				
nall Organ (Specify)	E	E	E		Е	E	E	E	E			
eonatal Cephalic												<u> </u>
dult Cephalic								_ 				ļ—
ardiac												ļ
ansesophageal			П									
ansrectal										ļ	ļ	<u> </u>
ansvaginal										ļ		
ansurethral	\top			Г		·					ļ	<u> </u>
travascular												↓
eripheral Vascular	E	E	E	\Box	E	E	Е	E	E	ļ		<u> </u>
aparoscopic	_ _		1							<u> </u>		<u> </u>
lusculo-skeletal	E	Е	E		E	E	E	E	E			
uperficial										-		-
lusculo-skeletal	E	E	E		Е	E	E	Е	Е			
onventional			ł		1				Appendix	<u> </u>	<u> </u>	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

							Mode of	f Operation	on			F
inical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-0
ohthalmic	\top	\neg		\neg								<u> </u>
tal												
odominal	1											<u> </u>
traoperative (Specify)	1											
traoperative eurological												
diatric	\perp						T2	E	E			
nall Organ (Specify)	E	E	E		E	E	Е	<u> </u>	E			
eonatal Cephalic		<u> </u>	L				ļ					
dult Cephalic								ļ	 	-		┼—
ardiac								1		<u> </u>	ļ	↓ .—
ransesophageal												-
ransrectal		<u> </u>		_			ļ		<u>. </u>		ļ	-
ransvaginal		_				ļ	ļ <u>-</u>		ļ <u> </u>		ļ	-
ransurethral		_					ļ		ļ	 	-	
travascular			L.	_					ļ	ļ	 	
eripheral Vascular	E	E	E	_	E	E	Е	E	E		 	-
aparoscopic										ļ	ļ	
Iusculo-skeletal	E	E	E		Е	E	E	E	E			
uperficial	_	1_	L	1_			<u></u>	E	E		 	
Iusculo-skeletal	E	E	E		E	E	Е	it.	I.			
onventional		1	1	1			<u> </u>		Appendix		<u></u>	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

	T						Mode of	f Operation	on			
linical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-
phthalmic												<u> </u>
etal	E	E	E		E	E	Е	E	E		<u> </u>	
bdominal	E	E	E		E	E	E	E	Е			
traoperative (Specify)	\top											
ntraoperative leurological												
ediatric	E	E	E		E	E	Е	E	E			ļ
mall Organ (Specify)		1								ļ		
leonatal Cephalic	1-	†		I^-	"							
dult Cephalic		1										ļ
Cardiac		1								<u> </u>		
ransesophageal	\top	T	Π									<u> </u>
ransrectal		1		Г								1
ransvaginal	\top	I^-		Γ						<u> </u>	<u> </u>	_
ransurethral		1								ļ	<u> </u>	-
ntravascular		1	Γ								ļ	1
eripheral Vascular	_ _	T	Π	1							<u> </u>	+-
aparoscopic		1-	Τ	1					<u> </u>	ļ	<u> </u>	
Musculo-skeletal		1										
Superficial			<u> </u>	<u> </u>					<u> </u>	 	 	
Musculo-skeletal												
Conventional		\perp	L			ed by FDA			<u> </u>	1	<u></u>	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Clinical Application								Mode of	Operation	on			
Fetal	Clinical Application	В	М	w	w			Velocity					TDI-C
Fetal	Ophthalmic								,				<u> </u>
Abdominal													
Intraoperative (Specify) Intraoperative Neurological Pediatric Small Organ (Specify) Neonatal Cephalic Cardiac Cardiac Transsophageal Transrectal Transvaginal Transvaginal Transvaginal Transvaginal Transvaginal Transvascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;													<u> </u>
Intraoperative												ļ	
Pediatric	Intraoperative												
Small Organ (Specify) Neonatal Cephalic Adult Cephalic Cardiac E E E E E E E E E E E E E E E E E E		E	E	E	Е	E	Е	E	E	E			
Neonatal Cephalic		1											<u> </u>
Adult Cephalic Cardiac E E E E E E E E E E E E E E E E E E		E	E	E	E	E	E	E	E	E		<u> </u>	
Cardiac E E E E E E E E E E E E E E E E E E E	<u> </u>	1											↓
Transectal Transvaginal Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;		E	E	E	Е	E	E	Е	E	Е	Е		
Transvaginal Transvaginal Transvaginal Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;		1										ļ	ļ
Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: BDF/PWD; BDF/MDF; BDF/MDF/PWD; B-TDI; M-TDI; 2D/CWD; BDF/CWD;			Г										<u> </u>
Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;											<u> </u>	ļ	↓
Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;		1		1								<u> </u>	
Peripheral Vascular Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	Intravascular	1	Г									ļ	
Laparoscopic Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;												<u> </u>	
Musculo-skeletal Superficial Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;			1		Ī.								
Musculo-skeletal Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;													
Conventional N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	Superficial		<u> </u>		<u> </u>		<u></u>				. 	 	-
N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	Musculo-skeletal			1		1							
N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF) Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	Conventional		Į								<u> </u>	<u> </u>	
BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;	N= new indication;		= Pı	revi						Appendix	E (LTI	F)	
	BDF/PWD; BDF/M	DF:	Bl	DF/	MI	OF/PWD	<u>d Modes:</u> E ;B-TDI; M	7M; B/PW -TDI; 2D/	(D; CWD; BD	F/CWD;			
CHI/2D; FEI/2D; CHI/BDF; FEI/BDF	CHI/2D; FEI/2D; C	HI	BD	F;	F <u>E</u>	I/B <u>DF</u>							-
					_								•

Prescription Use (Per 21 CFR 801.109)

<u> </u>	T -		_				Mode of	Operation	on		<u>.</u>	
linical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
phthalmic												1
etal	Π											 -
bdominal								<u> </u>				
ntraoperative (Specify)										<u> </u>		
ntraoperative Ieurological												
ediatric			L.					E	E			
mall Organ (Specify)	E	E	E		E	E	Е	F.	T.	<u> </u>		-
leonatal Cephalic									<u></u>		<u> </u>	<u> </u>
dult Cephalic		Γ										
Cardiac						<u> </u>		<u> </u>			<u> </u>	-
ransesophageal		T -									ļ	
ransrectal	1 -										ļ	
Transvaginal		T	1	Г							ļ	<u> </u>
Transurethral	\top		1	Ī .								
ntravascular	\top	<u> </u>				Ţ						<u> </u>
Peripheral Vascular	E	E	E	 	E	E	E	E	Е			
_aparoscopic	十	\top	1-	1								ļ
Musculo-skeletal	+E	E	E	1 -	E	E	Е	E	E			
Superficial					1				ļ	<u> </u>	<u></u>	
Musculo-skeletal	E	E	E	1	E	E	E	E	E			
Conventional								<u> </u>	<u> </u>	<u> </u>	<u> </u>	
N= new indication;	р.	= P	rev	iou	sly Clear	ed by FDA:	E = Ad	lded under	Appendix	E (LTI	₹)	
14- New Indication,	_	-										
Additional Commer	nts:		_	_ (Combine Combine	d Modes: B	/M; B/PW	<u>/D,</u>				
BDF/PWD; BDF/M	IDF	; Bl	D <u>E</u>	MI	DF/PWD	<u>;B-TDI; M-</u>	TDI; 2D/	<u>CWD; BD</u>	F/CWD;			
CHI/2D; FEI/2D; C	CHL	BD	F;	FE	I/BDF_						<u>-</u> .,	-
												-
											_	-

(Division Sign-Off)

510(k) Number _

and Radiological Devices

Division of Reproductive, Abdominal,

Prescription Use (Per 21 CFR 801.109)

							Mode of	Operation	on			1
linical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-C
phthalmic		\neg										<u> </u>
etal	П											ļ
bdominal	\Box									<u> </u>		ļ
ntraoperative (Specify)												
ntraoperative leurological												
ediatric	E	Е	Е	E	E	E	E	E	Е			ļ
mall Organ (Specify)	1-		\vdash		_ 			<u> </u>				<u> </u>
leonatal Cephalic	E	E	E	E	E	E	E	Е	E			<u> </u>
dult Cephalic	╁	l –										
Cardiac	E	E	E	E	E	E	Е	E	E	E		P
ransesophageal	† –		I^-	1								<u> </u>
ransrectal	-	┢	1	† —				·				
ransvaginal	+-	\vdash	t	-							<u> </u>	<u> </u>
ransurethral	1-	-	1	 							ļ	
ntravascular	+-	\vdash	\vdash	1-						<u> </u>		
Peripheral Vascular	+-	╁	╁	+-								<u> </u>
	+-	╁┈	╁─	╁╌								
aparoscopic Musculo-skeletal		┨	╁	╁─	 							
Superficial												
	+	-	+	\dagger	1		1					
Conventional											<u> </u>	
N- new indication:	p.	<u>- P</u>	rev	iou	sly Clear	ed by FDA	E = Ac	lded under	Appendix	E (LT)	. (E)	
Musculo-skeletal Conventional N= new indication;	P :	= P	rev	iou	sly Clear	ed by FDA	; E = Ac	lded under	Appendix	E (LT)	<u> </u> F)	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

							Mode of	f Operation	n			т
linical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 THI	1.5 RSI	TDI-Q
phthalmic												 -
etal								<u> </u>	10	-		┧───
Abdominal	E	E	E		E	E	E	E	E		-	-
ntraoperative (Specify)	E	E	E		E	E	E	E	E .		<u> </u>	╁──
ntraoperative Veurological												
rediatric	E	Е	E		E	E	E	E	E	<u> </u>	ļ—	——
Small Organ (Specify)		T										
Neonatal Cephalic	1	-										
Adult Cephalic	1									ļ	<u> </u>	
Cardiac	1	†									<u> </u>	<u> </u>
Fransesophageal	\dagger		1								ļ	<u> </u>
Transrectal Transrectal	1-	1									ļ	<u> </u>
Fransvaginal	1		1	1						ļ	<u> </u>	
Pransurethral	1	T		Ϊ –					<u> </u>	ļ		.
ntravascular	1-	T	Τ	1						ļ	<u>↓</u>	
Peripheral Vascular	 	Τ	1	1							<u> </u>	1
Laparoscopic	\top	T	1	1 -							<u> </u>	
Musculo-skeletal Superficial												
Musculo-skeletal	\top	\dagger	\top	†-	<u> </u>							
Conventional		1		1		<u></u>					1	
N= new indication; Additional Commer BDF/PWD; BDF/M	its: DF	; <u>B</u>	 DF	/M	Combine	d Modes: B	8/M; B/PV	VD;		E(LT	F)	
					I/BDF_							

Prescription Use (Per 21 CFR 801.109)

	T						Mode o	f Operati	on			
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI Q
Ophthalmic												<u> </u>
Fetal								<u> </u>			-	├ -
Abdominal								<u></u>			 	-
Intraoperative (Specify)												 - -
Intraoperative	†											
Neurological	1								ļ	ļ	ļ	╁
Pediatric	1								ļ		-	
Small Organ (Specify)	1							<u> </u>			<u> </u>	-
Neonatal Cephalic	1-	-									ļ	<u> </u>
Adult Cephalic	+		-	1								<u> </u>
Cardiac	\dashv	-		t —								
Transesophageal	E	E	E	E	E	E	E	E	E	Е		E
Transceophagear		1-	t^-	一							<u></u>	
		┨ -	╁	1		 						
Transvaginal		}		H		 	 					
Transurethral	+	 −	-	-		1						
Intravascular	_}-		-	 —	 							1
Peripheral Vascular	-	╁—	╀	╀	<u> </u>		 		 			<u> </u>
Laparoscopic		1-	 	╨		 		 		 	 	
Musculo-skeletal	1			ì		1						1
Superficial		—	ļ _	↓				 		 	_	
Musculo-skeletal						1						
Conventional N= new indication;			ل		1			المامدا بيندامة	Appandix	E (LTE)		
Additional Comme BDF/PWD; BDF/N CHI/2D; FEI/2D; C	nts: 1DF	; B	DF.	/ <u>M</u>]	Combine DF/PWL	ed Modes: F	8/M: B/PV	VD:				
		.,,										
					<u></u> .							
	_											

(Division Sign-Off)

510(k) Number __

Division of Reproductive, Abdominal,

and Radiological Devices

							Mode o	f Operati	on			т
Clinical Application	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI Q
Ophthalmic												├
Petal								 			-	-
Abdominal				!				<u> </u>				-
Intraoperative (Specify)						ļ						
Intraoperative Neurological												
Pediatric	1_			_		 			 		 	+-
Small Organ (Specify)	ļ_			_			<u>. </u>				 	╁──
Neonatal Cephalic	.			<u> </u>			<u> </u>		-		 	+
Adult Cephalic	<u> </u>	_		<u> </u>	ļ		ļ		<u> </u>		 	
Cardiac	<u> </u>	ļ_				ļ	ļ	ļ	-		 	<u> </u>
Transesophageal	1_	L		ļ	<u> </u>	E	E	E	E		 	+
Transrectal	E	<u> </u>		1_	E	E	E	E	E		1-	1
Transvaginal	E	E	E	<u> </u>	E	E	<u> </u>	· · · · · · · · · · · · · · · · · · ·	 		 	+
Transurethral	\downarrow	<u> </u> _	_	<u> </u>				-		 	┼ -	┪
Intravascular	1_	<u> </u>	Ĺ	<u> </u>	ļ	-	 	- 	 		 	+
Peripheral Vascular	↓_	↓_	_	┡		ļ			- 		-	┪-
Laparoscopic	_	<u> </u>	_		ļ	ļ	<u> </u>				+	-
Musculo-skeletal												
Superficial	4_	-	┞-	┼	<u> </u>				 	 	+	+
Musculo-skeletal				ļ								
Conventional N= new indication;	ᆜ_	<u> </u>		╀-	1 (2)	- J. S	. E - A	ldad under	Appendix	E (LTF)	1	1

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Prescription Use (Per 21 CFR 801.109)

System Transducer X
Model PVT-375BT
510(k) Number(s)

Clinical Application	Mode of Operation												
	В	М	P W D	C W D	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	1.5 Harmonic	1.5 RSI	TDI- Q	
Ophthalmic								E	E			 −−	
Fetal	E	E	E		E	Е	E		E			├	
Abdominal .	E	E	E	<u>L</u>	E	Е	E	Е	E .			 	
Intraoperative (Specify)		L.						-			├ -	 	
Intraoperative Neurological	<u> </u>	L		<u> </u>			ļ	E	E		├	┼	
Pediatric	E	E	E	_	Е	E	Е	F.	E2		 	┼	
Small Organ (Specify)	L	_	\perp	L				<u> </u>				 	
Neonatal Cephalic		<u> </u>	<u> </u>	<u> </u>							-	┼─	
Adult Cephalic		_		_			ļ				┼─	+-	
Cardiac	\perp	_		<u> </u>		ļ		ļ			-	┼	
Transesophageal		<u> </u>		L		<u> </u>		ļ	<u> </u>		├	+	
Transrectal		L		ļ			!	<u></u>			 -	+-	
Transvaginal		_	<u> </u>	L			<u> </u>				╂	+	
Transurethral		L	<u> </u>	Ļ							-	+-	
Intravascular			_	1_				<u> </u>				+-	
Peripheral Vascular		<u> </u>		↓_	<u> </u>					<u> </u>	 	+	
Laparoscopic			_	↓_		ļ	<u> </u>				-	+-	
Musculo-skeletal Superficial	_	_	L	1	<u> </u>		ļ	-				+-	
Musculo-skeletal							1					1	
Conventional			1_	1_		<u> </u>			1	T (LTT)			

N= new indication: P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments:	Combined Modes: B/M; B/PWD;	
RDF/PWD: BDF/MDF: BDF/M	ADF/PWD;B-TDI; M-TDI; 2D/CWD;	BDF/CWD;
CHI/2D; FEI/2D; CHI/BDF; F	EI/BDF	
CITALD, I BB 20, CALLET		

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

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And Radiological Devices
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System Transducer <u>X</u>	
Model PVT-382BT	
510(k) Number(s)	

Clinical Application	Mode of Operation												
	В	М	P W D		Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify)	Harmonic Imaging	L5 Harmonic	1.5 RS1	TDI- Q	
Ophthalmic			Ĺ.				E	E	E			-	
Fetal	E	1_		L	E	E	E	E	E		<u> </u>	 	
Abdominal	E	E	E		Е	E	F	F.				┼─~	
Intraoperative (Specify)		L						 			 	 	
Intraoperative Neurological	L	L	_	<u> </u>			E	E	E		-	+	
Pediatric	E	E	E	<u> </u>	E	Е	E E	E.			<u> </u>	+-	
Small Organ (Specify)	_	\perp	↓_	ļ.,				 	<u> </u>		┼	+	
Neonatal Cephalic		_	<u> </u>	↓_				<u> </u>			 	 	
Adult Cephalic		_	<u> </u>	ļ			ļ				 	+	
Cardiac	<u> </u>	\perp	L	1_					 		 -	┼	
Transesophageal		L	lacksquare	<u> </u>			<u> </u>		<u> </u>		 -	+	
Transrectal	_ـــــــــــــــــــــــــــــــــــــ	┨	ļ	<u> </u>	ļ						+	+	
Transvaginal	<u> </u>	_	\perp	_		<u> </u>		 			-	+	
Transurethral		↓_		\perp	<u> </u>			_	+		-	+-	
Intravascular	<u> </u>	1_	1_	1_	<u> </u>						-	+	
Peripheral Vascular	_	1_	↓_	1_	<u> </u>		<u> </u>	_	 		+	+	
Laparoscopic	\perp	1_	ļ	1					- ·	 	 	+-	
Musculo-skeletal Superficial	1	\perp	<u> </u>	_ _		<u> </u>	 			 	1-	+	
Musculo-skeletal		İ		1									
Conventional			┸		<u> </u>	LL EDA	<u> </u>	ldad undar		T (T CTT)	1		

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF	

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)