510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: KD83505

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888 Fax: +86 755 2658 2680

Contact Person:

Tan Chuanbin Shenzhen Mindray Bio-medical Electronics Co., LTD Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: October 24, 2008

2. <u>Device Name</u>: DC-3/DC-3T Diagnostic Ultrasound System

Classification

Regulatory Class: II Review Category: Tier II

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

3. Marketed Device:

The subject device is substantially equivalent in its technologies and functionality to the original DC-3/DC-3T Diagnostic Ultrasound System that is already cleared under premarket notification number K081320, and the other predicate devices are listed below: Mindray M5 (K083001), Mindray DC-6 (K072164).

4. Device Description:

The DC-3/DC-3T Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, Color mode, PW mode, CW mode, Power mode, DirPower mode or the combined mode (i.e. B/M Mode). This system is a Track 3 device that employs an array of probes that include linear array, convex array and phased array with a frequency range of approximately 2.0 MHz to 12.0 MHz.

5. Intended Use:

The device is intended for use by a qualified physician for ultrasound evaluation of abdominal, cardiac, small parts (breast, testes, thyroid, etc.), peripheral vascular, fetal, transrectal, transvaginal, intraoperative (abdominal, thoracic, and vascular etc.), pediatric, neonatal cephalic, musculoskeletal (general and superficial).

6. Safety Considerations:

The DC-3/DC-3T Diagnostic Ultrasound System has been tested as Track 3 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in September 2008. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004 and NEMA UD 3 Output Display Standard: 2004. The device conforms to applicable medical device safety standards, such as IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-2-37 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the DC-3/DC-3T Diagnostic Ultrasound System demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEC 1 2 2008



Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

% Mr. Robert Mosenkis

President

CITECH, Medical Device Testing and Consulting

mg an

5200 Butler Pike

Plymouth Meeting, PA 19462-1298

Re: K083505

Trade/Device Name: DC-3/DC-3T Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: November 25, 2008 Received: November 26, 2008

Dear Mr. Mosenkis:

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 DC-3/DC-3T Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

<u>6CV1</u>	<u>10L4</u>	<u>3C1</u>
<u>3C5A</u>	<u>6C2</u>	<u>2P2</u>
<u>7L4A</u>	<u>6LE7</u>	<u>7L5</u>
<u>7L6</u>	<u>6LB7</u>	<u>7LT</u> 4

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 (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,

Joyce M. Whang, Ph.D.

Acting Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure(s)

System	×	Transducer	
Model:	DC-3/DC-3T		
510(k) Number(s)	KOP3505		
and the second s			

					Mode of (Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	P	. Р	P		P	P	P	Note 1, 2, 3, 4
Abdominal	P	P	Ρ.	N	P	P	P	Note 1, 2, 3, 4
Intraoperative (specify)*	N	N	N		N	N	N	Note 2, 3, 4
Intraoperative (Neuro)								
Laparoscopic								· · · · · · · · · · · · · · · · · · ·
Pediatric	P	P	Р	N	P	P	P	Note 1, 2, 3, 4
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P	N	P	Р	P	Note 1, 2, 3, 4
Adult Cephalic	Z	N	N	N	N	N	N	Note 1,2, 3
Trans-rectal	P	P	P		P	Р	Р	Note 2, 3, 4
Trans-vaginal	P	P	P		P	P	P	Note 2, 3
Trans-urethral								
Trans-esoph.(non- Card.)								
Musculo-skeletal Conventional	P	P	Р		P	Р	P	Note 2, 3, 4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
Intravascular							·	
Cardiac Adult	N	N	N	N	N	N	N	Note1,2, 3
Cardiac Pediatric	N	N	N	N	N	N	N	Note1,2, 3
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)		L					-	
Intra-Cardiac								
Peripheral Vascular	P	P	P		P	P	P P	Note1, 2, 3, 4
Other (specify)***	P	P	P		P	P	Р	Note1, 2, 3, 4

N=new indication; P=previously cleared by FDA; E=added under Appendix E	
Additional comments: Combined modes: B+M, PW+B, Color + B, Power + B, F	PW +Color+ B, Power + PW +B.
*Intraoperative includes abdominal, thoracic, and vascular etc.	
**Small organ-breast, thyroid, testes, etc.	
***Other use includes Urology.	
Note 1: Tissue Harmonic Imaging. The feature does not use contrast	agents
Note 2: Smart3D	
Note 3: iScape	
Note 4: iBeam	· i

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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 ____

K083505

System Model:			CV1	Transot	IUGI -	<u> </u>	•	
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	T	-			Mode of	Operation		
Clinical Application	<u> </u>	T	Τ	T	Color	Amplitude	Combined	
	В	М	PWD	CWD	Doppler		(specify)	Other (specify
Ophthalmic								
Fetal	P	P	P		P	P	P	Note 2, 3
Abdominal						· ·		
Intraoperative (specify)*				ļ		ļ		
Intraoperative (Neuro)		<u> </u>						
Laparoscopic		ļ		<u> </u>				
Pediatric	<u> </u>							
Small organ(specify)**						<u> </u>		
Neonatal Cephalic			<u> </u>	<u> </u>				
Adult Cephalic		<u> </u>						
Trans-rectal	P	P	P	<u> </u>	P	P	P	Note 2, 3
Trans-vaginal	P	P	P		P	P	P	Note 2, 3
Trans-urethral							· ·	· ·
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional			<u> </u>	<u> </u>	ļ		<u> </u>	
Musculo-skeletal Superficial					ŀ			
Intravascular								
Cardiac Adult					}			
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	P	P	P		P	P	P	Note 2, 3
N=new indication; P=previously	cleared !	by FD.	; E=add	ed under	Appendix	E		· · · · · · · · · · · · · · · · · · ·
Additional comments:Combined	modes:	в+м, г	W+B, C	olor + B	, Power +	B, PW +Col	or+ B, Powe	r + PW +B.
*Intraoperative include	ies abdoi	ninal, t	horacic,	and vasc	ular etc.		_	
**Small organ-breast	, thyroid,	testes,	etc.				· · · · ·	
***Other use include	s Urolog	y.						
Note 1: Tissue Harmo	mic Imag	ging. T	he featur	e does n	ot use cont	rast agents.		
Note 2: Smart3D								· · · · · · · · · · · · · · · · · · ·
Note 3: iScape								
Note 4: iBeam								
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Prescription USE (Per 21 C	FR 801	.109)		2	elest	four		
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System				Transdu	cer	×		
Mođeł:		30	C5A					
510(k) Number(s)	K	283.	505				÷	
		-						
					Mode of	Operation	. ,	
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic							·	
Petal	P	P	Р		- Р-	P	P	Note 1, 2, 3
Abdominal	P	P	P		P	P	P	Note 1, 2, 3
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	P	P	P		P	P	P	Note 1, 2, 3
Small organ(specify)**		L						*
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial								
Intravascular		ļ						
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)					Ī			
Trans-esoph.(Cardiae)								
Intra-Cardiac								
Peripheral Vascular	N	N	N		N	N	N	Note 1, 2, 3
Other (specify)***	N	N	N		N	N	N	Note 1, 2, 3 Note 1, 2, 3
N=new indication; P=previously	cleared l	y FDA	, E=add	ed under	Appendix	E	····	
Additional comments:Combined	modes: l	8+M, P	W+B, C	Color + B	, Power +	B, PW +Col	or+ B, Powe	r + PW +B.
*Intraoperative include	les abdor	ninal, t	horacic,	and vasc	ular etc.			
**Small organ-breast	thyroid,	testes,	etc.		·			
***Other use include:	Urolog	у.						
Note 1: Tissue Harmo	nic lmag	ging. Th	ıc featur	e does no	ol use cont	rast agents.		
Note 2: Smart3D								·
Note 3: iScape								,
Note 4: iBeam	-							
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Concurrence of CDRH, (Office o	f Dev	ice Ev	aluatio	n(ODE)			
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	-		Ra	Idiolog	ical De	vices	Lan	2/-
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Diagnostic Ultrasound Indications for Use Form

System		_		Transduc	er	×		
Model:		7	L4A				•	
510(k) Number(s)	K	283	505		<u> </u>			
				<u>`</u>	- 			
					Mode of (Operation		
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic			1		- оррго	20ррия	(Specify)	
Fetal		<u> </u>	"					
Abdominal	N	N	N		N	N	N	Note 2, 3, 4
Intraoperative (specify)*						<u> </u>		
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	. N		И	N	N	Note 2, 3, 4
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4
Adult Cephalic								
Trans-rectal		<u> </u>						
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)	1		<u> </u>					
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2, 3, 4
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4
Intravascular	 		 					
Cardiac Adult			-				_	
Cardiac Pediatric			•	<u> </u>				-
Intravascular (Cardiac) Trans-esoph (Cardiac)	 							
Intra-Cardiac	-		1					<u> </u>
Peripheral Vascular	P	P	P					
Other (specify)***	+	r	P		P	P	P	Note 2, 3, 4
	1	EDA. E						
N=new indication; P=previously c								
Additional comments: Combined n						+Color+ B, F	ower + PW +	В.
*Intraoperative include			cic, and va	iscular etc	•	<u> </u>		
**Small organ-breast, t		stes, etc.						
***Other use includes								
Note 1: Tissue Harmon	ic Imagin	g. The fe	ature does	not use co	ontrast age	nts.		
Note 2: Smart3D								
Note 3: iScape			·			·		
Note 4: iBeam								
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Prescription USE (Per 21 CFI	₹ 801.10	9)	•					

(Division Sign-Off)

Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number __

System				Transduc	er	×	,				
Model:		-	7L6								
510(k) Number(s)	1	508	71.6 3505		-						
					-						
-	Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify			
Ophthalmic				· · · ·	э орргол	Doppici	(specify)	 			
Fetal											
Abdominal	N	N	N		N	N	N	Note 2, 3, 4			
Intraoperative (specify)*	T							Note 2, 3, 4			
Intraoperative (Neuro)											
Laparoscopic		i .				· · · · · ·					
Pediatric	N	N	N		N	N	N	Note 2, 3, 4			
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4			
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4			
Adult Cephalic								11000 2, 3, 4			
Trans-rectal							·	· · · · · · · · · · · · · · · · · · ·			
Trans-vaginal							-				
Trans-urethral											
Trans-esoph (non-Card.)											
Musculo-skeletal Conventional	P	P	P		Р	. P	P	Note 2, 3, 4			
Musculo-skeletal Superficial	Р	P	P		P	P	P				
Intravascular								Note 2, 3, 4			
Cardiac Adult											
Cardiac Pediatric							•				
ntravascular (Cardiac)											
Trans-esoph.(Cardiac)								· · · · · · · · · · · · · · · · · · ·			
ntra-Cardiac							-				
Peripheral Vascular	P	P	P		P	P	P	Note 2, 3, 4			
Other (specify)***								Note 2, 3, 4			
N=new indication; P=previously c	leared by	FDA; E	added und	ler Appen	dix E						
Additional comments: Combined n	odes: B+	M, PW+	B, Color +	B, Power	+ B, PW	+Color+ B. I	Power + PW +	-B			
*Intraoperative include	s abdomii	ial, thors	cic, and v	scular etc				. <u> </u>			
**Small organ-breast, t				-				<u> </u>			
***Other use includes !		,									
Note 1: Tissue Harmon		o The fe	eture does	not use o	antenat and			<u> </u>			
Note 2: Smart3D		6. THO IC	aune does	not use ca	niu ast age	nts.		_			
Note 3: iScape								 -			
Note 4: iBeam											
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Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and

Radiological Devices

510(k) Number

System				Transduc	er	×							
Model:		-	101.4				-						
510(k) Number(s)	k	cn X	10L4 3505		•								
			23 23	·	-								
	T	Mode of Operation											
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)					
Ophthalmic	·				- оррга	Боррго	(ареспу)						
Fetal				-									
Abdominal	N	N	N		N	N	N	Note 2 2 4					
Intraoperative (specify)*						1	11	Note 2, 3, 4					
Intraoperative (Neuro)			T										
Laparoscopic													
Pediatric	N	N	N		N	N	N	Note 2, 3, 4					
Small organ(specify)**	P	P	P		P	P	P	Note 2, 3, 4					
Neonatal Cephalic	P	P	P		P	P	P	Note 2, 3, 4					
Adult Cephalic								11000 2, 3, 4					
Trans-rectal						-							
Trans-vaginal								-					
Trans-urethral													
Trans-esoph.(non-Card.)				-									
Musculo-skeletal Conventional	P	P	P		P	P	P	Note 2, 3, 4					
Musculo-skeletal Superficial	P	P	P		P	P	P	Note 2, 3, 4					
Intravascular								11000 2, 5, 4					
Cardiac Adult													
Cardiac Pediatric													
ntravascular (Cardiac)													
Frans-esoph (Cardiac)													
ntra-Cardiac													
Peripheral Vascular	P	P	P		P	P	P	Note 2, 3, 4					
Other (specify)***								11016 2, 3, 4					
N=new indication, P=previously cl	eared by I	DA; E=	added unde	er Append	ix E		<u></u>	····					
Additional comments: Combined m	odes: B+l	A, PW+F	3, Color +	B. Power	+ B. PW +	Color+ B. Po	wer + DW +T						
*Intraoperative includes	abdomin	al, thorac	ic, and vas	cular etc.		2,10	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	, <u> </u>					
**Small organ-breast, ti					·								
***Other use includes U		,				· · · · ·	<u> </u>						
Note 1: Tissue Harmoni		The fee	4			 							
Note 2: Smart3D	c miaRitiR	. 1110 108	iture does r	iot use coi	ntrast agen	ts.							
Note 3: iScape													
Note 4: iBeam	.						·						
Note 4. IBCall					·								
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(Division Sign-Off)

510(k) Number

Division of Reproductive, Abdominal and Radiological Devices

System

Diagnostic Ultrasound Indications for Use Form

Transducer

Model:			6C2		_		-						
510(k) Number(s)	K083505												
	T				Mode of (memtion							
Clinical Application	В	М	PWD	CWD	Cotor Doppler	Amplitude Doppler	Combined (specify)	Other (specify)					
Ophthalmic			<u> </u>										
Fetal													
Abdominal	N	N	N		N	N	N	Note 2, 3					
Intraoperative (specify)*													
Intraoperative (Neuro)	1												
Laparoscopic	· ·												
Pediatric	N	N	N		N	N	N	Note 2, 3					
Small organ(specify)**					 	-							
Neonatal Cephalic	N	N	N		N.	N	N	Note 2, 3					
Adult Cephalic	N	N	N	· ·	N	N	N	Note 2, 3					
Trans-rectal	1				 			11010 2, 3					
Trans-vaginal			1		 								
Trans-urethral	1				1	 							
Trans-esoph.(non-Card.)			1		 								
Musculo-skeletal Conventional			· · · · · ·		1			**					
Musculo-skeletal Superficial	1				 								
Intravascular					1 -								
Cardiac Adult	N	N	N		N	N	N	Note 2, 3					
Cardiac Pediatric	N	N	N		N	N	N	Note 2, 3					
Intravascular (Cardiac)	1				 -	 -		11000 2, 3					
Trans-esoph.(Cardiac)			 										
Intra-Cardiac	1	<u> </u>		-									
Peripheral Vascular						1		· · · · · · · · · · · · · · · · · · ·					
Other (specify)***	N	N	N		N	N	N	Note 2, 3					
N=new indication; P=previously				nder Ann				11010 2, 3					
Additional comments:Combined						V +Color+ B	Power + PV	V +B					
*Intraoperative includ							,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,						
**Small organ-breast,													
***Other use includes				· · · · · ·				<u></u>					
Note 1: Tissue Harmo			feature do	es not use	contrast a	gents.							
Note 2: Smart3D													
Note 3: iScape					:		- 						
Note 4: iBeam								-					
						- -							
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Concurrence of CDRH, O	ffice of	Device	Evalus	tion(O	DE) /								
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			. DIA	isiUH ()	Repro	auctive, /	\bdomina	l and					
•			нас	Hologic	al Devi	ces ,	,	,					
			E40	VAA 84.									

System

Diagnostic Ultrasound Indications for Use Form

Transducer

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Model:			LE7					
510(k) Number(s)		26	358	25				
				, ,	Mode	of Operation	l	
Clinical Application	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	. N	N	Note 2, 3, 4
Abdominal								
Intraoperative (specify)*	1.							
Intraoperative (Neuro)								
Laparoscopic								
Pediatric			\Box					
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note 2, 3, 4
Trans-vaginal							·	
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal Conventional								
Musculo-skeletal Superficial			l					
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac			<u> </u>					
Peripheral Vascular								
Other (specify)***	N	N	N		N-	N	N	Note2, 3, 4
N=new indication; P=previously	cleared	by F	DA, E	-added u	ınder App	endix E		
Additional comments:Combined	modes	: B+M	i, PW	B, Colo	r + B, Pow	ér + B, PW	+Color+ B, I	ower + PW +B.
*Intraoperative include	des abd	omina	i, thor	acic, and	vascular e	tc.		
**Small organ-breast	, thyroi	d, test	es, etc	,				
***Other use include	s Urolo	gy.				· · · · · · · · · · · · · · · · · · ·		
Note 1: Tissue Harme	onic Im	aging.	The f	eature do	es not use	contrast age	nis.	
Note 2: Smart3D	<u> </u>				<u>.</u>			
Note 3: iScape							·	-
Note 4: iBeam	:							
				,	W		 	•
(PLEASE DO NOT WRITE BE							AGE IF NEE	DED)
Concurrence of CDRH, (Office	of D	evice	Evalua	ation(Ol	DE)		/
Prescription USE (Per 21 C	FR 80	1.109)		0	ly.	ne	
•				(Divi	sion Si	gn-Off)		المستد وسيروس
	٠			Divid	ion of	Reproduc	ctive, Abo	lominal and
				DIVE	intenier	1 Devices	2	
					(OlOGICA	i Devices	KOST	2505

System				Transdu	cer	×						
Model:	6LB7											
510(k) Number(s)	K083505											
	·					·						
50 t 3 t 4			,	,		of Operation						
Clinical Application	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)				
Ophthalmic	١						"'					
Fetal												
Abdominal												
Intraoperative (specify)*												
Intraoperative (Neuro)	1					:		, , ,				
Laparoscopic	T			}								
Pediatric						ĺ						
Small organ(specify)**												
Neonatal Cephalic	1	1	1									
Adult Cephalic	1	1				<u> </u>						
Trans-rectal	N	N	N		N	N	N	Note 2, 3, 4				
Trans-vaginal	1			Ĭ								
Trans-wethral	1			1		1	l					
Trans-esoph.(non-Card.)	1	 				1						
Musculo-skeletal Conventional					1	<u> </u>	·					
Musculo-skeletal Superficial	- 		l	1	†		<u> </u>					
Intravascular	 	1										
Cardiac Adult		<u> </u>			1		-					
Cardiac Pediatric	+-	 	╁		 	 						
Intravascular (Cardiac)	╅	┢	+			 						
Trans-esoph.(Cardiac)	+	<u> </u>	-	 		 						
Intra-Cardiac	╅		<u> </u>	· · · · · ·	···							
Peripheral Vascular	+		+ -	<u> </u>	<u> </u>							
Other (specify)***	N	N	N	 	N	N	N	Noto? 7.4				
						<u> </u>	. N	Note2, 3, 4				
N=new indication; P=previously							Sile I D De					
Additional comments:Combined *Intraoperative includ							JOIOIT B, PO	WETT PW TB.				
**Small organ-breast,				CIC, BNU Y	asculai eic							
***Other use includes			8, ELC.			•		<u> </u>				
		·	Th. C									
Note 1: Tissue Harmo Note 2: Smart3D	nic ina	gmg.	THE IE	ature doe	s not use c	onuast agen	S					
Note 3: iScape												
					-i							
Note 4: iBeam												
(PLEASE DO NOT WRITE BEI	OWT	110 T	NIP 4	OVERDI	E ON AN	OTHER NA	موسوده بالد بالد	ED)				
						<u> </u>	JC IT NEED.	(עם)				
Concurrence of CDRH, C	mice (ען זע	AICE	Lyaiua	mon(OI)	E)						
Bearing LIGHT (B. C. C.	70. 004	iam			/	1.1 /	/ J					
Prescription USE (Per 21 CI	K 801	.109)	}		W	l. IVa	1					
					4m			_				
				(Div	sion Si	an-Off)						
				Divid	ion of I	Zanradus	dua Al-a					
				راه در] ۱۳۱۶ است	nun ur l	rehinning	uve, ADQ	ominal and				
•				naci	viogica	Devices	1/	_				
				510(k) Num	ber/	Z083	<i>5</i> 05				

3	JUL U	4	JUUII			tor Use I	. V. III	
System	Transdu			cer	<u>×</u>			
Model:			3C1	- 4-			•	
510(k) Number(s)	}	KD!	284	105				
					Mode	of Operation		
Clinical Application	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N.	N	N		N-	N	N	Note 1, 2, 3
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic			-					
Pediatric	N	N	N		N	N	N	Note 1, 2, 3
Small organ(specify)**	T							
Neonatal Cephalic	T							
Adult Cephalic								
Trans-rectal	1							
Trans-vaginal	1							
Trans-urethral								
Trans-esoph.(non-Card.)	1		1	1	1			
Musculo-skeletal Conventional			1					
Musculo-skeletal Superficial	1							
Intravascular	1	1	1	-				-
Cardiac Adult	N	N	N		N	N	N	Note 1, 2, 3
Cardiac Pediatric	N	N	N	<u> </u>	N	N	N	Note 1, 2, 3
Intravascular (Cardiac)	1	 	1		1		 	
Trans-esoph.(Cardiac)	1	1	1					
Intra-Cardiac	\top							
Peripheral Vascular	†	1	1	1	 	1		
Other (specify)***	+	 	1	-	 -	 	1	<u> </u>
N-new indication; P-previously	cleared	l by Fi	DA: F	added u	nder Appe	ndix E	<u> </u>	
Additional comments:Combined							+Color+ B. P	ower + PW +B.
*Intraoperative includ								
**Small organ-breast		_	-					
***Other use include:		-						
Note 1: Tissue Harmo			The fi	eature do	es not use	contrast age	nts.	
Note 2: Smart3D								
Note 3: iScape								
Note 4: iBeam	 -				<u>—i</u>	· · · · · · · · · · · · · · · · · · ·		-
								
(PLEASE DO NOT WRITE BEI							AGE IF NEE	DED)
Concurrence of CDRH, C)ffice	of D	evice	Evalu	ation(O	DK)		<u> </u>
Prescription USE (Per 21 Cl	FR 80	1.109))		d	WX		
				(Div	ision Sig	in-Off)		
				•		•	ivo Abdo	minal and
	•						uvo, AUUU	minal and
				Kad	ologica	Devices		

510(k) Number _

	suc (utra	soun	ia indi	cations	for Use]	form	
System		-		Transdu	cer	X		
Model:			2P2					
510(k) Number(s)		Ko	835	:05	•			
	Т					of Operation		
Clinical Application	<u> </u>							
<u> </u>	В	М	PW D	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N	N	N	N	N	Note 1, 2
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	Ń	N	N	N	N	Note 1, 2
Small organ(specify)**								
Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2
Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2
Trans-rectal								1,010 1,2
Trans-vaginal								
Trans-urethral	 							
Frans-esoph (non-Card.)								
Musculo-skeletal Conventional	<u> </u>							
Musculo-skeletal Superficial	 							. •
Intravascular	 						 	
Cardiac Adult	N	N	·N	N	N	N	N	Note 1 2
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1, 2
Intravascular (Cardiac)	 	<u> </u>	-			- 19	. 14	Note 1, 2
Trans-esoph (Cardiac)	╁			<u> </u>				
Intra-Cardiac	╁──							· · · · · · · · · · · · · · · · · · ·
Peripheral Vascular	 	-			· ,			
Other (specify)***	-							-
	leaned	1 YPIP		31.1				
N=new indication; P=previously of								·
Additional comments:Combined a *Intraoperative include							Color+ B, Po	wer + PW +B.
**Small organ-breast,				cic, and v	ascular etc			
***Other use includes			s, cic.					
Note 1: Tissue Harmon			The Co	. 				
Note 2: Smart3D	iic ima	Ring.	ine tes	iture doe	s not use c	ontrast agent	S.	· · · · · · · · · · · · · · · · · · ·
Note 3: iScape								·
Note 4: iBeam			1			·		<u></u>
1401C 4. 12CBIN								· · · · · · · · · · · · · · · · · · ·
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Concurrence of CDRH, O							JE IF NEED	ED)
Prescription USE (Per 21 CF			VICE I	Q.	(Les))	

(Division Sign-Off)
Division of Reproductive, Abdominal and

Radiological Devices 510(k) Number

System				Transduc	er	×					
Model:			7L5				-	•			
510(k) Number(s))	<08	3509	>	•						
					-						
	T	Mode of Operation									
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic							(411.7)				
Fetal			 								
Abdominal	N	N	N		N	N	N	Note 2, 3, 4			
Intraoperative (specify)*						-					
Intraoperative (Neuro)						<u> </u>					
Laparoscopic			 			<u> </u>					
Pediatric	N	N	N		N	N	N	Note 2, 3, 4			
Small organ(specify)**	N	N	N		N	N	N				
Neonatal Cephalic	N	N	N		N	N	N	Note 2, 3, 4			
Adult Cephalic	1						- '`	Note 2, 3, 4			
Trans-rectal	1										
Trans-vaginal	1	 -	 								
Trans-urethral	 		 								
Trans-esoph.(non-Card.)	1		 				<u> </u>				
Musculo-skeletal Conventional	N	N	N		N		-,, -				
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 2, 3, 4			
Intravascular	 		 '`		IN	N	N	Note 2, 3, 4			
Cardiac Adult	 		-								
Cardiac Pediatric	 		 								
Intravascular (Cardiac)	 -		 								
Trans-esoph.(Cardiac)	 			<u> </u>							
Intra-Cardiac	 		-					·			
Peripheral Vascular	N	- N1									
Other (specify)***	 	N	N	-	N	N	N N	Note 2, 3, 4			
	<u> </u>										
N=new indication; P=previously o								<u> </u>			
Additional comments:Combined t	nodes: B-	-M, PW-	+B, Color	+ B, Pow	# + B, PW	+Color+ B	Power + PW	′+B.			
*Intraoperative include				ascular el	<u></u>						
**Small organ-breast,		estes, etc	·			-	• • •	·			
***Other use includes	Urology.				 		<u> </u>				
Note 1: Tissue Harmon Note 2: Smart3D	ne imagin	ig. The f	eature doe	s not use	contrast ag	ents.					
Note 3: iScape						· ·	<u> </u>				
Note 4: iBeam											
140te 4. 1Death				·			**	<u></u>			
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Concurrence of CDRH, O	ffice of	Davice	Evolue	BONAN	NP)	AGE IF NE	EDED)				
	ince or	DCTICE	Litalina	non(OI	<i>(L)</i>						
Prescription USE (Per 21 CF)	R 801 10	101			1						
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	Division of Reproductive, Abdominal and Radiological Devices										
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System		_		Transduc	er	×					
Model:	7LT4										
510(k) Number(s)											
	Mode of Operation										
Clinical Application	В	М	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)			
Ophthalmic					Doppier	Doppier	(specify)				
Fetal					 						
Abdominal	N	N	N		N	N	N	Note 2, 3, 4			
Intraoperative (specify)*	N	N	N	100	N	N	- N	Note 2, 3, 4			
Intraoperative (Neuro)			1		 		- " -	11010 2, 3, 4			
Laparoscopic			<u> </u>	 	·						
Pediatric	N	N	N		N	N	N	Note 2, 3, 4			
Small organ(specify)**	N	N	N		N	N	N	Note 2, 3, 4			
Neonatal Cephalic	1	—	1	 	 			1100 2, 3, 4			
Adult Cephalic			-				- 				
Trans-rectal		Ė			 	 					
Trans-vaginal			1		·						
Trans-urethral					 		<u> </u>				
Trans-esoph.(non-Card.)			1		 			 -			
Musculo-skeletal Conventional	N	N	N		N	N	N	Note 2, 3, 4			
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 2, 3, 4			
Intravascular		ļ ——	<u> </u>	<u> </u>	 			11000 2, 3, 1			
Cardiac Adult			 								
Cardiac Pediatric				 -	<u> </u>						
Intravascular (Cardiac)								· · · · · · · · · · · · · · · · · · ·			
Trans-esoph.(Cardiac)								·			
Intra-Cardiac		-									
Peripheral Vascular	N	N	N		N	N	N	Note 2, 3, 4			
Other (specify)***			<u> </u>			-					
N=new indication; P=previously	leared by	FDA; I	=added u	nder Appe	ndix E						
Additional comments:Combined						/ +Color+ B	Power + PW	/ +B.			
*Intraoperative include											
**Small organ-breast,	thyroid, t	estes, etc						·			
***Other use includes	Urology.		٠,		***						
Note 1: Tissue Harmon	nic Imagin	ng. The i	cature do	es not use	contrast a	gents.					
Note 2: Smart3D					· · · · · · · · · · · · · · · · · · ·	-		. '			
Note 3: iScape						· · · · · · · · · · · · · · · · · · ·	•	······································			
Note 4: iBeam											
(PLEASE DO NOT WRITE BEL	OW THE	S LINE-	CONTINI	IE ON A	VOTUER I	DACE TE SIT	(FIDER)				
Concurrence of CDRH, O						raue If Ne	EDED)	<u> </u>			
Concurrence of CDRH, U	mice of	Device	E LYAIUS	mon(O)	nr)						

Prescription USE (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices

510(k) Number