

May 28, 2020

Shenzhen Mindray Bio-Medical Electronics Co., LTD.
% Shi Jufang
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

#### Re: K200979

Trade/Device Name: DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 3, 2020
Received: April 13, 2020

#### Dear Shi Jufang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

#### **Indications for Use**

510(k) Number (if known)

K200979

Device Name

DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System

Indications for Use (Describe)

DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative (abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes, etc.), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric), peripheral vascular .The system is designed to be used by a trained operator in a clinical setting.

 Prescription Use (Part 21 CFR 801 Subpart D)
CONTINUE ON A SEPARATE PAGE IF NEEDED.
This section applies only to requirements of the Paperwork Reduction Act of 1995.
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Type of Use (Select one or both, as applicable)

PRAStaff@fda.hhs.gov

Page 1 of 13

System:	DP-50/DP-50T/DP-50Expert/D	P-50S/C	P-501	Pro Digi	tal Ultra	sonic Diagr	ostic Imaging	System	
Transducer:	N/A								
Intended Use:	Diagnostic ultrasound imaging or fluid	flow analy	sis of t	he human	body as fo	llows:			
Clinical Applicatio	n	Mode	e of Op	eration					
General	Specific (Track 1 & 3)	В	М	PWD	CWD	Color	Amplitude	Combined	Other (Specify)
(Track 1 Only)		Б	IVI	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	Р	Р	Ν		Ν	N	Р	Note 1,2,6,7
Other	Abdominal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6,7
	Intra-operative (Specify*)	Ν	Ν	Ν		Ν	N	Ν	Note 1,2,3,6
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Small Organ (Specify**)	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Neonatal Cephalic	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Adult Cephalic	Р	Р	Ν		Ν	Ν	Р	Note 1,2,6
	Trans-rectal	Р	Р	Ν		Ν	N	Р	Note 1,2,6
	Trans-vaginal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,6
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
	Musculo-skeletal (Superficial)	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult	Ν	Ν	Ν		Ν	Ν	Ν	Note 1,2,6
	Cardiac Pediatric	Р	Р	Ν		Ν	Ν	Р	Note 1,2,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Other (Specify***)								
N=new indication;	P=previously cleared by FDA; E=adde	d under A	ppendi	хE					
Additional commen	nts: Combined modesB+M, PW+B, C	color + B	Power	r+B、PW	V+Color+	B  Power + H	PW +B.		
*Intrac	operative includes abdominal, thoracic, and	l vascular.							
**Smal	ll organ-breast, thyroid, testes.								
***Oth	er use includes Urology.								
Note 1:	Tissue Harmonic Imaging.								
Note 2:	Biopsy Guidance								
Note 3:	iScape								
Note 4:	TDI								
Note 5:	Color M								
Note 6:	Smart3D								
Note 7:	4D(Real-time 3D)								
(PLEASE DO NOT	I WRITE BELOW THIS LINE-CONTINU	JE ON AN	NOTHE	R PAGE	NEEDED)				
Concurrence of C	DRH, Office of In Vitro Diagnostics and	Radiolog	rical He	ealth (OII	8)				

	Digital Ultrasor	nic Di	agnost	tic Imagin	g System	Indications	For Use Forma	at	
System:	DP-50/DP-50T/DP-50Expert/DP-50S	/DP-50	Pro Dig	gital Ultraso	nic Diagnosti	ic Imaging Sys	tem		
Transducer:	35C50EA								
Intended Use:	Diagnostic ultrasound imaging or fluid	d flow	analysis	s of the hum	an body as fo	ollows:			
Clinical Application	n	Mo	ode of C	peration					
General (Track 1	Specific (Track 1 & 3)	В	М	PWD	CWD	Color	Amplitude	Combined	Other (Specify)
Only)		Б	101	TWD	CWD	Doppler	Doppler	(specify)	Ouler (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging &	Fetal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,6
Other	Abdominal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	N		Ν	N	Р	Note 1,2,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Р	Р	N		Ν	Ν	Р	Note 1,2,6
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	Р	Р	N		Ν	Ν	Р	Note 1,2,6
	Other (Specify***)								
N=new indication;	P=previously cleared by FDA; E=ado	led und	ler App	endix E	•	•	•		
Additional commen	tts: Combined modesB+M, PW+B,	Color	+ B、 P	ower + B , 1	PW +Color+	B, Power + H	PW +B.		
*Intrao	perative includes abdominal, thoracic, an	nd vasc	ular.						
**Smal	l organ-breast, thyroid, testes.								
***Oth	er use includes Urology.								
Note 1:	Tissue Harmonic Imaging.								
Note 2:	Biopsy Guidance								
Note 3:	iScape								
Note 4:	TDI								
Note 5:	Color M								
Note 6:	Smart3D								
Note 7:4	4D(Real-time 3D)								
(PLEASE DO NOT	WRITE BELOW THIS LINE-CONTIN	JUE OI	N ANO	THER PAG	E NEEDED)	)			
Concurrence of Cl	DRH, Office of In Vitro Diagnostics an	nd Rad	iologica	al Health (O	DIR)				
Prescription USE (I	Per 21 CFR 801.109)								

System:	DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System										
Transducer:	65EC10EA										
Intended Use:	Diagnostic ultrasound imaging or flui	d flow	analysis	of the hum	an body as fo	ollows:					
Clinical Application	n	Mo	ode of C	peration							
General (Track 1	Specific (Track 1 & 3)					Color	Amplitude	Combined			
Only)		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging &	Fetal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,6		
Other	Abdominal										
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Specify**)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,6		
	Trans-vaginal	Р	Р	N		Ν	Ν	Р	Note 1,2,6		
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)										
	Musculo-skeletal (Superficial)										
	Intravascular										
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral vessel	Peripheral vessel										
	Other (Specify***)										
N=new indication;	P=previously cleared by FDA; E=ado	ied und	ler App	endix E		1					
Additional commer	nts: Combined modesB+M, PW+B,	Color -	+ B、 P	ower $+ B \sqrt{1}$	PW +Color+	B, Power + H	PW +B.		1		
*Intrac	perative includes abdominal, thoracic, a	nd vasc	ular.								
**Smal	l organ-breast, thyroid, testes.										
***Oth	er use includes Urology.										
Note 1:	Tissue Harmonic Imaging.										
	Biopsy Guidance										
Note 3:											
Note 4:	-										
	Color M										
	Smart3D										
	4D(Real-time 3D)										
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	DRH, Office of In Vitro Diagnostics an					,					

	Digital Ultras	onic E	Diagno	stic Imag	ging Syster	n Indication	s For Use Form	at	
System:	DP-50/DP-50T/DP-50Expert/DP-50S	/DP-501	Pro Dig	ital Ultraso	nic Diagnost	ic Imaging Syst	em		
Transducer:	75L38EA								
Intended Use:	Diagnostic ultrasound imaging or flui	d flow a	nalysis	of the hum	an body as fo	ollows:			
Clinical Applicat	ion	Mod	le of Op	peration					
General (Track	Specific (Track 1 & 3)			DUUD		Color	Amplitude	Combined	
1 Only)		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Small Organ (Specify**)	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Neonatal Cephalic	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
	Musculo-skeletal (Superficial)	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
vessel	Other (Specify***)								
N=new indication	n; P=previously cleared by FDA; E=	added u	nder Ap	opendix E					
Additional comm	ents: Combined modesB+M, PW+E	3、Colo	r + B、	Power + B	、PW +Colo	r+ B、 Power +	PW +B.		
*Intr	aoperative includes abdominal, thoracic	, and va	scular.						
**Sm	all organ-breast, thyroid, testes.								
***O	ther use includes Urology.								
Note	1: Tissue Harmonic Imaging.								
Note	2: Biopsy Guidance								
Note	3: iScape								
Note	4: TDI								
Note	5: Color M								
Note	6: Smart3D								
Note	7:4D(Real-time 3D)								
(PLEASE DO NO	OT WRITE BELOW THIS LINE-CON	FINUE (	ON AN	OTHER PA	GE NEEDE	D)			
Concurrence of	CDRH, Office of In Vitro Diagnostics	and Ra	diologi	ical Health	(OIR)				
Prescription USE	(Per 21 CFR 801.109)								

System:	DP-50/DP-50T/DP-50Expert/DP-50S		-	-			s For Use Form		
Transducer:	65C15EA					6 6 7			
Intended Use:	Diagnostic ultrasound imaging or flui	id flow a	nalvsis	of the hum	an body as fo	ollows:			
Clinical Applicat		1	· · ·	peration					
General (Track	Specific (Track 1 & 3)					Color	Amplitude	Combined	
1 Only)		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	Р	Р	N		N	N	Р	Note 1,2,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	N		N	N	Р	Note 1,2,6
	Small Organ (Specify**)	-	-	11		11	11	-	11010 1,2,0
	Neonatal Cephalic	Р	Р	N		Ν	N	Р	Note 1,2,6
	Adult Cephalic	P	r P	N		N	N	P	Note 1,2,6
	Trans-rectal	г	Г	19		IN	IN	Г	Note 1,2,0
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)	-							
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	Р	Р	N		Ν	N	Р	Note 1,2,6
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)								
N=new indicatio	n; P=previously cleared by FDA; E=	added u	nder Ap	opendix E					
Additional comm	nents: Combined modesB+M, PW+H	3、Colo	r + B、	Power + B	W+Colo	r+ B, Power +	PW +B.		
*Int	raoperative includes abdominal, thoracic	, and va	scular.						
**Sn	nall organ-breast, thyroid, testes.								
***(	Other use includes Urology.								
Note	1: Tissue Harmonic Imaging.								
Note	2: Biopsy Guidance								
Note	3: iScape								
Note	4: TDI								
Note	5: Color M								
Note	6: Smart3D								
Note	7:4D(Real-time 3D)								
	OT WRITE BELOW THIS LINE-CON	TINUE (	ON AN	OTHER PA	GE NEEDF	D)			
	CDRH, Office of In Vitro Diagnostics					,			
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System:	DP-50/DP-50T/DP-50Expert/DP-50S	DP-50	Pro Dio	ital Ultraso	nic Diagnost	c Imaging Syst	tem		
Transducer:	35C20EA					6 6 9			
Intended Use:	Diagnostic ultrasound imaging or flui	id flow a	malvsis	of the hum	an body as fo	ollows:			
Clinical Applicat		-		peration	j				
General (Track	Specific (Track 1 & 3)					Color	Amplitude	Combined	
1 Only)	Specific (Hack F & S)	В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
	Orthelasia					Doppier	Doppier	(speeny)	
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	N	N	N		N	N	N	Note 1,2,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ν	Ν	N		Ν	N	N	Note 1,2,6
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	Ν	N	N		Ν	N	N	Note 1,2,6
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac		1						
Peripheral	Peripheral vessel								
vessel	Other (Specify***)								
N=new indicatio	n; P=previously cleared by FDA; E=	added u	nder A	opendix E					
	nents: Combined modesB+M, PW+H			-	New +Colo	r+ B、Power +	- PW +B.		
*Int	raoperative includes abdominal, thoracic	, and va	scular.						
**Sn	nall organ-breast, thyroid, testes.								
	Other use includes Urology.								
	1: Tissue Harmonic Imaging.								
	2: Biopsy Guidance								
	3: iScape								
	4: TDI								
	5: Color M								
	6: Smart3D								
	7:4D(Real-time 3D)		<b></b>		OF MESS				
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Concurrence of	CDRH, Office of In Vitro Diagnostics	and Ra	diologi	ical Health	(OIR)				

	Digital Ultras	onic D	Diagno	ostic Imag	ging Syster	n Indication	s For Use Form	at	
System:	DP-50/DP-50T/DP-50Expert/DP-50S	/DP-501	Pro Dig	ital Ultraso	nic Diagnost	c Imaging Syst	em		
Transducer:	10L24EA								
Intended Use:	Diagnostic ultrasound imaging or flui	d flow a	nalysis	of the hum	an body as fo	ollows:			
Clinical Applicati	on	Mod	le of Op	peration					
General (Track	Specific (Track 1 & 3)			DUUD	CILIE	Color	Amplitude	Combined	
1 Only)		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	N		Ν	N	Р	Note 1,2,3,6
	Small Organ (Specify**)	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
	Neonatal Cephalic	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Р	Р	N		Ν	N	Р	Note 1,2,3,6
	Musculo-skeletal (Superficial)	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
vessel	Other (Specify***)								
N=new indication	; P=previously cleared by FDA; E=	added u	nder Ap	opendix E					
Additional comm	ents: Combined modesB+M, PW+F	3、Colo	r + B	Power + B	、PW +Colo	r+ B、Power +	- PW +B.		
*Intr	aoperative includes abdominal, thoracic	, and va	scular.						
**Sm	all organ-breast, thyroid, testes.								
***0	ther use includes Urology.								
Note	1: Tissue Harmonic Imaging.								
Note	2: Biopsy Guidance								
Note	3: iScape								
Note	4: TDI								
Note	5: Color M								
Note	6: Smart3D								
Note	7:4D(Real-time 3D)								
(PLEASE DO NO	OT WRITE BELOW THIS LINE-CON	FINUE (	ON AN	OTHER PA	GE NEEDE	D)			
Concurrence of	CDRH, Office of In Vitro Diagnostics	and Ra	diologi	ical Health	(OIR)				
Prescription USE	(Per 21 CFR 801.109)								

System:	DP-50/DP-50T/DP-50Expert/DP-50S	5/DP-50	Pro Dig	ital Ultraso	nic Diagnost	ic Imaging Syst	em		
Transducer:	65EB10EA								
Intended Use:	Diagnostic ultrasound imaging or flui	id flow a	analysis	of the hum	an body as fo	ollows:			
Clinical Applicat	tion	Mod	le of O <sub>I</sub>	peration					
General (Track	Specific (Track 1 & 3)	_				Color	Amplitude	Combined	
1 Only)		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	Р	Р	Ν		Ν	Ν	Р	Note 1,2,6
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)								
N=new indication	n; P=previously cleared by FDA; E=	added u	nder Aj	ppendix E					
Additional comm	nents: Combined modesB+M, PW+H	3、Colo	or + B,	Power + B	W+Colo	r + B, Power +	PW +B.		
*Inti	raoperative includes abdominal, thoracic	, and va	scular.						
**Sn	nall organ-breast, thyroid, testes.								
***C	Other use includes Urology.								
Note	1: Tissue Harmonic Imaging.								
Note	2: Biopsy Guidance								
	3: iScape								
	4: TDI								
	5: Color M								
	6: Smart3D								
	7:4D(Real-time 3D)								
	OT WRITE BELOW THIS LINE-CON					D)			
<b>Concurrence</b> of	CDRH, Office of In Vitro Diagnostics	and Ra	diologi	ical Health	(OIR)				

	Digital Ultras	sonic E	Diagno	ostic Imag	ging Syster	n Indication	s For Use Form	at	
System:	DP-50/DP-50T/DP-50Expert/DP-50S		-	-					
Transducer:	65EC10ED								
Intended Use:	Diagnostic ultrasound imaging or flui	id flow a	inalysis	of the hum	an body as fo	ollows:			
Clinical Applicat	ion	Mod	le of Op	peration					
General (Track	Specific (Track 1 & 3)					Color	Amplitude	Combined	
1 Only)		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal	Ν	N	N		N	N	N	Note 1,2,6
& Other	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic		İ						
	Adult Cephalic								
	Trans-rectal	Ν	N	Ν		N	N	N	Note 1,2,6
	Trans-vaginal	Ν	N	N		Ν	Ν	Ν	Note 1,2,6
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel								
vessel	Other (Specify***)								
N=new indication	n; P=previously cleared by FDA; E=	added u	nder Ap	ppendix E					
Additional comm	nents: Combined modesB+M, PW+H	3、Colo	r + B、	Power + B	、PW +Colo	r+ B、Power +	- PW +B.		
*Intr	aoperative includes abdominal, thoracic	, and va	scular.						
**Sm	nall organ-breast, thyroid, testes.								
***0	ther use includes Urology.								
Note	1: Tissue Harmonic Imaging.								
Note	2: Biopsy Guidance								
Note	3: iScape								
Note	4: TDI								
Note	5: Color M								
Note	6: Smart3D								
Note	7:4D(Real-time 3D)								
(PLEASE DO NO	OT WRITE BELOW THIS LINE-CON	ΓINUE (	ON AN	OTHER PA	AGE NEEDE	D)			
Concurrence of	CDRH, Office of In Vitro Diagnostics	and Ra	diologi	ical Health	(OIR)				
Prescription USE	C (Per 21 CFR 801.109)								

	Digital Ultras	sonic E	liagno	stic Imag	ing Syster	n Indication	s For Use Form	at	
System:	DP-50/DP-50T/DP-50Expert/DP-50S		-	-					
Transducer:	75LT38EA								
Intended Use:	Diagnostic ultrasound imaging or flui	id flow a	nalysis	of the hum	an body as fo	ollows:			
Clinical Applicat	ion	Mod	e of Op	peration					
General (Track	Specific (Track 1 & 3)					Color	Amplitude	Combined	
1 Only)		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	Ν	Ν	Ν		Ν	N	Ν	Note 1,2,3,6
	Intra-operative (Specify*)	Ν	Ν	Ν		Ν	N	Ν	Note 1,2,3,6
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Ν	N	Ν		Ν	N	Ν	Note 1,2,3,6
	Small Organ (Specify**)	Ν	N	Ν		Ν	N	N	Note 1,2,3,6
	Neonatal Cephalic	N	N	N		N	N	N	Note 1,2,3,6
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,3,6
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	N	N	N		N	N	N	Note 1,2,3,6
vessel	Other (Specify***)								
N=new indication	n; P=previously cleared by FDA; E=	added u	nder Ar	opendix E					
	ents: Combined modesB+M、PW+H			-	W +Colo	r+ B、Power +	- PW +B.		
*Intr	aoperative includes abdominal, thoracic	, and va	scular.						
	all organ-breast, thyroid, testes.								
	ther use includes Urology.								
	1: Tissue Harmonic Imaging.								
	2: Biopsy Guidance								
	3: iScape								
	4: TDI								
	5: Color M								
	6: Smart3D								
	7:4D(Real-time 3D)								
	OT WRITE BELOW THIS LINE-CON	<b>FINUE</b> (	)N AN	OTHER PA	GE NEEDE	D)			
	CDRH, Office of In Vitro Diagnostics					- /			
		anu Ka	anoiogi	icar manul					
Tescription USE	(Per 21 CFR 801.109)								

	Digital Ultras	sonic E	Diagno	ostic Imag	ging Syster	n Indication	s For Use Form	at	
System:	DP-50/DP-50T/DP-50Expert/DP-50S		-						
Transducer:	75L53EA								
Intended Use:	Diagnostic ultrasound imaging or flui	id flow a	analysis	of the hum	an body as fo	ollows:			
Clinical Applicat	ion	Mod	le of Op	peration					
General (Track	Specific (Track 1 & 3)				~~~~~	Color	Amplitude	Combined	
1 Only)		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)
Ophthalmic	Ophthalmic								
Fetal Imaging	Fetal								
& Other	Abdominal	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	Р	Р	Ν		Ν	Ν	Р	Note 1,2,3,6
	Small Organ (Specify**)	Р	Р	N		Ν	N	Р	Note 1,2,3,6
	Neonatal Cephalic	Р	Р	N		Ν	N	Р	Note 1,2,3,6
	Adult Cephalic		1						
	Trans-rectal		1						
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	Р	Р	N		Ν	N	Р	Note 1,2,3,6
	Musculo-skeletal (Superficial)	Р	Р	N		Ν	N	Р	Note 1,2,3,6
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral	Peripheral vessel	Р	Р	Ν		Ν	N	Р	Note 1,2,3,6
vessel	Other (Specify***)								
N=new indication	n; P=previously cleared by FDA; E=	added u	nder Aj	ppendix E	•		•		
Additional comm	ents: Combined modesB+M、PW+H	3、Colo	r + B,	Power + B	• PW +Cold	r+ B, Power +	- PW +B.		
*Intr	aoperative includes abdominal, thoracic	, and va	scular.						
**Sm	all organ-breast, thyroid, testes.								
***0	ther use includes Urology.								
Note	1: Tissue Harmonic Imaging.								
Note	2: Biopsy Guidance								
Note	3: iScape								
Note	4: TDI								
Note	5: Color M								
Note	6: Smart3D								
Note	7:4D(Real-time 3D)								
(PLEASE DO NO	OT WRITE BELOW THIS LINE-CON	TINUE (	ON AN	OTHER PA	GE NEEDE	D)			
Concurrence of	CDRH, Office of In Vitro Diagnostics	and Ra	diolog	ical Health	(OIR)				
Prescription USE	(Per 21 CFR 801.109)								

Transducer:     1       Intended Use:     1       Clinical Application       General (Track       1 Only)       Ophthalmic       Fetal Imaging       & Other       1	Diagnostic ultrasound imaging or fluid	flow a				0.0.1				
Intended Use: 1 Clinical Application General (Track 1 1 Only) 1 Ophthalmic 6 Fetal Imaging 1 & Other 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Diagnostic ultrasound imaging or fluid	1	nalveie		D6-2EA					
Clinical Application General (Track 5 1 Only) Ophthalmic 6 Fetal Imaging 1 & Other 7 1 1	n	1		of the hum	an body as fo	ollows:				
General (Track 1 1 Only) Ophthalmic 6 Fetal Imaging 1 & Other 1 1 1				peration	j					
1 Only) Ophthalmic Fetal Imaging & Other	speeme (maan 1 ca s)					Color	Amplitude	Combined		
Ophthalmic G Fetal Imaging G & Other G G G G G G G G G G G G G G G G G G G		В	М	PWD	CWD	Doppler	Doppler	(specify)	Other (Specify)	
Fetal Imaging	Ophthalmic					Doppier	Doppier	(speeny)		
& Other		N	N	N		N	N	N	N-4-107	
	Fetal	N	N	N		N	N	N	Note 1,2,7	
1	Abdominal	N	N	N		Ν	N	N	Note 1,2,7	
]	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
i	Laparoscopic									
_	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
, 	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
-	Musculo-skeletal (Conventional)									
J	Musculo-skeletal (Superficial)									
]	Intravascular									
Cardiac	Cardiac Adult									
-	Cardiac Pediatric									
!	Intravascular (Cardiac)									
,	Trans-esoph. (Cardiac)									
1	Intra-cardiac									
Peripheral	Peripheral vessel									
vessel	Other (Specify***)									
N=new indication;	P=previously cleared by FDA; E=ac	dded u	nder Aj	ppendix E						
Additional commen	tts: Combined modesB+M、PW+B、	Colo	r + B、	Power + B	V PW +Colo	r+ B、Power +	- PW +B.			
*Intraoj	perative includes abdominal, thoracic, a	and va	scular.							
**Small	l organ-breast, thyroid, testes.									
***Othe	er use includes Urology.									
Note 1:	Tissue Harmonic Imaging.									
Note 2:	Biopsy Guidance									
Note 3:	iScape									
Note 4:	TDI									
Note 5:	Color M									
Note 6:	Smart3D									
Note 7:4	4D(Real-time 3D)									
	WRITE BELOW THIS LINE-CONTI	INUE (	ON AN	OTHER PA	GE NEEDE	D)				
	DRH, Office of In Vitro Diagnostics a									

# 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: <u>K200979</u>

#### 1. Submitter:

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#### **Contact Person:**

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Date Prepared: April 3, 2020

2. <u>Device Name</u>: DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System

Classification Regulatory Class: II Review Category: Tier II 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN) 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO) 21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

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# 3. <u>Main Predicate Device</u>: DP-50 Digital Ultrasonic Diagnostic Imaging System Classification

Regulatory Class: II Review Category: Tier II 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO) 21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

#### 4. Device Description:

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is a general purpose, portable, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, Color-Mode, Power/Dirpower Mode, THI, Smart3D, 4D, iScape, Biopsy Guidance or the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color).

This system is a Track 3 device that employs an array of probes that include Linear array, Convex array probe.

The software of DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is based on the main predicate DP-50, and it has a Moderate level of concern.

## 5. Indications for Use:

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, Intra-operative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes, etc.), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac(adult, pediatric), peripheral vascular. The system is designed to be used by a trained operator in a clinical setting.

## **6. Summary of Modifications**

- Newly Added Models: DP-50T, DP-50Expert, DP-50S, DP-50Pro;
- Newly Added Transducers: D6-2EA, 65EC10ED, 35C20EA, 75LT38EA;
- Newly Added Needle-guided Brackets: NGB-003, NGB-010;
- Main Added Features and Modifications:
  - 1. Appearance change;
  - 2. Add PW mode to all transducers;
  - 3. Add Color mode to all transducers;
  - 4. Add Power mode to all transducers;
  - 5. Add 4D and Smart 3D;
  - 6. Add Free Xros M;
  - 7. Add iScape View;
  - 8. Add iLive;
  - 9. Add iWorks;
  - 10. Add Smart Face;
  - 11. Add Smart OB;
  - 12. Add Smart Bladder;
  - 13. Add iNeedle;
  - 14. Add iPage;
  - 15. Add HPRF;
  - 16. Add mobile trolley UMT-160 and UMT-170;
  - 17. Change the probe board;
  - 18. Add function of transducer element check.

## 7. Comparison with Predicate Devices:

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
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1. Primary predicate device	Mindray	DP-50	K111435
2. Reference device	Mindray	Z6	K182603
3. Reference device	Mindray	Resona 7	K171233
4. Reference device	Mindray	DC-N2	K132779
5. Reference device	Mindray	DP-6900	K090912
6. Reference device	Mindray	DC-N3	K140030

# > Below is comparative tables of new added special functions:

Items	Subject Device DP-50/DP-50T/DP-50Expert/DP-50 S/DP-50Pro	Predicate Device Resona 7 (K171233)	S/ D	
4D	The probe performs the scanning automatically. During the scanning, the system renders 3D images in real time, and all 3D images are displayed in real time.	The probe performs the scanning automatically. During the scanning, the system renders 3D images in real time, and all 3D images are displayed in real time.	S	
Conclusion	These two devices both provide 4D fund the 4D function are the same. So they a	ction. The technological characteristics or resubstantial equivalent.	of	
Smart 3D	The operator manually moves the probe to changes its position/angle when performing the scanning, the system carries out image rendering automatically, and then displays a frame of 3D image.	The operator manually moves the probe to changes its position/angle when performing the scanning, the system carries out image rendering automatically, and then displays a frame of 3D image.	S	
Conclusion	These two devices both provide Smart 3D function. The technological characteristics of the Smart 3D function are the same. So they are substantial equivalent.			
Free Xros M	In the Anatomical M mode, you can manipulate the M-mark line to move to any position at desired angles. The system supports anatomical M scanning in 2D imaging modes(B, Color, Power mode)	In the Anatomical M mode, you can manipulate the M-mark line to move to any position at desired angles. The system supports anatomical M scanning in 2D imaging modes(B, Color, Power mode)	S	
Conclusion	Color, Fower mode)       Color, Fower mode)         These two devices both provide Free Xros M function. The technological characteristics of the Free Xros M function are the same. So they are substantial equivalent.			

	1	[	1
	iLive brings a better imaging	iLive brings a better imaging	
	experience by adding a light	experience by adding a light	
	rendering effect to the traditional	rendering effect to the traditional	
iLive	method. It supports the global	method. It supports the global	s
	lighting mode as well as the partial	lighting mode as well as the partial	5
	scattering mode, allowing human	scattering mode, allowing human	
	tissue texture to be revealed more	tissue texture to be revealed more	
	clearly.	clearly.	
Conclusion	These two devices both provide iLive fi	unction. The technological characteristic	es of
Conclusion	the iLive function are the same. So they	v are substantial equivalent.	
	Provide several step by step	Provide several step by step	
	workflow protocols according to	workflow protocols according to	
	clinical operation custom. User can	clinical operation custom. User can	
	activate necessary display modes and	activate necessary display modes and	
	image parameters, measurements and	image parameters, measurements and	
iWorks	calculation items, add comments and	calculation items, add comments and	S
TWOIRS	pictograms as per the steps provided	pictograms as per the steps provided	3
	in the exam. This function reduces	in the exam. This function reduces	
	the operations, especially reduces the	the operations, especially reduces the	
	excessive number of control panel	excessive number of control panel	
	key strokes.	key strokes.	
Conclusion	These two devices both provide iWorks	function. The technological characterist	tics
	of the iWorks function are the same. So	they are substantial equivalent.	1
	The iScape panoramic imaging	The iScape panoramic imaging	
	feature extends your field of view by	feature extends your field of view by	
i Saana Viaw	piecing together multiple B images	piecing together multiple B images	G
iScape View	into a single, extended B image. Use	into a single, extended B image. Use	S
	this feature, for example, to view a	this feature, for example, to view a	
	complete hand or thyroid.	complete hand or thyroid.	
	These two devices both provide iScape	function. The technological characterist	tics of
Conclusion	the iScape function are the same. So the	-	0
	iNeedle makes needle display clearer	iNeedle makes needle display clearer	
	in the course of biopsy or anesthesia	in the course of biopsy or anesthesia	
iNeedle	by providing an additional deflection	by providing an additional deflection	S
	transmission.	transmission.	
			tion
Conclusion	of the iNeedle function are the same. So	e function. The technological characteris	Sucs S
iDecco			G
iPage	iPage is a new "Visualization" mode	iPage is a new "Visualization" mode	S

	I		1
	for displaying sectional images. The	for displaying sectional images. The	
	data is presented as slices through the	data is presented as slices through the	
	data set, which are parallel to each	data set, which are parallel to each	
	other.	other.	
	iPage is an option and is not available	iPage is an option and is not available	
	for Smart 3D images.	for Smart 3D images.	
Conclusion	These two devices both provide iPage f	unction. The technological characteristi	cs of
conclusion	the iPage function are the same. So the	y are substantial equivalent.	
	HPRF function is used when detected	HPRF function is used when detected	
	velocities exceed the processing	velocities exceed the processing	
	capabilities of the currently selected	capabilities of the currently selected	
HPRF	PW Doppler scale, or when the	PW Doppler scale, or when the	G
	selected anatomical site is too deep	selected anatomical site is too deep	S
	for the selected PW Doppler scale.	for the selected PW Doppler scale.	
	HPRF enhances the range of	HPRF enhances the range of	
	detecting high-velocity flow.	detecting high-velocity flow.	
Conclusion	These two devices both provide HPRF	function. The technological characterist	ics of
Conclusion	the HPRF function are the same. So the	ey are substantial equivalent.	
	This feature allows the system to	This feature allows the system to	
	recognize fetal face automatically	recognize fetal face automatically	
Smart Face	and then display the face in a	and then display the face in a	S
	recommended viewing angle.	recommended viewing angle.	
	These two devices both provide Smart	Face function. The technological	
Conclusion	_	ion are the same. So they are substantial	
	equivalent.	, j	
	The Smart OB is obstetric	The Smart OB is obstetric	
Smart OB	measurement tools. It is used to	measurement tools. It is used to	S
	calculate the obstetric measurements.	calculate the obstetric measurements.	
	These two devices both provide Smart (	OB function The technological	1
Conclusion	characteristics of the Smart OB function		
2 on chapton	equivalent.	n are me sume. So mey are substantiat	
	cynivaichi.		

Items	Subject Device DP-50/DP-50T/DP-50Expert/DP-50 S/DP-50Pro	Predicate Device DC-N3 (K140030)	S/ D
Smart Bladder	The Smart Bladder is provided to	The Smart Bladder is provided to	c
Sinart Diadder	measure the volume of the urine in	measure the volume of the urine in	3

	the bladder automatically.	the bladder automatically.
Conclusion	These two devices both provide Smart I characteristics of the Smart Bladder fu equivalent.	Bladder function. The technological nction are the same. So they are substantial

> Below is comparative tables of new added imaging modes:

Items	Subject Device DP-50/DP-50T/DP-50Expert/DP- 50S/DP-50Pro	Predicate Device DC-N2(K132779)	S/D	
PW mode to all transducers	PW (Pulsed Wave Doppler) mode is used to provide blood flow velocity and direction utilizing a real-time spectral display. The horizontal axis represents time, while the vertical axis represents Doppler frequency shift.	PW (Pulsed Wave Doppler) mode is used to provide blood flow velocity and direction utilizing a real-time spectral display. The horizontal axis represents time, while the vertical axis represents Doppler frequency shift.	S	
Conclusion	These two devices both provide PW mode. The technological characteristics of PW mode are the same. So they are substantial equivalent.			
Color mode to all transducers	The Color mode is used to detect color flow information, and the color is designed to judge the direction and speed of blood flow.	The Color mode is used to detect color flow information, and the color is designed to judge the direction and speed of blood flow.	S	
Conclusion	These two devices both provide Color mode. The technological characteristics the Color mode are the same. So they are substantial equivalent.			
Power mode to all transducers	Power mode provides a non-directional display of blood flow in the form of intensity as opposed to flow velocity. DirPower (Directional Power mode) provides additional information of flow direction towards or away from the probe.	Power mode provides a non-directional display of blood flow in the form of intensity as opposed to flow velocity. DirPower (Directional Power mode) provides additional information of flow direction towards or away from the probe.	S	
Conclusion	These two devices both provide Powe the Power mode are the same. So they	r mode. The technological characterist	ics of	

Detailed information of newly added imaging modes to these transducers are as follows:

# 35C50EA

N. LI	35C50EA&	25050EA 8 DC NA (7122550)	C/D
Model	DP-50/DP-50T/DP-50Expert/D P-50S/DP-50Pro	35C50EA & DC-N2 (K132779)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Fetal Abdominal Pediatric Musculo-skeletal(Conventional)	Fetal Abdominal Pediatric Musculo-skeletal(Conventional) Peripheral vessel	S
Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Convex	Convex	S

## 65C15EA

Model	65C15EA& DP-50/DP-50T/DP-50Expert/	65C15EA & DC-N2 (K132779)	S/D
	DP-50S/DP-50Pro		
Manufacturer	Shenzhen Mindray Bio-Medical	Shenzhen Mindray Bio-Medical	/

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	Electronics Co., Ltd.	Electronics Co., Ltd.		
510(K) Number	/	K132779	/	
	Abdominal	Abdominal		
	Pediatric	Pediatric		
	Neonatal Cephalic	Neonatal Cephalic		
Indication(s) for use	Adult Cephalic	Adult Cephalic	S	
	Cardiac Pediatric	Cleared in K111435 already.		
	B/M/PWD/Color Doppler	B/M/PWD/Color Doppler		
	/ Amplitude Doppler	/ Amplitude Doppler		
Modes of operation	/ B+M/PW+B	/ B+M/PW+B		
	/Color+B/ Power+B	/Color+B/ Power+B	S	
	/PW+Color+B	/PW+Color+B	~	
	/Power+PW+B	/Power+PW+B		
	/THI/ Biopsy Guidance	/THI/ Biopsy Guidance/iScape		
	/Smart3D	/Smart3D		
Is the acoustic output below				
Ispta.3 = $720 \text{mW/cm2}$ and	yes	yes	S	
either MI=1.9 or Isppa.3	yes	yes	5	
=190W/cm2?				
Acoustic output is				
measured and recorded	yes	yes	S	
according to the procedures	500	,05	5	
in 510(k) guidance?				
Geometrical shape	Convex	Convex	S	

## 65EC10EA

Model	65EC10EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro	D6-2P& DC-N2 (K132779)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Fetal Trans-rectal Trans-vaginal	Fetal Trans-rectal Trans-vaginal Urology	S

	B/M/PWD/Color Doppler	B/M/PWD/Color Doppler	
	/ Amplitude Doppler	/ Amplitude Doppler	
	/B+M/PW+B	/ B+M/PW+B	
Modes of operation	/Color+B/ Power+B	/Color+B/ Power+B	S
would be of operation	/PW+Color+B	/PW+Color+B	5
	/Power+PW+B	/Power+PW+B	
	/THI/ Biopsy Guidance	/THI/ Biopsy Guidance/iScape	
	/Smart3D	/Smart3D	
Is the acoustic output below			
Ispta.3 = $720 \text{mW/cm2}$ and			S
either MI=1.9 or Isppa.3	yes	yes	3
=190W/cm2?			
Acoustic output is			
measured and recorded			S
according to the procedures	yes	yes	3
in 510(k) guidance?			
Geometrical shape	Convex	Convex	S

#### 75L38EA

Model	75L38EA& DP-50/DP-50T/DP-50Expert/D P-508/DP-50Pro	75L38EA & DC-N2 (K132779)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical	Shenzhen Mindray Bio-Medical	1
Wandracturer	Electronics Co., Ltd.	Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
	Abdominal	Abdominal	
	Pediatric	Pediatric	
	Small Organ	Small Organ	
Indication(s) for use	Neonatal Cephalic	Neonatal Cephalic	S
	Musculo-skeletal(Conventional)	Musculo-skeletal(Conventional)	
	Musculo-skeletal (Superficial)	Musculo-skeletal (Superficial)	
	Peripheral vessel	Peripheral vessel	

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B	S
	/Power+PW+B	/Power+PW+B	
	/THI/ Biopsy Guidance/iScape	/THI/ Biopsy Guidance/iScape	
	/Smart3D	/Smart3D	
Is the acoustic output			
below Ispta.3 =			
720mW/cm2 and either	yes	yes	S
MI=1.9 or Isppa.3			
=190W/cm2?			
Acoustic output is			
measured and recorded			
according to the	yes	yes	S
procedures in 510(k)			
guidance?			
Geometrical shape	Linear	Linear	S

## 75L53EA

Model	75L53EA& DP-50/DP-50T/DP-50Expert/D P-50S/DP-50Pro	75L38EA & DC-N2 (K132779)	S/D
	Shenzhen Mindray Bio-Medical	Shenzhen Mindray Bio-Medical	
Manufacturer	Electronics Co., Ltd.	Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
	Abdominal	Abdominal	
	Pediatric	Pediatric	
	Small Organ	Small Organ	
Indication(s) for use	Neonatal Cephalic	Neonatal Cephalic	S
	Musculo-skeletal(Conventional)	Musculo-skeletal(Conventional)	
	Musculo-skeletal (Superficial)	Musculo-skeletal (Superficial)	
	Peripheral vessel	Peripheral vessel	

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B	S
	/Power+PW+B	/Power+PW+B	
	/THI/ Biopsy Guidance/iScape	/THI/ Biopsy Guidance/iScape	
	/Smart3D	/Smart3D	
Is the acoustic output			
below Ispta.3 =			
720mW/cm2 and either	yes	yes	S
MI=1.9 or Isppa.3			
=190W/cm2?			
Acoustic output is			
measured and recorded			
according to the	yes	yes	S
procedures in 510(k)			
guidance?			
Geometrical shape	Linear	Linear	S

### 10L24EA

	10L24EA&		
Model	DP-50/DP-50T/DP-50Expert/D	10L24EA & DC-N2 (K132779)	S/D
	P-50S/DP-50Pro		
Manufacturer	Shenzhen Mindray Bio-Medical	Shenzhen Mindray Bio-Medical	/
Manufacturer	Electronics Co., Ltd.	Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
	Abdominal	Abdominal	
	Pediatric	Pediatric	
	Small Organ	Small Organ	
Indication(s) for use	Neonatal Cephalic	Neonatal Cephalic	S
	Musculo-skeletal(Conventional)	Musculo-skeletal(Conventional)	
	Musculo-skeletal (Superficial)	Musculo-skeletal (Superficial)	
	Peripheral vessel	Peripheral vessel	

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape	S
	/Smart3D	/Smart3D	
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Linear	Linear	S

### 65EB10EA

Model	65EB10EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro	65EB10EA & DC-N2 (K132779)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Trans-rectal	Fetal Trans-rectal Trans-vaginal Urology	S

Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance/iScape /Smart3D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	/Smart3D yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Geometrical shape	Convex	Convex	S

➢ Below is comparative tables of new added transducers:

### **D6-2EA**

Model	D6-2EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro	D6-2P&Z6 (K182603)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K182603	/
Indication(s) for use	Fetal Abdominal	Fetal Abdominal	S

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Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/Smart3D/4D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/Smart3D/4D	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Distance between adjacent elements(mm)	0.6048	0.6048	S
Geometrical shape	Convex	Convex	S
Array elements	128	128	S
Radius/Width(mm)	40	40	S
Axis size(mm)	11	11	S
Nominal frequency(MHz)	4.0	4.0	S

### 65EC10ED

Model	65EC10ED& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro	65EC10ED &DC-N2 (K132779)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.	/
510(K) Number	/	K132779	/
Indication(s) for use	Fetal Trans-rectal Trans-vaginal	Fetal Trans-rectal Trans-vaginal Urology	S

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Modes of operation	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D	B/M/PWD/Color Doppler / Amplitude Doppler / B+M/PW+B /Color+B/ Power+B /PW+Color+B /Power+PW+B /THI/ Biopsy Guidance /Smart3D/iScape	S
Is the acoustic output below Ispta.3 = 720mW/cm2 and either MI=1.9 or Isppa.3 =190W/cm2?	yes	yes	S
Acoustic output is measured and recorded according to the procedures in 510(k) guidance?	yes	yes	S
Distance between adjacent elements(mm)	0.312	0.312	S
Geometrical shape	Convex	Convex	S
Array elements	80	80	S
Radius/Width(mm)	10	10	S
Axis size(mm)	5	5	S
Nominal frequency(MHz)	6.5	6.5	S

#### 35C20EA

Model	35C20EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro	35C20EA & DC-N2 (K132779)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical	Shenzhen Mindray Bio-Medical	/
510(K) Number	Electronics Co., Ltd.	Electronics Co., Ltd. K132779	/
Indication(s) for use	Abdominal Pediatric Cardiac Adult	Abdominal Pediatric Cardiac Adult Cardiac Pediatric	S

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	B/M/PWD/Color Doppler	B/M/PWD/Color Doppler	
	/ Amplitude Doppler	/ Amplitude Doppler	
	/ B+M/PW+B	/ B+M/PW+B	
Modes of operation	/Color+B/ Power+B	/Color+B/ Power+B	S
	/PW+Color+B	/PW+Color+B	2
	/Power+PW+B	/Power+PW+B	
	/THI/ Biopsy Guidance	/THI/ Biopsy Guidance	
	/Smart3D	/Smart3D/iScape	
Is the acoustic output below			
Ispta.3 = $720 \text{mW/cm2}$ and	Was	Nos	S
either MI=1.9 or Isppa.3	yes	yes	
=190W/cm2?			
Acoustic output is			
measured and recorded	yes	yes	S
according to the procedures	yes		5
in 510(k) guidance?			
Distance between adjacent	0.4	0.4	S
elements(mm)		0.1	5
Geometrical shape	Convex	Convex	S
Array elements	80	80	S
Radius/Width(mm)	20	20	S
Axis size(mm)	12.4	12.4	S
Nominal frequency(MHz)	3.5	3.5	S

### 75LT38EA

Model	75LT38EA& DP-50/DP-50T/DP-50Expert/ DP-50S/DP-50Pro	7LT4P & Z6 (K182603)	S/D
Manufacturer	Shenzhen Mindray Bio-Medical	Shenzhen Mindray Bio-Medical	/
Manufacturer	Electronics Co., Ltd.	Electronics Co., Ltd.	/
510(K) Number	/	K182603	/
Indication(s) for use	Abdominal	Abdominal	
	Intra-operative	Intra-operative	
	Pediatric	Pediatric	S
	Small Organ	Small Organ	3
	Neonatal Cephalic	Neonatal Cephalic	
	Musculo-skeletal(Conventional)	Musculo-skeletal(Conventional)	

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	Musculo-skeletal (Superficial)	Musculo-skeletal (Superficial)	
	Peripheral vessel	Peripheral vessel	
	B/M/PWD/Color Doppler	B/M/PWD/Color Doppler	
	/ Amplitude Doppler	/ Amplitude Doppler	
	/ B+M/PW+B	/ B+M/PW+B	
Modes of operation	/Color+B/ Power+B	/Color+B/ Power+B	S
	/PW+Color+B	/PW+Color+B	~
	/Power+PW+B	/Power+PW+B	
	/THI/ Biopsy Guidance /iScape	/THI/ Biopsy Guidance /iScape	
	/Smart3D	/Smart3D	
Is the acoustic output below			
Ispta.3 = 720mW/cm2 and	VAC	yes	S
either MI=1.9 or Isppa.3	yes		۵
=190W/cm2?			
Acoustic output is		yes	S
measured and recorded			
according to the procedures	yes		
in 510(k) guidance?			
Distance between adjacent	0.48	0.315	D
elements(mm)			
Geometrical shape	Linear	Linear	S
Array elements	80	128	D
Radius/Width(mm)	/	/	S
Axis size(mm)	4	4	S
Nominal frequency(MHz)	7.5	7.5	S

#### Note:

Due to new design, the distance between adjacent elements and array elements of 75LT38EA is different from 7LT4P. This difference does not influence the diagnostic, and use of the device. The added 75LT38EA has been tested under the IEC60601-1, IEC60601-1-2 etc. This difference does not influence the safety and effectiveness of this transducers.

Meaning of symbols used in the above table: S: Same D: Different

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System has the same technological characteristics, is comparable in key

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safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate devices. All systems transmit ultrasonic energy into patients and perform post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

• Subject device

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System has the similar intended uses as the predicated device DP-50 (K111435)

Subject Device	Predicate device
DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro	DP-50 (K111435)
The Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes, etc.), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(pediatric), peripheral vascular .	The Digital Ultrasonic Diagnostic Imaging System is applicable for adults, pregnant women, pediatric and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes, etc.), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(pediatric), peripheral vascular .
Intra-operative (abdominal, thoracic, and vascular) ,cardiac(adult)	Cleared in Z6 (K182603)

- The acoustic power levels of DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro are below the limits of FDA, which is the same as the predicated device DP-50 (K111435)
- The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro is designed in compliance with the FDA recognized electrical and physical safety standard, which is the same as the predicated device DP-50 (K111435)

The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro has similar probes as the predicated device.

## 8. Non-clinical Tests:

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The DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- AAMI/ANSI ES60601-1: Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- IEC 60601-2-37: Medical electrical equipment Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62304: Medical device software Software life cycle processes
- IEC 62366:Medical devices application of usability engineering to medical devices
- IEC 60601-1-6: medical electrical equipment part 1-6: general requirements for basic safety and essential performance collateral standard: usability.
- ISO14971: Medical devices Application of risk management to medical devices
- ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

#### 9. Clinical Studies

Not applicable. The subject of this submission,

DP-50/DP-50T/DP-50Expert/DP-50S/DP-50Pro Digital Ultrasonic Diagnostic Imaging System, does not require clinical studies to support substantial equivalence.

#### **Conclusion:**

Intended uses and other key features are consistent with traditional clinical practices,

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FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DP-50/DP-50T/DP-50Expert/DP-50S /DP-50Pro Digital Ultrasonic Diagnostic Imaging System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.