APR 1 5 2009

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: K090912

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: March 6, 2009

2. Device Name: DP-6900 Digital Ultrasonic Diagnostic Imaging System

Classification
Regulatory Class: II
Review Category: Tier II
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Marketed Device:

DP-6900 Digital Ultrasonic Diagnostic Imaging System is substantially equivalent to the following devices: Mindray DC-6 (K#072164), Mindray DP-9900 (K#070526), Mindray DP-6600 (K#060949) and GE Logiq 9 (K061129).

4. Device Description:

The DP-6900 Digital Ultrasonic Diagnostic Imaging System is a general purpose,

portable, software controlled, ultrasound diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode or the combined mode (i.e. B/M Mode). This system is a Track 1 device that employs an array of probes that include linear array and convex array with a frequency range of approximately 2.0 MHz to 10.0 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.), urology, peripheral vascular, fetal, transrectal, transvaginal, intraoperative, pediatric, neonatal cephalic, musculoskeletal (general and superficial).

6. Safety Considerations:

The DP-6900 Digital Ultrasonic Diagnostic Imaging System had been tested as Track 1 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: 2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment. 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, IEC 60601-1-4 and ISO 10993-1.

Conclusion:

The conclusions drawn from testing of the DP-6900 Digital Ultrasonic Diagnostic Imaging System demonstrate that the device is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2009

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Robert Mosenkis
President
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462-1298

Re: K090912
Trade/Device Name: DP-6900 Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: March 31, 2009
Received: April 1, 2009

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 DP-6900 Digital Ultrasonic Diagnostic Imaging System, as described in your premarket notification:

Transducer Model Number

35C20EA
35C50EA
65EC10EA
65C15EA
65EL60EA

75L38EA
75LT38EA
75L53EA
75L60EA

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 Federal Register.

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" (21CFR 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 Paul Hardy at (240) 276-3666.

Sincerely yours,

for Herbert Lerner

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

System × Transducer

Model: DP-6900

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N					N	Note 1
	Abdominal	N	N					N	Note 1
	Intra-operative (Specify)*	N	N					N	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N					N	Note 1
	Small Organ(Specify)**	N	N					N	
	Neonatal Cephalic	N	N					N	
	Adult Cephalic	N	N					N	
	Trans-rectal	N	N					N	
	Trans-vaginal	N	N					N	
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)	N	N					N	Note 1
	Musculo-skeletal (Superficial)	N	N					N	
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult	N	N					N	
	Cardiac Pediatric	N	N					N	
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel	N	N					N	Note 1
	Other(Specify)								

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

Additional comments:Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090912

K(4)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 35C20EA

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N					N	
	Intra-operative (Specify)*								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N					N	
	Small Organ(Specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)	N	N					N	
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult	N	N					N	
	Cardiac Pediatric	N	N					N	
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel	N	N					N	
	Other(Specify)								

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

Additional comments:Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular etc.

**Small organ-breast, thyroid, testes, etc.

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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 K090912

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 35C50EA

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N					N	Note 1
	Abdominal	N	N					N	Note 1
	Intra-operative (Specify)*								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N					N	Note 1
	Small Organ(Specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)	N	N					N	Note 1
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel	N	N					N	Note 1
	Other(Specify)								

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

Additional comments:Combined modes: B+M.

*Intraoperative includes abdominal, thoracic, and vascular etc.

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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 K090912

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 65EC10EA

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	N	N					N	
	Abdominal								
	Intra-operative (Specify)*								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ(Specify)**								
	Neonatal Cephalic	N	N					N	
	Adult Cephalic								
	Trans-rectal	N	N					N	
	Trans-vaginal	N	N					N	
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel								
	Other(Specify)								

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Additional comments:Combined modes: B+M.

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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 K090912

Diagnostic Ultrasound Indications for Use Form

System
Transducer ×
Model: 65C15EA
510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N					N	
	Intra-operative (Specify)*								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N					N	
	Small Organ(Specify)**								
	Neonatal Cephalic	N	N					N	
	Adult Cephalic	N	N					N	
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)	N	N					N	
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	N	N					N	
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel	N	N					N	
	Other(Specify)								

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Additional comments:Combined modes: B+M.

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Prescription USE (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090912

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 65EL60EA

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify)*								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ(Specify)**								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	N	N					N	
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel								
	Other(Specify)								

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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 K090912

Diagnostic Ultrasound Indications for Use Form

System

Transducer ×

Model: 75L38EA

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N					N	
	Intra-operative (Specify)*								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N					N	
	Small Organ(Specify)**	N	N					N	
	Neonatal Cephalic	N	N					N	
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)	N	N					N	
	Musculo-skeletal (Superficial)	N	N					N	
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel	N	N					N	
	Other(Specify)								

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Additional comments:Combined modes: B+M.

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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 K090912

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 75LT38EA

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N					N	
	Intra-operative (Specify)*	N	N					N	
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N					N	
	Small Organ(Specify)**	N	N					N	
	Neonatal Cephalic	N	N					N	
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)	N	N					N	
	Musculo-skeletal (Superficial)	N	N					N	
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel	N	N					N	
	Other(Specify)								

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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 K090912

Diagnostic Ultrasound Indications for Use Form

System

Transducer ×

Model: 75L53EA

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N					N	
	Intra-operative (Specify)*								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N					N	
	Small Organ(Specify)**	N	N					N	
	Neonatal Cephalic	N	N					N	
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)	N	N					N	
	Musculo-skeletal (Superficial)	N	N					N	
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel	N	N					N	
	Other(Specify)								

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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 K090912

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer x

Model: 75L60EA

510(k) Number(s) K090912

Clinical Application									
General	Specific	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N					N	
	Intra-operative (Specify)*								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N					N	
	Small Organ(Specify)**	N	N					N	
	Neonatal Cephalic	N	N					N	
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card.)								
	Musculo-skeletal (Conventional)	N	N					N	
	Musculo-skeletal (Superficial)	N	N					N	
	Intravascular								
	Other (specify)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral vessel	Peripheral vessel	N	N					N	
	Other(Specify)								

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(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090912