DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 30 2005

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Mr. Robert Mosenkis
President
Citech
5200 Butler Pike
PLYMOUTH MEETING PA 19462-1298

Re: K052113
Trade Name: DP-6600 Digital Ultrasonic Diagnostic Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: IYO and ITX
Dated: August 2, 2005
Received: August 4, 2005

Dear Mr. Mosenkis:

This letter corrects our substantially equivalent letter of August 23, 2005.

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-6600 Digital Ultrasonic Diagnostic Imaging System, as described in your premarket notification:

Transducer Model Number

35C20EA
35C50EA

65EC10EA
75L38EA

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 (301) 443-6597 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 Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
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 6600

510(k) Number(s)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small organ(specify)		N	N						N	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal		N	N						N	
Transvaginal		N	N						N	
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other (specify)										

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

Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation(ODE)

David R. Lyman

(Division Sign-Off)

Division of Reproductive, Abdominal, and Radiological Devices

Prescription USE (Per 21 CFR 801.109)

510(k) Number K052113

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Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 35C20EA

510(k) Number(s)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small organ(specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional comments: Combined mode: 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 K052163

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 35C50EA

510(k) Number(s)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organ(specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052113

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer x

Model: 65EC10EA

510(k) Number(s)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organ(specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		N	N						N	
Transvaginal		N	N						N	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional comments: Combined mode: 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 K052113 01

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 75L38EA

510(k) Number(s)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small organ(specify)		N	N						N	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other (specify)										

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

Additional comments: Combined mode: B+M

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

David A. Jeyson

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K052113

AUG 9 - 2005

Exhibit #B 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.

The assigned 510(k) number is: K052113

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:
Li Dongling
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:

May 31, 2005

Name of the device:

- Trade/Proprietary Name:
DP-6600 Digital Ultrasonic Diagnostic Imaging System

- Common Name: Ultrasonic Imaging System and Transducers

- Classification

Regulatory Class: II
Review Category: Tier II

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

Legally Marketed Predicate Device:

K990490 SSA-320A JUST VISION 200 Ultrasound Imaging System

Description:

The DP-6600 Digital Ultrasonic Diagnostic Imaging System is a general purpose, portable, software controlled, ultrasound diagnostic system. This ultrasonic device is designed to project ultrasound waves into body tissue and to present the returned echo information on the monitor. The resulting information is displayed in B-Mode, M-Mode, or in 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 linear array with a frequency range of approximately 2 MHz to 10 MHz.

Statement of intended Use:

The system is a general-purpose, fully digital ultrasound system for abdominal, gynecologic and obstetric, small parts, and cardiac applications.
The DP-6600 digital ultrasonic diagnostic imaging system is intend to used for the following type of studies: fetal organ, abdominal, pediatric, small organs, neonatal cephalic, cardiac, transvaginal, peripheral vascular, and musculo-sleletal (both conventional and superficial). This device is intended to adult, pregnant woman, pediatric and neonate. The DP-6600 digital ultrasonic diagnostic imaging system is a prescription device intended to be used by or on the order of a physician or similarly qualified health care professional. This Device is not intended for home use.

Technological Characteristics:

The DP-6600 digital ultrasonic diagnostic imaging system incorporates the same fundamental technology as the predicate device. The device has been tested as Track 1 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 1997. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 1998. All transducers used with the DP-6600 digital ultrasonic diagnostic imaging system are track 1. All patient contact

materials are biocompatible.
The technology characteristics of the DP-6600 digital ultrasonic diagnostic imaging system do not affect the safety or efficacy of the device. Any safety issues raised by a software controlled medical device are either the same as the issues already addressed by the predicate device or are addressed in the system hazard analysis or in the system validation.

Testing:

Laboratory testing was conducted to verify that the DP-6600 digital ultrasonic diagnostic imaging system met all design specification and was substantially equivalent to the currently marketed Toshiba SSA-320A JUST VISION 200 Ultrasound Imaging System. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. Acoustic output is measured and calculated according to "Acoustic Output Measuring Standard for Diagnostic Ultrasound Equipment (NEMA 1998)"

Applicable Standards

The DP-6600 digital ultrasonic diagnostic imaging system conforms to the following Standards:

NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic ultrasound Equipment: 1998
IEC 60601-1
IEC 60601-1-2

Clinical Test:

No clinical testing was required

Conclusion:

The conclusions drawn from testing of the DP-6600 Digital Ultrasonic Diagnostic Imaging System demonstrates that the device is as safe and effective as the legally marketed predicate device, the SSA-320A JUST VISION 200 Ultrasound Imaging System, K#990490.