JUN - 1 2006

Exhibit 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.

The assigned 510(k) number is: K061189

Submitter:

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- **Contact Person:**

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Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

April 20, 2006

Name of the device:

- **Trade/Proprietary Name:**

DP-9900 Digital Ultrasonic Diagnostic Imaging System

- **Common Name:** Diagnostic Ultrasound System and Transducers

- **Classification**

Regulatory Class:
Review Category: Tier

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

Legally Marketed Predicate Device: K061189

K053346 DP-9900 Digital Ultrasonic Diagnostic Imaging System

Description:

The DP-9900 Digital Ultrasonic Diagnostic Imaging System with added transducer is a general purpose, mobile, 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 2.5 MHz to 10 MHz. The modification will provide users with an additional transducer and change the acoustic lens of some transducers along with the addition of software functions.

Statement of intended Use:

The DP-9900 Digital Ultrasonic Diagnostic Imaging System with added transducer is a general-purpose, fully digital ultrasound system for abdominal, gynecologic and obstetric, small parts, and cardiac applications.
The system is intended to use 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 Device 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-9900 digital ultrasonic diagnostic imaging system with added transducer 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: 2004. All transducers used with the DP-9900 digital ultrasonic diagnostic imaging system

are track 1. All patient contact materials are biocompatible.
The technology characteristics of the DP-9900 digital ultrasonic diagnostic imaging system with these modifications do not affect the safety or efficacy of the device.

Testing:

Laboratory testing was conducted to verify that the DP-9900 digital ultrasonic diagnostic imaging system with added transducer met all design specification and was substantially equivalent to the currently marketed Predicate Device as above. 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"

Applicable Standards

The DP-9900 digital ultrasonic diagnostic imaging system with added transducer conforms to the following Standards:

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

Clinical Test:

No clinical testing was required

Conclusion:

The conclusions drawn from testing of the DP-9900 Digital Ultrasonic Diagnostic Imaging System with added transducer demonstrates that the device is as safe, as effective as well as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
c/o Ms. Susan Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK 11021

JUN - 1 2006

Re: K061189
Tradename: DP-9900 Digital Ultrasonic Diagnostic Imaging System
Regulation Number : 21 CFR §892.1560
Regulation Name: Diagnostic pulsed echo imaging system
Product Code: IYO
Regulation Number : 21 CFR §892.1570
Regulation Name: Diagnostic ultrasound transducer
Product Code: ITX
Regulatory Class: II
Dated: April 20, 2006
Received: April 28, 2006

Dear Ms. Goldstein-Falk:

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-9900 Digital Ultrasonic Diagnostic Imaging System as described in your premarket notification:

Transducer Model Number

75L60HB

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 Robert A. Phillips, Ph.D. 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

Enclosures

K061189

Diagnostic Ultrasound Indications for Use Form

System × Transducer

Model: DP-9900

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		P	P						P	P
Abdominal		P	P						P	P
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		P	P						P	
Small organ(specify)		P	P						P	
Neonatal Cephalic		P	P						P	
Adult Cephalic										
Cardiac		P	P						P	
Transesophageal										
Transrectal		P	P						P	
Transvaginal		P	P						P	
Transurethral										
Intravascular										
Peripheral Vascular		P	P						P	
Laparoscopic										
Musculo-skeletal Conventional		P	P						P	
Musculo-skeletal Superficial		P	P						P	
Other (specify)										

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

Additional comments: Combined mode: B+M

*Other: Tissue Harmonic Imaging. The feature does not use contrast agents

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Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061189

Prescription USE (Per 21 CFR 801.109)

K061189

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 75L60HB

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

(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)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K061189

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