K081873

JUL 16 2008

Emperor Shenzhen Emperor Electronic Technology Co., Ltd

Appendix VI 510(k) Summary

As Required by CFR 807.92

1. **Submission Date:** May 21, 2008

2. **Sponsor Information**

Shenzhen Emperor Electronic Technology Co., Ltd.
2/F, Building7, Tian'an Nanyou Industrial Area, Nanshan District,
Shenzhen, 518054, China
Contact Person: Ms. Cheng Guiyuan
Tel: +86-755-26073381
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3. **Submission Correspondent:**

Ms. Diana Hong
Shanghai Mid-Link Business Consulting Co., Ltd
Suite 8D, Zhongshan Zhongxin Mansion
No.19, Lane 999, Zhongshan No.2 Road(S)
Shanghai, 200030, China.

4. **Subject Device Information**
   - **Device Trade/Proprietary Name:** EMP-2100 Full Digital Ultrasound Diagnostic Device
   - **Device Classification Name:** System, Imaging, Pulsed echo, Ultrasonic Transducer, Ultrasonic, Diagnostic
   - **Device Common Name:** Ultrasonic pulsed echo imaging system
   - **Review Panel:** Radiology
   - **Product Code:** 90-IYO & 90-ITX
   - **Regulation Number:** 892.1560
   - **Device Class:** II
   - **Review Category:** Tier II
   - **Intended Use:**

     EMP-2100 Full Digital Ultrasound Diagnostic System is a general-purpose, digital ultrasound diagnostic system for abdomen, gynecology, obstetric, urology, small-parts, and cardiology application.

     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-skeletal(both conventional and superficial). The device is intended to adult, pregnant woman, pediatric and neonate.

The system is a prescription device intended to be used by or on the order of a physician or similar qualified health care professional. This device is not intended for home use.

5. Predicate Device:

DP-6600 Digital Ultrasonic Diagnostic Imaging System with added transducers

K-number: K060949

Product Code: IYO

Intended Use:

The system 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, and peripheral vascular and musculo-skeletal (both conventional and superficial).

This device is intended to adult, pregnant woman, pediatric and neonate. The 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.

Manufactured by:

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

6. Device Description

EMP-2100 Full Digital Ultrasound Diagnostic Device is a portable digital ultrasonic diagnostic B/W system applied in ultrasound diagnostic examination of abdomen, gynecology, obstetric, urology, small-parts, and cardiology application.

It is designed to produce ultrasound waves into body tissue and to present the returned echo information on the monitor. The resulting information is displayed in five display modes as listed below. This system is a Track 1 device that employs an array of probes that include linear array, convex linear array and microconvex linear array with a frequency range of approximately 2.5MHz~7.5MHz.

The subject device is not for life-supporting or life-sustaining, not for implant. The device or transducers are not provided sterile and the transducer does not need sterilization and the transducer is reusable but does not need re-sterilization.

The system consists of a main unit, a display and four transducers.

Table VI-1 Transducer List

Transducer Model	Type	Nominal Frequency	Application	Track
C080-13G	Micro Convex	6.5 MHz	gynecology, obstetric, urology and transvaginal	1
L096-42C	Liner Probe	6.5 MHz	small-parts, neonatal cephalic, peripheral vascular and musculo-skeletal	1
C096-20A	Micro Convex	3.5 MHz	cardiology, pediatric, abdomen, gynecology and obstetric	1
C128-50	Convex	3.5 MHz	abdomen, pediatric, gynecology and obstetric	1

7. Technology Characteristics

Table VI-2 Technology Characteristics

Display Mode	B,B/B,4B,B/M,M
Gray Scales	256
Frame rate	60 frames/second max. （various according different probes and the frequency）
Display	10"SVGA
Video output	PAL-D
Digital Scanning Converter	576 ×460 ×8 bits
Zoom	11 levels, partial zoom
Body mark	38 types indicating probe positions
Power Supply	AC 100～240V , 47～60Hz
Input Power	200 VA
Continuous Operation Period	＞8 hours
Dimensions	365（height）×292 (width) ×380（depth）
Weight	Net weight 10 Kg
Working Condition	Temperature 5°C -40°C ,relative humidity up to 90%RH
Storage Condition	Temperature -5-40°C , relative humidity up to 90%RH (no water drop) air pressure 70-106Kpa

8. Effectiveness and Safety Considerations

Effectiveness:

Clinical Measurement Effectiveness Test was conducted on the subject device to evaluate its measurement accuracy.

Safety Considerations:

The Electrical Safety Testing following IEC 60601-1 and Electromagnetic Compatibility Testing following IEC 60601-1-2 was conducted on the subject device

Per FDA Guideline "INFORMATION FOR MANUFACTURERS SEEKING MARKETING CLEARANCE OF DIAGNOSTIC ULTRASOUND SYSTEMS AND TRANSDUERS" dated May 1, 1997 and with regard to Table 1 Initial Evaluation Tests for Consideration and Table 2 Supplementary Evaluation Tests for Consideration in ISO 10993-1:2003(E), Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing, the necessary tests for Biocompatibility Testing includes: Cytotoxicity, Sensitization, Irritation.

9. Substantially Equivalent Analysis

The subject device has same classification information, same indication for use, similar product design, same performance effectiveness, performance safety as the predicate device.

The differences are included as followings:

Scanning angle

Linear probe width

Micro-convex probe scanning angle

Power supply: 110V±10%, 230V±10% vs 100~240VAC±10%

Volume and Weight: 306 mm (W)*426 mm (L)*357 mm (H), 12KG vs 86 mm(W)*385 mm(L)*306 mm(H), 11KG

Image Process: the subject device does not have Line Density as the predicate device

Storage: 16 images in main unit vs 100 images in main unit

Operation Environment: Temperature 5°C -40°C ,relative humidity 30-80%RH vs Temperature 5°C-40°C ,relative humidity 30-85%RH

Storage Environment.: Temperature -5-40°C ,relative humidity 30-80%(no water drop) air pressure 86-106Kpa vs Temperature -22°C -55°C , relative humidity 30-85% (no condensation) air pressure 70-106Kpa

Display Mode

The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no question is raised regarding to effectiveness and safety.

No new unique technology is applied in the subject device. Most of the main aspects on effectiveness and safety between the subject device and predicate device are same. The

differences are slight so that no substantial influence on the effectiveness and safety.

10. Substantially Equivalent Determination

The subject device, EMP-2100 Full Digital Ultrasound Diagnostic Device, is **substantially equivalent** to the predicate device, DP-6600 Digital Ultrasonic Diagnostic Imaging System with added transducers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2008

Shenzhen Emperor Electronic Technology Co., Ltd
% Mr. Morten Simon Christensen
Staff Engineer & FDA Accredited Person Program Coordinator, Program Reviewer
Underwriters Laboratories, Inc.
UL Silicon Valley Office
455 E. Trimble Road
SAN JOSE CA 95131-1230

Re: K081873
Trade/Device Name: EMP-2100 Full Digital Ultrasound Diagnostic System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: June 24, 2008
Received: July 2, 2008

Dear Mr. Christensen:

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 EMP-2100 Full Digital Ultrasound Diagnostic System, as described in your premarket notification:

Transducer Model Number

C128-50
C080-13G
L096-42C
C096-20A

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 (240) 276-3666.

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)

Indication for Use

510(k) Number:

Device Name: EMP-2100 Full Digital Ultrasound Diagnostic System

Indications for Use:

EMP-2100 Full Digital Ultrasound Diagnostic System is a general-purpose, digital ultrasound diagnostic system for abdomen, gynecology, obstetric, urology, small-parts, and cardiology application.

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-skeletal(both conventional and superficial). The device is intended to adult, pregnant woman, pediatric and neonate.

The system is a prescription device intended to be used by or on the order of a physician or similar qualified health care professional. This device is not intended for home use.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081873

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: EMP-2100 Full Digital Ultrasound Diagnostic System (C128-50 Transducer)

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 (B/M)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Comments:

(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 K081873

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: EMP-2100 Full Digital Ultrasound Diagnostic System (C080-13G Transducer)

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 (B/M)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal		N	N						N	
Transurethral		N	N						N	
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

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

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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 K081873

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: EMP-2100 Full Digital Ultrasound Diagnostic System (L096-42C Transducer)

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 (B/M)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)		N	N						N	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletalConventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other (specify)										

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

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081873

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: EMP-2100 Full Digital Ultrasound Diagnostic System (C096-20A Transducer)

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 (B/M)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric		N	N						N	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										
Cardiac		N	N						N	

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

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