510(K) Summary

JUL - 3 2007

This summary of 510(k) safety and effectives information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K071156

Submitter / Distributor:

Sounmed, Inc.
6800 N.W. 77th Court
Miami, Fl 33166
Establishment Registration # 3004483577

Telephone: 305-477-0986
Fax: 305-477-5351

- **Contact Person:**

Jhoana Lores
Email: jhoana@sounmed.com

- **Manufacturer:**

Xuzhou Kaixin Electronic Instrument Co., LTD
Kaixin Mansion
C-01, Economic Development Zone
221004 Xuzhou, Jiangsu
REPUBLIC OF CHINA

- **Date Prepared:**

April 20, 2007

Name of the device:

- Trade/Proprietary Name: Sounmed SD-2000 Plus Portable Ultrasound scanner and Transducers.
- Common Name: Ultrasonic Imaging Systems and Transducers.
- Classification:

Regulatory Class: II

	FR Number	Product Code
Ultrasonic pulsed echo imaging system	892.1560	90-IYO
Diagnostic ultrasonic transducer	892.1570	90-ITX

Legally Marketed Predicate Device:

K000030 SonoAce 600 Diagnostic Ultrasound System.

Device Description:

The Sounmed SD-2000 Plus (KX2000G) is a black and white mobile diagnostic ultrasound imaging system. This device is designed to project ultrasound waves into body tissue and to present the returned echo information on the monitor. Operating Modes of SD-2000 Plus (KX2000G) are B, B/B, B/M, and M .

The Sounmed SD-2000 Plus (KX2000G) supports a selection of Linear and Convex probes for wide variety of application. It is an ultrasound scanner, which provides high resolution, high penetration, and various measurement functions. Probes are supported in frequencies from 3.5 MHz to 7.5 MHz.

All transducers used with SD the SD-2000 Plus ultrasonic diagnostic imaging system are track 1

Statement of Intended Use:

- Fetal-OB/GYN
- Abdominal
- Small Organs (breast, thyroid, testicle)
- Trans-Vaginal
- Trans-Rectal

Typical examinations performed using the system are:

- General abdominal and pelvic studies including organ surveys, assessment, and retroperitoneal cavity studies.
- Study of small parts and superficial structures including breasts, shoulders, thyroid, and the abdominal wall.
- First, second and third trimester pregnancy studies.
- Prostate, bladder and rectum visualization.

Comparison of Technological Characteristics:

The Sounmed SD-2000 Plus (KX2000G) ultrasonic imaging system with added transducers operates identical to the predicate device in that piezoelectric material in the transducer is used as an ultrasound source to transmit sound waves into the body. Sound waves are reflected back to the transducer and converted to electrical signals that are processed and displayed as a 2D and M-mode images.

Applicable Standards:

The Sounmed SD-2000 Plus (KX2000G) Portable Ultrasound Device with added transducers conforms to the following standards:

EN60601-1, Medical electrical equipment. General requirements for safety

EN60601-1-2, Medical electrical equipment. General requirements for safety. Collateral standard. Electromagnetic compatibility.

EN60601-1-4, Medical electrical equipment. General requirements for safety. Collateral standard. General requirements for programmable electric.

EN60601-2-37, Medical electrical equipment. Particular requirements for the safety of ultrasonic diagnostic and monitoring equipment.

EN61157, Requirements for the declaration of the acoustic output of medical diagnostic ultrasonic equipment

EN980, medical device labeling standard for CE mark compliance

ISO 14971, Medical devices - Application of risk management to medical devices

ISO 13485:2003, Medical devices - Quality management systems

ISO 9001:2000, Quality management systems

CE Mark 93/42/EEC

Clinical Tests:

Not Required

Conclusion:

The conclusions drawn from testing of the The Sounmed SD-2000 Plus (KX2000G) ultrasonic imaging system with added transducers 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

JUL - 3 2007

Ms. Jhoana Lores
Regulatory Affairs
Soundmed, Inc.
6800 NW 77th Court
MIAMI FL 33166

Re: K071156
Trade Name: Soundmed SD-2000 Plus Portable Ultrasound Scanner
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: April 23, 2007
Received: April 26, 2007

Dear Ms. Lores:

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 Soundmed SD-2000 Plus Portable Ultrasound Scanner, as described in your premarket notification:

Transducer Model Number

3.5MHz Convex Array (3.5C60A2)
6.5MHz Endocavity (6.5C13B2)
7.5MHz Linear Array (7.5L40B2)

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 (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 Andrew Kang at (240) 276-3666.

Sincerely yours,

Nancy C Brogdon

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

510(k) Number : K071156
Device Name : Sounmed SD-2000 Plus Portable Ultrasound Scanner

Intended Use: Diagnostic ultrasound imaging or fluid flowd analyisis of the human body as follows:

Clinical Application	Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Color Velocity Imaging	Combined (B-M)	Other (specify
Ophtalmic									
Fetal		N	N					N	
Abdominal		N	N					N	
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify)		N	N					N	Note 1
Neonatal Cephalic		N	N					N	
Adult Cephalic									
Cardiac									
Trasesophageal									
Transrectal		N	N					N	
Transvaginal		N	N					N	
Transurethral									
Intravascular									
Peripheral Vascular		N	N					N	
Laparoscopic									
Musculo-skeletal Conventional									
Musculo-skeletal Superficial		N	N					N	
Other (specify)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Note 1: Small Organ: breast, thyroid, testes.

Additional 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071156

Diagnostic Ultrasound Indications for Use Form

510(k) Number : K071156
Device Name : Sounmed SD-2000 Plus Portable Ultrasound scanner
Transducer: 3.5Mhz Convex Array Probe Model : 3.5C60A2

Intended Use: Diagnostic ultrasound imaging or fluid flowd analyisis of the human body as follows:

Clinical Application	Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Color Velocity Imaging	Combined (B - M)	Other (specify
Ophtalmic									
Fetal		N	N					N	
Abdominal		N	N					N	
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Trasesophageal									
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: _____

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071156

Diagnostic Ultrasound Indications for Use Form

510(k) Number : K071156
Device Name : Sounmed SD-2000 Plus Portable Ultrasound scanner
Transducer: 6.5 Mhz Endocavity Probe model: 6.5C13B2

Intended Use: Diagnostic ultrasound imaging or fluid flowd analyisis of the human body as follows:

Clinical Application	Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Color Velocity Imaging	Combined (B + M)	Other (specify
Ophtalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify)									
Neonatal Cephalic									
Adult Cephalic									
Cardiac									
Trasesophageal									
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: _____

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071156

Diagnostic Ultrasound Indications for Use Form

510(k) Number : K071156
Device Name : Sounmed SD-2000 Plus Portable Ultrasound scanner
Transducer: 7.5Mhz Linear Array Probe Model: 7.5L40B2

Intended Use: Diagnostic ultrasound imaging or fluid flowd analyisis of the human body as follows:

Clinical Application	Mode of Operation								
	A	B	M	PWD	CWD	Color Doppler	Color Velocity Imaging	Combined (B + M)	Other (specify
Ophtalmic									
Fetal									
Abdominal									
Intraoperative (specify)									
Intraoperative Neurological									
Pediatric									
Small Organ (specify)		N	N					N	
Neonatal Cephalic		N	N					N	
Adult Cephalic									
Cardiac									
Trasesophageal									
Transrectal									
Transvaginal									
Transurethral									
Intravascular									
Peripheral Vascular		N	N					N	Note 1
Laparoscopic									
Musculo-skeletal Conventional									
Musculo-skeletal Superficial		N	N					N	
Other (specify)									

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Note 1: Small Organ: breast, thyroid, testes.

Additional 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071156