K090505

510(k) Summary

MAY - 7 2009

1. **Sponsor:**
Signostics Pty Ltd
Lot 1, 40 – 46 West Thebarton Road
PO Box 736, Torrensville
Thebarton, SA 5031
Australia

2. **Contact Person:**
Charles F. Hottinger, Ph.D., RAC,
Regulatory Affairs Consultant
Telephone: (206) 780-7945

3. **Date Prepared:**
April 21, 2009

4. **Device Name:**
Speq

5. **Proprietary/Marketed Names:**

Signos Personal Ultrasound (subject to change)

Signos (subject to change)

6. **Common/Usual Name:**

Diagnostic ultrasound system and transducer

7. **Classification**

Regulatory Class: II

Review Category: Tier II

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

8. **Predicate Devices**

Pie Medical 50S Tringa (K020112)

Siemens Acuson P10 (K063761)

Sonosite iLook (K021628)

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9. Basis for Substantial Equivalence

Signostics Pty Ltd believes the Speq ultrasound system described in this Submission is substantially equivalent to the predicate devices as follows:

a. Pie Medical 50S Tringa (K020112);

b. Siemens Acuson P10 (K063761); and

c. Sonosite iLook (K021628).

The Speq ultrasound system is substantially equivalent to the predicate devices listed above. All systems transmit ultrasonic energy into patients, then process received echoes to produce on-screen images of anatomic structures within the body. All systems allow for measurements of structures to aid in diagnosis.

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10. Device Description

The Signostics Pty Ltd Speq ultrasound system is a hand-held, diagnostic ultrasound system with an on-screen display. Its purpose is to acquire ultrasound echo data and display it in B-Mode or M-Mode on an LCD display.

Technical specifications for the Signostics Speq ultrasound system are as follows:

System				
Transducer frequencies:	3.5MHz & 7.5MHz			
Frame rate:	8Fps maximum (Imaging only)			
Ultrasound lines/frame:	360 lines for 90° frame			
Fields of View:	1-18 cm for 3.5MHz, 1-8.4cm for 7.5MHz			
External Video Output:	No			
Liquid-Crystal Display:	18 bit, 262,000 Color, Active Matrix TFT LCD			
Size: -				
Width:	6.8 cm			
Height:	11.5 cm			
Depth:	2.0 cm			
Weight:	0.31 kg			
Electrical				
External Power:	Input:	100-240 VAC, 50-60Hz	Output:	5 VDC @ 2A
Battery:	Li-Ion battery pack (2 Whr)			
Leakage Current:	10 µA maximum			
Primary Breakdown Voltage:		6000VDC		
Safety Standards:	IEC 60601-1, UL 2601-1, Can/CSA C22.2 601.1-M90			
Protection Class:	Class II: per IEC 60601-1			
Degree of Protection:		Type BF: per IEC 60601-1		

Environmental	
Mechanical Shock :	Drop Testing per IEC60601-1, Vibration Testing over 5Hz-5kHz/0-50G
Mechanical Vibration:	5Hz-5kHz/0-50G
Drop Test (to concrete):	1 meter
Operating Temperature:	0 to 45 C
Humidity:	0 to 90% RH, non-condensing
Water Resistance:	Transducer IPX7 degree of protection against water
Altitude:	0.7 – 1.05 standard atmospheres (2500m or 8200 feet)operating
Storage	
Temperature:	-20 to 50 C
Humidity:	0 to 90% RH, non-condensing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Signostics Pty Ltd
% Charles F. Hottinger, Ph.D., RAC
Regulatory Affairs Consultant
P.O. Box 10074, 13221 NE Teem Loop Road
BAINBRIDGE ISLAND WA 98110

Re: K090505
Trade/Device Name: Speq Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: February 13, 2009
Received: February 26, 2009

Dear Dr. Hottinger:

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 Speq Ultrasound System, as described in your premarket notification:

Transducer Model Number

3.5 MHz (P03010)
7.5 MHz (P03011)

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 Lauren Hefner at (240) 276-3666.

Sincerely yours,

Colin M. Pollard

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

Enclosure(s)

Indications For Use

510(k) Number (if known): K090505

Device Name: Speq Ultrasound System

Indications For Use:

The Speq ultrasound system is for non-invasive imaging of the human body and is intended for the following applications: Fetal, Abdominal, Pediatric, Musculo-skeletal, Cardiac and Peripheral Vessel. Users must have ultrasound training before using the device. See the attached Indications for Use form for specific imaging modes and applications.

The following warnings apply:

Warning: Use in B-mode is not indicated where body structures are in rapid motion.

Warning: Use in B-mode is not indicated where the application of pressure on the transducer will displace the tissue of interest.

Warning: Use in B-mode is not indicated for catheter or needle placement where the real-time visualization of the structure of interest and needle is required.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE).

Colin M Pollard

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090505

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1.3 Indications for Use

The Speq ultrasound system is intended for the uses described in the following Indications for Use Forms.

1.3.1 510(k) Indications for Use Form

TABLE 1 - SPEQ ULTRASOUND SYSTEM INDICATIONS FOR USE FORM

System: Speq ultrasound system
Intended Use: Diagnostic ultrasound imaging of the human body as follows:

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

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Additional Comments:
Note 1: Use in B-mode is not indicated where body structures are in rapid motion.
Note 2: Use in B-mode is not indicated where the application of pressure on the transducer will displace the tissue of interest.
Note 3: Use in B-mode is not indicated for catheter or needle placement where the real-time visualization of the structure of interest and needle is required.

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Prescription Use: X

(Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
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TABLE 2 - SPEQ ULTRASOUND SYSTEM INDICATIONS FOR USE FORM

System: Speq ultrasound system

Transducer: 3.5 MHz (P03010)

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

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

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

Additional Comments:

Note 1: Use in B-mode is not indicated where body structures are in rapid motion.

Note 2: Use in B-mode is not indicated where the application of pressure on the transducer will displace the tissue of interest.

Note 3: Use in B-mode is not indicated for catheter or needle placement where the real-time visualization of the structure of interest and needle is required.

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

Prescription Use:____ X

(Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090505

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Table 3 - Speq ultrasound system Indications For Use Form

System: Speq ultrasound system

Transducer: 7.5 MHz (P03011)

Intended Use: Diagnostic ultrasound imaging of the human body as follows:

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

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

Additional Comments:

Note 1: Use in B-mode is not indicated where body structures are in rapid motion.

Note 2: Use in B-mode is not indicated where the application of pressure on the transducer will displace the tissue of interest.

Note 3: Use in B-mode is not indicated for catheter or needle placement where the real-time visualization of the structure of interest and needle is required.

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

Prescription Use:____ X

(Per 21 CFR 801.109)

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