510(k) Summary

APR 3 2013

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

2. **Contact Person:**
Varda Swery
Quality and Regulatory Manager
Telephone: +61 (8) 8152 9400

3. **Date Prepared:**
September 25, 2012

4. **Device Name:**
SpeqRT

5. **Proprietary/Marketed Names:**

Signos RT Personal Ultrasound

SignosRT

Sonimage P3

6. **Common/Usual Name:**

Diagnostic ultrasound system and transducer

7. **Classification**

Regulatory Class: II

Review Category: Tier II

Ultrasonic Pulsed Doppler Imaging System	(21 CFR 892.1550, 90-IYN)
Diagnostic Ultrasound Transducer	(21 CFR 892.1570, 90-ITX)

Classification Panel: Radiology

8. **Predicate Devices**

Pie Medical 50S Tringa (K020112)

Siemens Acuson P10 (K063761)

Sonosite iLook (K021628)

Signos Personal Ultrasound (K090505)

9. Risk Analysis Method Used

Signostics Ltd applied ISO-14971 to the design and development of the SpeqRT ultrasound system. The conclusion from the risk analysis was the device was safe for its intended use and does not pose any unacceptable risks.

10. Basis for Substantial Equivalence

Signostics Ltd believes the SpeqRT 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);

c. Sonosite iLook (K021628); and

d. Signos Personal Ultrasound (K090505)

The SpeqRT 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 B-mode imaging and measurements of structures to aid in diagnosis equivalent to the SpeqRT ultrasound system. The Sonosite iLook, Pie Medical 50S Tringa and Signos Personal Ultrasound allow for M-mode imaging equivalent to the SpeqRT ultrasound system. The Sonosite iLook allows for Pulsed-Wave Doppler imaging equivalent to the SpeqRT ultrasound system. The indication for use statement of the SpeqRT ultrasound system is identical to the Signos Personal Ultrasound system (K090505). The SpeqRT ultrasound system display size is identical to the Signos Personal Ultrasound (K090505).

The SpeqRT ultrasound system, predicate Signos Personal Ultrasound system (K090505), and predicate Siemens Acuson P10 system (K063761) have all been bench tested for imaging performance and measurement accuracy, and have shown the SpeqRT imaging performance and measurement accuracy to be substantially equivalent to the predicate devices.

11. Device Description

The Signostics Ltd SpeqRT 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, M-Mode, or Spectral Doppler (PW Doppler) on an LCD display.

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

System				
Transducer frequencies:	3MHz (S3 transducer) & 3-5MHz (S3-5 transducer)			
Frame rate:	8Fps or 16Fps (Imaging only)			
Ultrasound lines/frame:	128 lines for 90° frame			
Fields of View:	1-18 cm for 3MHz, 0-18cm for 3-5MHz			
External Video Output:	No			
Liquid-Crystal Display:	18 bit, 262,000 Color, Active Matrix TFT LCD			
Materials	Sabic Cycoloy HC1204HF, Mitsui TPX-MED18, Sabic Versollen OMX1255NX-1			
Size: -				
Width:	6.8 cm			
Height:	11.5 cm			
Depth:	2.0 cm			
Weight:	0.13 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:		3000VAC		
Safety Standards:	IEC 60601-1:1988 + A1:1991 + A2:1995, IEC 60601-1:2005, UL60601-1:2003, IEC 60601-2-37:2001+ A1: 2004 + A2: 2005, IEC 60601-2-37:2007, IEC 60601-1-2:2007, ISO 10993-1:2003			
Protection Class:	Class II: per IEC 60601-1			
Degree of Protection:		Type BF: per IEC 60601-1		

Environmental	
Mechanical Shock :	Drop and push testing per IEC60601-1
Mechanical Vibration:	10Hz-55Hz/50G
Drop Test (to concrete):	1 meter
Operating Temperature:	0 to 40 C
Humidity:	20 to 80% RH, non-condensing
Water Resistance:	Transducer IPX5 degree of protection against water
Altitude:	0.7 – 1.05 standard atmospheres (2500m or 8200 feet) operating
Storage	
Temperature:	-20 to 45 C
Humidity:	20 to 80% RH, non-condensing

Signostics Ltd is applying FDA recognised standards as detailed in the tables above to evaluate the safety of the SpeqRT ultrasound system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2013

Signostics, Pty Ltd
c/o Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K130659
Trade/Device Name: SpeqRT Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX
Dated: March 8, 2013
Received: March 12, 2013

Dear Mr. Job,

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 SpeqRT Ultrasound System, as described in your premarket notification:

Transducer Model Number	
S3 (P03479)	S3-5 (P03611)

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 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

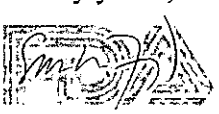
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K130659

Device Name: SpeqRT Ultrasound System

Indications for Use:

The SpeqRT 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.

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)

1.3 Indications for Use

The SpeqRT 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 - SPEQRT ULTRASOUND SYSTEM INDICATIONS FOR USE FORM

System: SpeqRT 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	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	N					
	Cardiac Pediatric	N	N					
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N				
	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)

Prescription Use: X

(Per 21 CFR 801.109)

TABLE 2 - SPEQRT ULTRASOUND SYSTEM INDICATIONS FOR USE FORM

System: SpeqRT ultrasound system

Transducer: S3 (P03479)

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	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	N					
	Cardiac Pediatric	N	N					
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N				
	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)

Prescription Use: X

(Per 21 CFR 801.109)

Table 3 - SpeqRT ultrasound system Indications For Use Form

System: SpeqRT ultrasound system

Transducer: S3-5 (P03611)

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

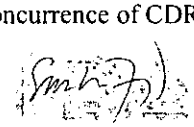
Clinical Application		**Mode of Operation**						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N					
	Abdominal	N	N	N				
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	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	N					
	Cardiac Pediatric	N	N					
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel	N	N	N				
	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)

Prescription Use: X
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)



(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health