



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

Signostics Limited
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street, NW
BUFFALO MN 55313

September 3, 2015

Re: K152250
Trade/Device Name: SpeqRT
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: August 7, 2015
Received: August 10, 2015

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a grey shadow effect behind the text.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152250

Device Name

SpeqRT

Indications for Use (Describe)

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Indications for Use

510(k) Number (if known)

K152250

Device Name

SpeqRT

510(k) Indications for Use Form

TABLE 1 - SPEQRT INDICATIONS FOR USE FORM

System: SpeqRT

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	P	P					
	Abdominal	P	P	P				
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P					
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P					
	Musculo-skeletal (Superficial)							
	Intravascular							
Other (Specify)								
Cardiac	Cardiac Adult	P	P					
	Cardiac Pediatric	P	P					
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P				
	Other (Specify)							

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

Additional Comments:

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Indications for Use

510(k) Number (if known)

K152250

Device Name

SpeqRT

TABLE 2 - SPEQRT INDICATIONS FOR USE FORM

System: SpeqRT

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	P	P					
	Abdominal	P	P	P				
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P					
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P					
	Musculo-skeletal (Superficial)							
Intravascular								
Other (Specify)								
Cardiac	Cardiac Adult	P	P					
	Cardiac Pediatric	P	P					
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P				
	Other (Specify)							

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Indications for Use

510(k) Number (if known)

K152250

Device Name

SpeqRT

TABLE 3 - SPEQRT INDICATIONS FOR USE FORM

System: SpeqRT

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	P	P					
	Abdominal	P	P	P				
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	P	P					
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	P	P					
	Musculo-skeletal (Superficial)							
Intravascular								
Other (Specify)								
Cardiac	Cardiac Adult	P	P					
	Cardiac Pediatric	P	P					
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
Other (Specify)								
Peripheral Vessel	Peripheral vessel	P	P	P				
	Other (Specify)							

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

Additional Comments:

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

Indications for Use

510(k) Number (if known)

K152250

Device Name

SpeqRT

TABLE 4 - SPEQRT INDICATIONS FOR USE FORM

System: SpeqRT

Transducer: L10 (P04000)

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							
	Abdominal							
	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							
	Cardiac Pediatric							
	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:

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

1. Sponsor:

Signostics Ltd
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1284 South Road
Clovelly Park, SA 5042
Australia

2. Contact Person:

Stewart Bartlett
Chief Operating Officer
Telephone: +61 (8) 7424 0600

3. Date Prepared:

June 30, 2015

4. Device Name:

SpeqRT

5. Proprietary/Marketed Names:

SignosRT, SONIMAGE P3

6. Common/Usual Name:

Diagnostic ultrasound transducer

7. Classification

Regulatory Class: II

Review Category: Tier II

Ultrasonic Pulsed Echo Imaging System (21 CFR 892.1560, 90-IYO)

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

SpeqRT Ultrasound System (K130659): This 510k is submitted due to a significant change to SpeqRT Ultrasound System (K130659), for the addition of a new transducer (L10).

Speq Ultrasound System (K090505): contains a 7.5MHz transducer, and therefore is used as a predicate for the new L10 transducer introduced in this application.

9. Risk Analysis Method Used

Signostics Ltd applied ISO-14971 to the design and development of the SignosRT and the change to include the L10 transducer. 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

This submission is for a significant change to the SpeqRT system described in K130659.

The changes are as follows:

- a. A new transducer (L10) is included. The new transducer is a high frequency transducer with a flat transducer surface for providing better superficial resolution and better ergonomics for imaging blood vessels. Note: There are no new indications for use included in the system.
- b. The software has been updated to v2.11.0. The significant changes to the software are to support the new L10 transducer.
- c. The user manual has been updated to v2.11.0 to add the new L10 transducer.
- d. A new packaging box has been created to ship the L10 transducer separate to the main system.
- e. The previously cleared S3 and S3-5 transducer have been updated to provide a more robust transducer lens. The previously cleared transducer contained two patient contact materials, a lens made from blue TPX-MED18, and a body made from white Cycloy HC1204HF. The updated S3 and S3-5 transducer design contains a single lens and body made from white TPX-MED18 (same as new L10). The ISO-10993 tests have been repeated for the new material.

Excluding the above changes, the previously cleared SpeqRT (K130659) and the new device are identical and unchanged. They transmit ultrasonic energy into patients, then process received echoes to produce on-screen images of anatomy. The indication for use statement of the SignosRT L10 transducer is a subset of the indications for use of the SignosRT S3-5 transducer.

The base SpeqRT system is identical in construction, materials, and controls to the previously cleared SpeqRT (K130659). The patient contact materials have been updated and retested to ISO-10993. The new L10 transducer operating frequency (7-10MHz) is higher than the S3-5 transducer operating frequency (3-5MHz), therefore providing better superficial resolution. Both systems contain sector transducers with annular (circular) acoustic elements generating pie shaped images. Both transducers maintain MI and TI to be <1.0 at all times.

11. Device Description

The Signostics Ltd SignosRT 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 SignosRT are unchanged after adding the L10 transducer and are as follows:

System				
Transducer frequencies:	3MHz (S3 transducer), 3-5MHz (S3-5 transducer) and 10MHz (L10 transducer)			
Frame rate:	8Fps or 16Fps (Imaging only)			
Ultrasound lines/frame:	128 lines for 90° frame			
Fields of View:	1-18 cm for 3MHz and 3-5MHz, 0-6cm for 10MHz			
External Video Output:	No			
Liquid-Crystal Display:	18 bit, 262,000 Color, Active Matrix TFT LCD			
Materials	Sabic Cycloy 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 60601-1:2005, ES60601-1:2005, 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 ES60601-1
Mechanical Vibration:	Random Acceleration Profile per JIS Z 0232:2004 5Hz-300Hz
Drop Test (to concrete):	1 meter
Operating Temperature:	0 to 40°C
Humidity:	20% to 80% RH, non-condensing
Water Resistance:	Transducer IPX7 lens, IPX1 probe degree of protection against water
Altitude:	0.7 – 1.05 standard atmospheres (2500m or 8200 feet) operating
Storage	
Temperature:	-20 to 45°C
Humidity:	10 to 90% RH, non-condensing
Altitude:	0.5 – 1.05 standard atmospheres storage

12. Non-clinical Performance Data

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

The new SpeqRT L10 transducer has been bench tested for imaging performance and measurement accuracy, with tests showing the SpeqRT L10 imaging performance and measurement accuracy to be substantially equivalent to the S3-5 transducer predicate devices. The measured lateral and axial resolution for the SpeqRT L10 is less than the S3-5 transducer and predicates 7.5MHz transducer (K090505), therefore providing better image resolution.

The SpeqRT L10 transducer has been tested by independent laboratories in conjunction with the SpeqRT system to IEC 60601-1:2005, IEC 60601-2-37:2007, IEC 60601-1-2:2007, ISO 10993-5:2009, ISO 10993-10:2002, ISO 10993-10:2010, ISO 10993-12:2007, NEMA UD-2-2004 (R2009), NEMA UD-3-2004(R2009) and found to comply with all standards.

The software and firmware in the SpeqRT has been developed and verified according to IEC 62304:2006. The verification reports (Appendix R and V), traceability (Appendix Q), and risk analysis (Appendix A) demonstrate the SpeqRT operates as intended with the L10 transducer and risks mitigated in firmware have been verified.

The conclusion from the testing is the device is safe and effective for its intended use, and performs as well or better than the predicate devices.