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

March 21, 2016

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

Re: K160420
Trade/Device Name: SpeqT
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: February 12, 2016
Received: February 16, 2016

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,

For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160420

Device Name
SpeqT

Indications for Use *(Describe)*
The SpeqT is for non-invasive imaging of the human body and is intended for the following applications: Abdominal, Musculoskeletal, Pediatric, and Small Organ. Users must have ultrasound training for abdominal, musculoskeletal, pediatric, and small organ imaging.
The SpeqT can also be used to obtain an image of the bladder that is used to automatically determine bladder volume.
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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

510(k) Number *(if known)*

K160420

Device Name
SpeqT

510(k) Indications for Use Form

TABLE 1 - SPEQT INDICATIONS FOR USE FORM

System: SpeqT
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	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						
	Small Organ (Specify)*	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	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							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
Additional Comments:
*Small organ imaging is prostate

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) Number *(if known)*

K160420

Device Name
SpeqT

TABLE 2 - SPEQT INDICATIONS FOR USE FORM

System: SpeqT

Transducer: B3-5 (P04200)

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	N						
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric	N						
	Small Organ (Specify)	N						
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal (Conventional)	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							
	Other (Specify)							

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

*Small organ imaging is prostate

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
   PO Box 1048, Pasadena
   1284 South Road
   Clovelly Park, SA 5042
   Australia

2. **Contact Person:**
   Stewart Bartlett
   Chief Operating Officer
   Telephone: +61 (8) 7424 0600

3. **Date Prepared:**
   January 22, 2016

4. **Device Name:**
   SpeqT

5. **Proprietary/Marketed Names:**
   Uscan

6. **Common/Usual Name:**

   Diagnostic ultrasound system

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)

   Classification Panel: Radiology

8. **Predicate Devices**

   SpeqRT Ultrasound System (K130659).

   Speq Ultrasound System (K090505).

   Philips Lumify Diagnostic Ultrasound System (K152899)

   Verathon BVI 9400 bladder scanner (K071217)

9. Risk Analysis Method Used

Signostics Ltd applied ISO-14971 to the design and development of the SpeqT. 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 SpeqT system described in this Submission is substantially equivalent to the predicate devices as follows:

a. SpeqRT Ultrasound System (K130659).
b. Speq Ultrasound System (K090505).
c. Philips Lumify Diagnostic Ultrasound System (K152899)
d. Verathon BVI 9400 bladder scanner (K071217)

All systems transmit ultrasonic energy into patients, then process received echoes to generate images of anatomy and perform measurements. The SpeqT system is substantially equivalent to the SpeqRT Ultrasound System, Speq Ultrasound System, and Lumify Diagnostic Ultrasound System as they allow for the display of real-time B-mode imaging. The SpeqT system is also substantially equivalent to the Verathon BVI 9400 as both allow automatic measurement of volume of urine in a bladder. The Verathon BVI 9400 only displays an image if the measurement is printed.

The SpeqT Ultrasound System is substantialy equivalent to the predicates as follows:

Transducer	**Signostics SpeqT**	**Signostics SpeqRT S3-5 (K130659)**	**Signostics Signos (K090505)**	**Philips Lumify (K152899)**	**Verathon BVI 9400 (K071217)**
Type	Sector	Sector	Sector	Electronic array	Sector
Geometry	Annular	Annular	Annular	Curved linear array Linear array	Annular
Intended Uses	Adominal, Pediatric, Musculoskeletal, Small Organ	Adominal, Fetal, Pediatric, Cardiac, Peripheral Vessel, Musculoskeletal	Adominal, Fetal, Pediatric, Cardiac, Peripheral Vessel, Musculoskeletal	Adominal, Fetal, Pediatric, Cardiac, Cardiac Fetal, Gynecology, Peripheral Vessel, Musculoskeletal, Small Organ, Urology	Adominal, Fetal, Pediatric, Cardiac, Peripheral Vessel, Musculoskeletal
Centre Frequency	3.5MHz	3.5MHz	3.5MHz/7.5MHz	3.5MHz/8.0MHz	3.0MHz/1.74MHz
Element Outer Diameter	15mm	15mm	12mm/5.6mm	NA	13mm
Number Elements	8	8	1	Unknown	1
Acoustic Output					
Max Ispta.3 (mW/cm^2)	5.69	162	26	Unknown	5
Max MI	0.823	0.679	0.56	Unknown	0.95
Max TIS	0.0903	0.160	0.05	Unknown	Unknown

The SpeqT system is a general ultrasound imaging device with automated bladder measurement functionality, and is intended for abdominal (including the bladder), pediatric (including the bladder), and small organ (prostate) scanning.

The SpeqT probe and transducer are almost identical in construction, materials (including patient contact materials), and design, to the SignosRT Personal Ultrasound probe and transducer (K130659). The differences are: the indications for use statement; the transducer field of view (120° for SpeqT versus 90° for SignosRT); and the display (Android off-the-shelf tablet for SpeqT versus custom Windows CE tablet for SignosRT). The transducer operating frequency (3.5MHz) is also identical. Both systems contain sector transducers with annular (circular) acoustic elements generating pie shaped images, have identical operating frequency, identical outer diameter of acoustic crystal, identical acoustic output in B-mode, and both maintain MI and TI to be <1.0 at all times.

The predicate Philips Lumify (K152899) is similar to the SpeqT system as follows: both system use an off-the-shelf Android based display; both are indicated for small organs although the SpeqT is limited to prostate. The SpeqT minimises risk associated by the Android display by configuring the system at the factory to limit user access to other tablet functions, and not allowing additional non-approved applications to be installed.

The SpeqT is similar to the predicate Verathon BVI 9400 (K071217) as both automatically measure the urine volume in a bladder. The Verathon has a printer as part of the device. The SpeqT can print to a wireless printer available as an accessory.

The indication for use statement of the SpeqT system and the predicates are summarised below:

Signostics SpeqT	**Signostics SpeqRT S3-5 (K130659)**	**Signostics Signos (K090505)**	**Philips Lumify (K152899)**	**Verathon BVI 9400 (K071217)**
The SpeqT is for non-invasive imaging of the human body and is intended for the following applications: Abdominal, Musculoskeletal, Pediatric, and Small Organ. Users must have ultrasound training for abdominal, musculoskeletal, pediatric, and small organ imaging. The SpeqT can also be used to obtain an image of the bladder that is used to automatically determine bladder volume.	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.	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.	The Lumify Ultrasound System is intended for diagnostic ultrasound imaging in B- (2D) mode and in color Doppler (color flow). The system is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal/Obstetric, Abdominal, Urology, Gynecological, Cardiac Fetal, Small Organ, Musculoskeletal, Peripheral Vessel, and Carotid. Lumify is intended for use in environments where healthcare is provided by healthcare professionals, with the exception of home, ambulance, and air.	The BladderScan BVI 9400 projects ultrasound energy through the lower abdomen of the patient to obtain an image of the bladder which is used to calculate bladder volume noninvasively.

The first part of the SpeqT statement of intended use is similar to the SpeqRT predicate (K130659) statement of intended use, with the exception of the addition of small organ imaging. However, the system performance and resolution required by small organ imaging is similar to that required by Peripheral Vessel and musculoskeletal imaging which is included in the SpeqRT predicate's statement of intended use. It should also be noted the Philips Lumify (K152899) intended use statement does include small organ and urology.

The second part of the SpeqT statement of intended use is similar to the Verathon BVI 9400 (K071217) predicate. The second part of the intended use statement was added, as the SpeqT, unlike the SpeqRT and Lumify, contains a mode of operation substantially equivalent to the Verathon BVI 9400 where bladder volume measurements are automatically performed.

The slight differences in the intended use statements are not critical as they do not affect safety and performance. The totality of the first part of the intended use statement is included in the SpeqRT and Lumify predicate intended use statements. Bench testing has shown substantially equivalent imaging performance, and there is no evidence of adverse events due to either of these predicate systems. The second part of the intended use statement is substantially equivalent to the Verathon BVI 9400 system, and internal clinical performance testing comparing the SpeqT and Verathon BVI 9400 shows the SpeqT to be equivalent or better performance than the Verathon BVI 9400.

11. Device Description

The Signostics Ltd SpeqT 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, on an off-the-shelf display. Automated bladder volume measurements are supported.

Technical specifications for the Signostics SpeqT system are as follows:

System				
Transducer frequencies:	3-7MHz (B3-5 transducer)			
Frame rate:	16Fps (Imaging only)			
Ultrasound lines/frame:	128 lines for 120º frame			
Fields of View:	1-18 cm			
External Video Output:	No			
Liquid-Crystal Display:	Minimum of 1200x780 pixels			
Materials	Sabic Cycoloy HC1204HF, Mitsui TPX-MED18, Sabic Versollan OM 1255NX-1			
Size: -	Probe only			
Width:	6.0 cm			
Height:	15.0 cm			
Depth:	3.2 cm			
Weight:	0.2 kg			
Electrical				
External Power:	Input:	100-240 VAC, 50-60Hz	Output:	5 VDC @ 2A
Battery:	Li-Ion battery pack - Display (>3.5V, >3950mAh) Probe (>3.5V, 1350mAh)			

Leakage Current:	IEC 60601-1 3rd Edition Compliant
Primary Breakdown Voltage:	3000VAC
Safety Standards:	IEC 60601-1:2005, ES60601-1:2005, EN 60601-1:2006, IEC 60601-2-37:2007, IEC 60601-1-2:2007, ISO 10993-1:2009, ISO-10993-5:2009, ISO 10993-10:2002, ISO 10993-10:2010, ISO 10993-12:2007
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:	Random Acceleration Profile per JIS Z 0232:2004 5Hz-300Hz
Drop Test (to concrete):	1 meter
Operating Temperature:	5 to 40 C
Humidity:	15 to 90% RH, non-condensing
Water Resistance:	Transducer IPX1 degree of protection against water
Altitude:	70kPa – 101.5kPa (0.7 – 1.015 standard atmospheres) (2500m or 8200 feet) operating
Storage	
Temperature:	-20 to 50 C
Humidity:	10 to 93% RH, non-condensing
Pressure:	50kPa – 101.5kPa (0.5 – 1.015 standard atmospheres)

12. Non-clinical Performance Data

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

The new SpeqT has been bench tested for imaging performance and measurement accuracy, with tests showing the SpeqT imaging performance and measurement accuracy to be substantially equivalent to the SpeqRT and Speq predicate devices.

The SpeqT has been tested by independent laboratories 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 SpeqT has been developed and verified according to IEC 62304:2006. The verification report (Appendix R), traceability (Appendix Q), and risk analysis (Appendix A) demonstrate the SpeqT operates as intended 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.