September 18, 2019

Qisda Corporation
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
SAINT PAUL, MN 55114

Re: K192254
Trade/Device Name: InnoSight Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 19, 2019
Received: August 20, 2019

Dear Prithul Bom:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192254

Device Name
InnoSight Diagnostic Ultrasound System

Indications for Use *(Describe)*
InnoSight Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), M-Mode, PW and CW Spectral Doppler, CPA, Tissue Harmonic imaging and Color Doppler modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Conventional), Other (Ob/GYN, Urology, Nerve), Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and Carotid. The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of-care for diagnosis of patients except environments where the intensity of electromagnetic disturbances is high.

The system is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the system user information, and only for the purposes for which it was designed.
The system should only be operated by someone who has received proper training in the use and operation of an ultrasound system. This system produces images derived from sound echoes; those images must be interpreted by a qualified medical professional. This system in no way interprets these images or provides a medical diagnosis of the patient being examined.

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.

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Diagnostic Ultrasound Indications for Use Form

System: **InnoSight Diagnostic Doppler Ultrasound System**
InnoSight Diagnostic Ultrasound Pulsed Echo System
InnoSight Diagnostic Ultrasound Pulsed Doppler Imaging System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**2D**	**M**	**PW Doppler**	**CW Doppler**	**Color**	**CPA**	**Other* Combined**	**Tissue Harmonic Imaging**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	Note 1	P
	Abdominal	P	P	P		P	P	Note 1	P
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	N	N	N		N	N	Note 1	N
	Small Organ (breast, thyroid, testes)	P	P	P		P	P	Note 1	P
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	Note 1	N
	Trans-rectal	P	P	P		P	P	Note 1	P
	Trans-vaginal	P	P	P		P	P	Note 1	P
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	Note 1	P
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)	P	P	P		P	P	Note 1	P
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	P
	Cardiac Pediatric	N	N	N		N	N	Note 1	N
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P	P		P	P	Note 1	P
	Other (specify)								

N = new indication; **P = previously cleared by FDA** **E = added under this appendix**

Note 1: Combined includes: 2D/M; 2D/PW Doppler; 2D/Color; 2D/CPA; 2D/Color /PW Doppler and 2D/CPA/PW Doppler

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

Transducer: C6-2 Curved Linear Array 2-6MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**2D**	**M**	**PW Doppler**	**Color Doppler**	**CPA**	**Other* Combined**	**Tissue Harmonic Imaging**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	Note1	P
	Abdominal	P	P	P	P	P	Note1	P
	Intra-operative Specify							
	Intra-operative Neuro							
	Laparoscopic							
	Pediatric	N	N	N	N	N	Note1	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 (Ob/GYN)	P	P	P	P	P	Note1	P
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 this appendix**

Note 1: Combined includes: 2D/M; 2D/PW Doppler; 2D/Color; 2D/CPA; 2D/Color /PW Doppler and 2D/CPA/PW Doppler

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

Transducer: L12-4 Linear Array 4-12MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**2D**	**M**	**PW Doppler**	**Color**	**CPA**	**Other* Combined**	**Tissue Harmonic Imaging**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	P	P	P	P	P	Note1	P
	Intra-operative Specify							
	Intra-operative Neuro							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testes)	P	P	P	P	P	Note1	P
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal (Conventional)	P	P	P	P	P	Note1	P
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular(Cardiac)							
	Trans-esoph.(Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note1	P
	Other (specify)							

N = new indication; **P = previously cleared by FDA;** **E = added under this appendix**

Note 1: Combined includes: 2D/M; 2D/PW Doppler; 2D/Color; 2D/CPA; 2D/Color /PW Doppler and 2D/CPA/PW Doppler

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

Transducer: S4-2 Phase Array 2-4MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application			Mode of Operation						
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**2D**	**M**	**PW Doppler**	**CW Doppler**	**Color**	**CPA**	**Other* Combined**	**Tissue Harmonic Imaging**
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	N	N	N	N	N	N	Note 1	N
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testes)								
	Neonatal Cephalic								
	Adult Cephalic	N	N	N	N	N	N	Note 1	N
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P	P	P	P	P	Note 1	P
	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 this appendix**

Note 1: Combined includes: 2D/M; 2D/PW Doppler; 2D/CW Doppler; 2D/Color; 2D/CPA; 2D/Color /PW Doppler; 2D/Color /CW Doppler; 2D/CPA/CW Doppler and 2D/CPA/PW Doppler

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

Transducer: C9-4v Micro Curved Linear Array 4-9MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**2D**	**M**	**PW Doppler**	**Color**	**CPA**	**Others* Combined**	**Tissue Harmonic Imaging**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	P	P	P	P	P	Note1	P
	Abdominal							
	Intra-operative Specify							
	Intra-operative Neuro							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testes)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P	P	P	Note 1	P
	Trans-vaginal	P	P	P	P	P	Note 1	P
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)	P	P	P	P	P	Note 1	P
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 this appendix

Note 1: Combined includes: 2D/M; 2D/PW Doppler; 2D/Color; 2D/CPA; 2D/Color /PW Doppler and 2D/CPA/PW Doppler

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diagnostic Ultrasound Indications for Use Form

Transducer: C83B Micro Curved Linear Array 3-8MHz
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**2D**	**M**	**PW Doppler**	**Color**	**CPA**	**Others* Combined**	**Tissue Harmonic Imaging**
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N	N	N	Note 1	N
	Intra-operative Specify							
	Intra-operative Neuro							
	Laparoscopic							
	Pediatric	N	N	N	N	N	Note 1	N
	Small Organ (breast, thyroid, testes)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph.(non-Card)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
	Other (Ob/GYN)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric	N	N	N	N	N	Note 1	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 this appendix

Note 1: Combined includes: 2D/M; 2D/PW Doppler; 2D/Color; 2D/CPA; 2D/Color /PW Doppler and 2D/CPA/PW Doppler

Prescription Use ____X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K192254

PREMARKET NOTIFICATION [510(k)] Summary

Company Name: Qisda Corporation
No.157, Shanying Rd., Shan-Ting Li, Gueishan Dist.,
Taoyuan City, Taiwan

Contact: Johnson Sheu <Johnson.Sheu@Qisda.com>

Device Name: InnoSight Diagnostic Ultrasound System

Common Name: Diagnostic Ultrasound Imaging System

Classification Name: Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology

Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Diagnostic Ultrasound Transducer 21 CFR 892.1570, Product Code 90-ITX

Registration Number: 3010220244

Factory Location: Qisda Corporation
No.159,Shanying Rd.,Shan-Ting Li, Gueishan Dist.,
Taoyuan City, Taiwan

Predicate Device Comparison:

The Philips CX50 and Sparq (K162329) is a comparable and substantially equivalent type. It has the same technological characteristics, key safety and effectiveness features, physical

design, and has the same intended uses and basic operating modes as the predicate device.

Comparison item	Predicate Device CX50 and Sparq Diagnostic Ultrasound Systems K162329	Submission Device InnoSight Diagnostic Doppler Ultrasound Pending	Difference
Indications for Use	The modified CX50 and Sparq Diagnostic Ultrasound Systems are intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical – mode), Pulse Wave Doppler, continuous Wave Doppler, color Doppler, tissue Doppler Imaging and Harmonics (Tissue and contrast) modes. The devices are indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic, Intracardiac echo, Intraoperative, Laparoscopic, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Neonatal Cephalic, Trans-vaginal, Trans-rectal, Musculoskeletal, Gynecological, Cardiac Adult, Cardiac pediatric, Trans-Esophogeal. (Cardiac), Peripheral Vessel, Other (Carotid).	The InnoSight Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in 2D, M-Mode, PW and CW Spectral Doppler, CPA, Tissue Harmonic imaging and Color Doppler modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Conventional), Other (OB/GYN, Urology, Nerve), Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and Carotid.	No new indications

Comparison item	Predicate Device CX50 and Sparq Diagnostic Ultrasound Systems K162329	Submission Device InnoSight Diagnostic Doppler Ultrasound Pending	Difference
working principle	The user typically uses a detector (called a probe) to place it directly on the patient's body and move it, then reads the image on the screen. Creating an ultrasound image is generally divided into three steps: generating ultrasound, receiving echoes and interpreting. These echoes as they appear on the screen.	Same	None
Mechanism of action	The intended use of this product is to collect ultrasound image data that can be used by clinicians for disease screening, diagnosis, and surgery. This product should have the ability to collect clinically acceptable images and ultrasound data for clinical applications.	Same	None
Product composition	Color ultrasound diagnostic systems and probes include mainframes (including displays, control panels and carts), probes and optional components (barcode scanners, printers, foot	The InnoSight color ultrasound system consists of a cart, a touch system, and a probe. Optional accessories include a printer.	Comparison of declared products with predicate product. Different structure of the cart and less

Comparison item	Predicate Device CX50 and Sparq Diagnostic Ultrasound Systems K162329	Submission Device InnoSight Diagnostic Doppler Ultrasound Pending	Difference
	pedals, ECG leads).		optional accessories. But these have been tested to prove that they are safe and effective.
Core components	Display: 43cm (17-in) LDC display.	11.6 – in touch panel	Compared with the predicate product, the screens are different, but they are used by doctors in clinically effective use to prove that they are safe and effective.
	Host signal input: Physiological ECG and breathing Three probe socket	Host signal input: Single probe socket Three probe socket by MTM	The signal input of the declared product host is a single probe socket, which is simpler than the comparison product. Has been tested to prove that it is safe and effective.
	The signal output of the host:	The signal output of the host:	The video

Comparison item	Predicate Device CX50 and Sparq Diagnostic Ultrasound Systems K162329	Submission Device InnoSight Diagnostic Doppler Ultrasound Pending	Difference
	External printer USB serial data Video: S-Video, VGA	USB serial data Video: HDMI	output of the declared product is HDMI. Unlike the comparison product, it has been tested for HDMI and proved to be safe and effective.
	Number of physical channels: Transmitting channel -128 Receiving channel -128	Number of physical channels: Transmitting channel -64 Receiving channel -64	There are fewer transmitting and receiving channels for the declared products, and relevant tests have been carried out to prove that they are safe and effective.

<table>
<tr><th>Comparison item</th><th>Predicate Device
CX50 and Sparq Diagnostic Ultrasound Systems
K162329</th><th>Submission Device
InnoSight Diagnostic Doppler Ultrasound
Pending</th><th>Difference</th></tr>
<tr><td></td><td><table><tr><th>Probe: model</th><th>Type</th></tr><tr><td>S4-2</td><td>Phased array probe</td></tr><tr><td>C6-2</td><td>Broadband Curved Array probe</td></tr><tr><td>C8-5</td><td>Broadband Curved Array probe</td></tr><tr><td>C9-4v</td><td>Broadband Curved Array probe</td></tr><tr><td>L12-4</td><td>Broadband linear array probe</td></tr><tr><td>X7-2t</td><td>TEE probe</td></tr></table></td><td><table><tr><th>Probe: model</th><th>Type</th></tr><tr><td>S4-2</td><td>Phased array probe</td></tr><tr><td>C6-2</td><td>Broadband Curved Array probe</td></tr><tr><td>C9-4v</td><td>Broadband Curved Array probe</td></tr><tr><td>L12-4</td><td>Broadband linear array probe</td></tr><tr><td>C83B</td><td>Broadband Curved Array probe</td></tr></table></td><td>Probe type and bandwidth range are smaller than Predicate device.</td></tr>
<tr><td>Imaging function</td><td>B
M
PWD
Color Doppler
B+PWD
B+Color Doppler
B+M
B+M+ Color Doppler</td><td>B
M
PWD
Color Doppler
B+PWD
B+ Color Doppler
B+M
B+M+ Color Doppler</td><td>No New imaging function</td></tr>
</table>

Comparison item	Predicate Device CX50 and Sparq Diagnostic Ultrasound Systems K162329	Submission Device InnoSight Diagnostic Doppler Ultrasound Pending	Difference
	B+ Color Doppler +PWD Tissue Harmonic Imaging (THI) Tissue Doppler Imaging Color Power Angio (CPA) iScan X-Res Contrast imaging SonoCT Imaging Biopsy guide Biopsy needle visualization	B+ Color Doppler +PWD Tissue Harmonic Imaging (THI) Color Power Angio (CPA) iScan X-Res SonoCT Imaging Biopsy guide Enhanced Needle Visualization	
Post processing function	2D depth； Continuous tracing； Distance； Ellipse； Heart Rate； High Q Automatic Doppler 2-Points Measurement； Time/ Slope； Volume； Angle； Area； Circumference； Simpson method	2D depth； Continuous tracing； Distance； Ellipse； Heart Rate； High Q Automatic Doppler 2-Points Measurement Time/ Slope； Volume； Angle； Area ； Circumference；	No new post processing function
Other features	DICOM networking DICOM structured report（SR）	Same	None
Applicable power	Rated voltage in the range of	Same	None

Comparison item	Predicate Device CX50 and Sparq Diagnostic Ultrasound Systems K162329	Submission Device InnoSight Diagnostic Doppler Ultrasound Pending	Difference
supply voltage range	± 10%, the device can work normally		
Continuous run time	>8h	Same	None
Electromagnetic compatibility	Meet the requirements of IEC 60601-1-2	Same	None
Sound output parameter	Meet the requirements of IEC60601-2-37	Same	None
Biocompatibility	Meet the appropriate requirements of the following standards: ISO 10993-1 ISO 10993-5 ISO 10993-10	Same	None
Electrical safety	Meet the appropriate requirements of the following standards: IEC 60601-1 IEC 60601-2-37 IEC 60601-1-1 IEC 60601-1-2	Same	None
Radiation safety	Comply with IEC 60601-2-37	Same	None
Software core function	By coordinating the buttons, soft keys and trackball of the control panel: Acoustic output power, focus, depth, THI, probe operating frequency (soft-frequency),	Through the touch panel: Acoustic output power, focus, depth, THI, probe operating frequency, color ROI size, color ROI position, sample packet size, line density, color sampling	No new function

Comparison item	Predicate Device CX50 and Sparq Diagnostic Ultrasound Systems K162329	Submission Device InnoSight Diagnostic Doppler Ultrasound Pending	Difference
	color ROI size, color ROI setting, sample package size (soft-pack), line density (soft-density), color sampling Scale, pulse repetition frequency, spectral ROI size (soft-gate), spectral ROI position (trackball), spectral sampling size, the system can change the above imaging parameters. By adjusting these parameters, the user can change the sound field devices.	size, pulse repetition frequency, spectral ROI size, spectral ROI position, spectral sampling size The system can change the above imaging parameters. By adjusting these parameters, the user can change the sound field devices.	
Applicable people	Adult, pediatric	Adult, pediatric	No difference
Applicable part	Fetus, Abdomen, Small organs (Thyroid, Scrotum, Thyroid, Prostate and Breast), Other (Gynecology), Adult heart, Peripheral blood vessels, Pediatrics, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other (Gynecology), Rectum , Transvaginal, Esophageal heart	Fetus, Abdomen, Small Organs (Thyroid, Scrotum, Thyroid, Prostate and Breast), Other (Gynecology), Adult heart, Peripheral blood vessels, Musculoskeletal (Conventional), Other (Gynecological), Rectal, Transvaginal, Adult cephalic vein	No new preset
Contact with the human body	Contacting the body surface, transthoracic electrocardiogram (heart),	Contacting the body surface, intraluminal	Less contact parts

Comparison item	Predicate Device CX50 and Sparq Diagnostic Ultrasound Systems K162329	Submission Device InnoSight Diagnostic Doppler Ultrasound Pending	Difference
	intraluminal		
Indication	Fetal imaging and other, heart, peripheral vascular	Same	No difference
Applicable disease stage and exten	Suitable for any stage and degree of disease	Same	No difference
Use environment	All departments of the hospital. Imaging Center, Professional Clinic, Primary and Secondary Care Centers.	Same	No difference
Instructions	Philips color ultrasound diagnostic system using conventional methods	Same	No difference
Precautions and warnings	Please refer to the user manual	Same	No difference
Contraindications	No known contraindications	Not for ophthalmology	
Sterilization/disinfection method	Non-sterile, routine disinfection	Same	No difference

BenQ T3300 Diagnostic Ultrasound System (K181313) is an additional predicate device for comparing form the biocompatibility point of view.

BenQ T3300 (K181313) is the Diagnostic Ultrasound System which equipped with three transducers L154BH, C62B and P42B6.

Since the materials used and the manufacturing process of C83B that has direct contact with the patients are equivalent to the transducer L154BH, therefore, Cytotoxicity, Irritation and Sensitization tests for C83B can reference the testing performed for transducer L154BH and the result is acceptable.

General Device Description:

InnoSight diagnostic ultrasound system is a compact and portable diagnostic ultrasound device, have integrated preprogrammed color ultrasound imaging system, capable of producing high detail resolution intended for clinical diagnostic imaging applications. The user interface is touch screen with 11.6" display. The all-digital architecture with progressive dynamic receive focusing allows the system to maximize the utility of all imaging transducers to enhance the diagnostic utility and confidence provided by the system. The exam dependent default setting allows the user to have minimum adjustment for imaging the patient, while the in depth soft-menu control allows the advanced user to set the system for different situations. The architecture allows cost-effective system integration to a variety of upgrade-able options and features.

The major features of the InnoSight diagnostic ultrasound:

- 64 Channel all digital beam former
- Progressive dynamic receive focusing
- Wide band all digital demodulation
- Native frequency digital scan converter
- InnoSight diagnostic ultrasound can be hand carried for portable use
- Full patient database solutions: DICOM3.0, MP4 /PNG, USB, SSD, PDF report
- Supports B (2-D), M, CFM, DPI, PW, Tissue Harmonic Image and combine mode

Intended Use:

The InnoSight Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in 2D, M-Mode, PW and CW Spectral Doppler, CPA, Tissue Harmonic imaging and Color Doppler modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Fetal, Abdominal, Pediatric, Small Organ (breast, thyroid, testes), Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Conventional), Other (OB/GYN, Urology, Nerve),

Cardiac Adult, Cardiac Pediatric, Peripheral Vessel and Carotid. The clinical environments where the system can be used include physician offices, clinics, hospitals, and clinical point-of care for diagnosis of patients except environments where the intensity of electromagnetic disturbances is high.

The system is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the system user information, and only for the purposes for which it was designed. The system should only be operated by someone who has received proper training in the use and operation of an ultrasound system. This system produces images derived from sound echoes; those images must be interpreted by a qualified medical professional. This system in no way interprets these images or provides a medical diagnosis of the patient being examined.

Technological Characteristics:

Display Modes	Single and dual 2-D; Display of Duplex 2-D/M-mode; 2-D/Pulsed Doppler and Triplex 2-D/CD/Pulsed Doppler image formats; Dual B and Color in real time.
Description of Transducers	InnoSight Diagnostic Ultrasound System with C6-2 Curved Linear Array 2-6MHz L12-4 Linear Array 4-12MHz S4-2 Phase Array 2-4MHz C9-4v Micro Curved Linear Array 4-9MHz C83B Micro Curved Linear Array 3-8MHz
Measurements	Distance; area; Volume; circumference; Heart Rate; calipers; velocity; PI, RI, Cardiac, OB/GYN and Vascular package.
Principle of Operation	Applying high voltage burst to the Piezoelectric material in the transducer and detect the reflected echo to construct the 2-D B-mode, Doppler color, and Doppler spectrum image for diagnostic purpose.

Operating Controls	• TGC 8 slider, +/- 22.5 dB • Depth Range: 1 to 30 cm • Image sector size: 32 lines to full B (256 lines) • Image Sector position: Steering within full maximum • B orientation flip: L/R key with marking on the screen • B Dynamic range control: preset 100 levels over 20-100 dB • Gray Scale Control: 4 Settings • Focal Number: 10 focal zone setting • B persistence: 30-90% recursive • Image Processing: Smoothing, edge enhancement • PW sweeping speed 2,4,8 sec over display. • PW Wall filter setting: 20 settings, 1% to 20% of PRF • PW sample volume: 0.5 to 10mm with 0.5mm step size. • PW/B update: with UPDATE key • PW cursor steering: Steer key • PW angle correction: +/- 72 degree user control • PW trace: Peak, Mean • PW spectrum dynamic range: 8 preset curve over 15-96 dB • Spectrum baseline shift and invert • Color ROI setting: Touch and drag to control size and position • Color steering on flat probe: +/- 20 • Color Wall Filter: Color wall filter with 20 settings, 1% to 20% of PRF • Color & B priority: C-B priority soft menu • Color Packet size: preset per Exam range from 8 to 12 • Color spatial filter: preset per Exam, horizontal, vertical, off • Zoom factor: Up to 10x • Freeze control: Touch freeze key • Cine control: step, play backward, play continuously
Acoustic Output	Conform to IEC60601-2-37 and AIUM UD2 requirements for all modes of all probes

SAFETY CONSIDERATIONS:

InnoSight diagnostic ultrasound has been designed to meet the following voluntary and measurement standards:

Recognition Number	Regulations No./ Version	Recognition Standard
12-105	NEMA UD 2-2004 (R2009)	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3 (Radiology)
12-293	IEC 60601-2-37 Edition 2.1 2015	Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
19-4	AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012,, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text)	Medical Electrical Equipment – Part 1: General Requirements For Basic Safety And Essential Performance (Iec 60601-1:2005, Mod). (General II (ES/EMC))
19-8	AAMI / ANSI / IEC IEC 60601-1-2, Ed. 4.0	Medical Electrical Equipment – Part 1-2: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements And Tests (Edition 4). (General II (ES/EMC))
2-220	ISO 10993-1 Fourth Edition 2009-10-15	Biological Evaluation Of Medical Devices – Part 1: Evaluation And Testing Within A Risk Management Process [Including: Technical Corrigendum 1 (2010)]. (Biocompatibility)

13-79	IEC 62304:2015	Medical device software – Software life cycle processes

Summary of Non-Clinical Performance Data

Non-clinical performance testing has been performed on the InnoSight Diagnostic Ultrasound Systems and demonstrates compliance with the following FDA recognized consensus standards:

* IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
* IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
* IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2007
* ISO 10993: Biological evaluation of medical devices

The device also comply with the FDA ultrasound specific guidance, Guidance for Industry and FDA Staff – Information for manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008).

Non-Clinical verification testing has been performed to cover system level requirements and the risk control measures. Non-Clinical validation testing covered the intended use and commercial claims as well as usability testing with representative intended users.All these tests were used to support substantial equivalence of the subject device and demonstrate that the InnoSight Diagnostic Ultrasound Systems complies with the aforementioned international and FDA-recognized consensus standards and FDA ultrasound guidance document, and meets the acceptance criteria and is adequate for its intended use.

Therefore, InnoSight is substantially equivalent to the predicate CX50 Diagnostic Ultrasound System in terms of safety and effectiveness

Summary of Clinical Performance Data

The InnoSight did not require clinical data since substantial equivalence to the primary currently

marketed predicate CX50 Diagnostic Ultrasound System demonstrated with indication for use, technological characteristics, Non-clinical performance testing; and Safety and effectiveness.

Substantial Equivalence Conclusion

The InnoSight Diagnostic Ultrasound Systems are substantially equivalent to the currently marketed predicate device

* The predicate device and the InnoSight Diagnostic Ultrasound Systems are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
* The predicate device and the InnoSight Diagnostic Ultrasound Systems have the same gray-scale and Doppler capabilities.
* The predicate device and InnoSight Diagnostic Ultrasound Systems use essentially the same technologies for imaging, Doppler functions and signal processing.
* The predicate device and InnoSight Diagnostic Ultrasound Systems have acoustic output levels within the Track 3 FDA limits.
* The predicate device and the InnoSight Diagnostic Ultrasound Systems are manufactured by bio safety materials.
* The predicate device and InnoSight Diagnostic Ultrasound Systems are designed and manufactured to the same electrical and physical safety standards.