December 13, 2017

Qisda Corporation
% Mr. Bob Leiker
Owner/manager
Leiker Regulatory & Quality Consulting
4157 North Del Ray Circle
CLOVIS CA 93619

Re: K172056
Trade/Device Name: InnoSight Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, ITX
Dated: November 7, 2017
Received: November 14, 2017

Dear Mr. Leiker:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara 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

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PREMARKET NOTIFICATION [510(k)] Summary

Company Name: Qisda Corporation
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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 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,* Product Code 90-ITX

Registration Number: 3010220244

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

Predicate Device Comparison:
The BenQ UP600 (K132690) and Philips CX50 and Sparq (K162329) are of 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.

Qisda	Predicate Device	Submission Device	Predicate Device
Product Name	BenQ Medical Technology UP600	InnoSight Diagnostic Doppler Ultrasound	CX50 and Sparq Diagnostic Ultrasound Systems
510(k) Number	K132690	Pending	K162329

Qisda	Predicate Device	Submission Device	Predicate Device
Indications for Use	This device is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen; Pediatric; Small Organ (breast, testes, thyroid); heart soft tissue; Peripheral Vascular; Musculo-skeletal; Ob/Gyn and Urology.	InnoSight Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), M-Mode,PW 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, Small Organ(Breast, Thyroid, testes), trans-rectal, trans-vaginal, Other (OB/GYN, Urology, Nerve), Cardiac Adult and Peripheral Vessel. The clinical environments where the system can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients.	Philips CX50 and Sparq Diagnostic Ultrasound Systems are intended for diagnostic ultrasound imaging in B (or 2-D), M-mode (including Anatomical M-mode), Pulse Wave Doppler, Continuous Wave Doppler, Color Doppler, Tissue Doppler Imaging and Harmonics (Tissue and Contrast) modes. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: Ophthalmic, Intraoperative, Laparoscopic, Fetal, Abdominal, Pediatric, Small Organ, Adult Cephalic, Neonatal Cephalic, Trans-vaginal, Musculo-skeletal, Gynecological, Cardiac Adult, Cardiac Pediatric, Trans-Esoph. (Cardiac), Intracardiac echo, Peripheral Vessel, Other (Carotid)
Design	Based on 128 channel full digital beam former.	Based on 64 channel full digital beam former.	Based on 128 channel full digital beam former.
Operating Controls	· Autocorrelation for color processing and FFT for pulse and CW Doppler processing. · Supporting both Linear, Curve linear and Phase array probes from 1.5 to 10 MHz. Cine play back capability and Image file archive Software upgrade with USB flash drive. Digital Scan Converter 1024x768 TGC 8 slider, +/- 24dB § Depth Range: 3 to 24 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 5 curves over 50-90 dB § Gray Scale Control: 7 Settings § Focal Number: 12 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: 15 settings, 0.25 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: 0 to 72 degree user control § PW spectrum dynamic range: 5 preset curve over 15-48 dB § Spectrum baseline shift and invert § M Process: Peak, Mean § Color ROI setting: trackball and set key to control size and position § Color steering on flat probe: +/- 15 § Color Wall Filter: Color wall filter with 15 selection, 0.25-20% 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: 1.2, 1.5, 2, 2.5, 3, 4 § Freeze control: Toggling freeze key § Cine control: step, play backward, play continuously	Autocorrelation for color processing and FFT for pulse and CW Doppler processing. Supporting both Linear, Curve linear and Phase array probes from 2 to 15 MHz. Cine play back capability and Image file archive Software upgrade with USB flash drive. Digital Scan Converter 1366x768 § TGC 8 slider, +/- 22.5 dB § Depth Range: 1 to 28 cm § Image sector size: 46 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 § Gray Scale Control: 5 levels § Focal Number: 10 focal zone setting § B persistence: 10 levels § Image Processing: Smoothing, edge enhancement § PW sweeping speed 1,2,4,8 sec over display. § PW Wall filter setting: 20 levels § PW sample volume: 0.23 to 20 mm § PW/B update: with UPDATE key § PW cursor steering: Steer key § PW angle correction: - 72,0,72 degree user control § PW spectrum dynamic range: 8 preset curve over 10-80 dB § Spectrum baseline shift and invert § M Process: Peak, Mean § Color ROI setting: Touch and drag to control size and position § Color steering on flat probe: +/- 15 § Color Wall Filter: Color wall filter with 20 settings § Color & B priority: C-B priority Key § Color Packet size: preset per Exam range from 8 to 11 § Zoom factor: Up to 5x § Freeze control: Touch freeze key § Cine control: step, play backward, play continuously	Autocorrelation for color processing and FFT for pulse and CW Doppler processing. It is indicated for diagnostic ultrasound imaging and fluid flow analysis in the following applications: * TGC 8 slider * Depth Range: 1 to 30 cm * Digital Scan Converter 1024x768 * B orientation flip: L/R invert key * B Dynamic range control: Up to 170 dB * Image Processing: Smoothing, edge enhancement * PW/B update: with UPDATE key * PW cursor steering: Steer key * Spectrum baseline shift and invert * Color ROI setting: trackball and set key to control size and position * Freeze control: Touch freeze key * PW Wall filter setting * PW sample volume: 0.8 to 24.6mm * Continuously variable steering in 2D, color Doppler, and Doppler modes * Color Wall Filter setting * PW selectable sweep speeds * Spectrum normal/invert display around baseline * High definition zoom * Cine control: step, play backward, play continuously Color & B (echo) priority: controls for echo write priority

Qisda	Predicate Device	Submission Device	Predicate Device
Safety Compliance	IEC 60601-1 International Electrotechnical Comission; Medical Electrical Equipment – Part 1 IEC60601-2 International Electrotechnical Comission; Electromagnetic Compatibility IEC 60601-2-37 International Electrotechnical Comission; Medical Electrical Equipment – Part 2-37	IEC 60601-1 International Electrotechnical Comission; Medical Electrical Equipment – Part 1 IEC60601-2 International Electrotechnical Comission; Electromagnetic Compatibility IEC 60601-2-37 International Electrotechnical Comission; Medical Electrical Equipment – Part 2-37	IEC 60601-1 International Electrotechnical Comission; Medical Electrical Equipment – Part 1 IEC60601-2 International Electrotechnical Comission; Electromagnetic Compatibility IEC 60601-2-37 International Electrotechnical Comission; Medical Electrical Equipment – Part 2-37
Patient Contact Materials	RTV664+Ultrason S2010 silicon rubber complies with ISO10993-5 and ISO10993-10	Housing: P1700 and Valox420/ Lens: RTV 664 and RTV560/ Glue:KE45 are compliance with ISO 10993-5 and ISO 10993-10	All patient contact materials of the CX50 Ultrasound System and transducers are detailed in K123754.
Operation Mode	B (2-D), M, CFM,CPA, PW, CW, Tissue Harmonic Image and combine mode	B (2-D), M, CFM, CPA, PW,CW, Tissue Harmonic Image and combine mode	2D Echo, M-mode, PW, CW, 2D Color, Tissue Tissue Doppler and Harmonics (Tissue and Contrast) and Combination modes
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	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	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
Display Annotations	Time/date/year; transducer type; power output in %; frames per second; persistence; and compression settings; image depth; patient name and ID; institution name; focal position; TGC curve display; Doppler & M scale in sec; Doppler angle correction cursor; free form annotation anywhere on image; trackball controlled; selective or global erase of the display annotations, body markers with transducer annotations	Time/date/year; transducer type; power output in %; frames per second; persistence; and compression settings; image depth; patient name and ID; institution name; focal position; TGC curve display; Doppler & M scale in sec; Doppler angle correction cursor; free form annotation anywhere on image; trackball controlled; selective or global erase of the display annotations, body markers with transducer annotations	transducer type and frequency, active clinical options and optimized presets, display depth, TGC curve, grayscale, color map, frame rate, compression map value, color gain, color image mode, hospital name, and patient demographic data, Scan plane orientation marker, User selectable depth scale display, Multiple trackball-driven annotation arrows, Pre-defined body markers.
Display Monitor	15" LCD color monitor	11.6" LCD Touch Screen	15" LCD color monitor (CX50)
Measurements	Distance; area; Volume; circumference; Heart Rate; calipers; velocity; PI, RI, Cardiac, OB/GYN and Vascular package.	Distance; area; Volume; circumference; Heart Rate; calipers; velocity; PI, RI, Cardiac, OB/GYN and Vascular package.	Distance; area; Volume; circumference; Heart Rate; calipers; velocity; PI, RI, Cardiac, OB/GYN and Vascular package and QLAB quantification
Transducer Types & Connectors	Convex, Phase array, and Linear array probes; Multi-port connector connects up to 2 transducers	Convex, Phase array, and Linear array probes; Single-port connector connect 1 transducer	Convex, Phase array, Linear array, xMATRIX and CW probes, Single-port connector connect 1 transducer (CX50), Multi-port connector connects up to 3 transducer (Sparq)
Transducer List	* C52 * E94 * L115 * P42	* C6-2 * C9-4v * L12-4 * S4-2	* C6-2 * C9-4v * L12-4 * S4-2 * C5-1 * L5-7io * X7-2t * C8-5 * C9-3io * C9-3v * C10-3v * D2 cwc * D5 cwc * L10-4lap * L12-3 * L12-5 * L15-7io * S2-4 * S5-1 * S7-3t * S8-3 * St. Jude Medical ViewFlex Xtra
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.	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.	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.
Users / Sites	Hospitals, clinics usage	Hospitals, clinics usage	Hospitals, clinics usage
Acoustic Output	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm2 max	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, TIS/TIB/TIC:0.1-4.0 Range, Mechanical Index: 1.9 Maximum, or Derated Isppa: 190 W/cm2 max	Track 3; MI, TIS, TIC, TIB Derated Ispta: 720mW/cm2 maximum, Mechanical Index: 1.9 Maximum, Thermal Index: 6.0 Maximum
Labeling	Operator's Manual, brochure	Operator's Manual, brochure	Operator's Manual, brochure
Dimensions / Weight	Dimension: Height 36.1cm Width 36.3cm Depth 18.7cm Weight: 9kg	Dimension: Height 223.2 mm Width 319.6 mm Depth 31.8 mm Weight: 2.46 kg	Dimension: Height 7.6 cm Width 41.3 cm Length 35.6 mm Weight: 6.17 kg (CX50)
Power Requirements	Power requirements: 100 Volts AC, 2.5 Amps 120 Volts AC, 2.1 Amps 230 Volts AC, 1.1 Amps 250 Volts AC, 1 Amps Power Consumption: 180 watts, max Operating temperature 5-40° C; relative humidity 10-80%;	Power requirements: 115 Volts AC, 1.14 Amps 230 Volts AC, 0.79 Amps Power Consumption: 65 watts, max Operating temperature 10-40° C; relative humidity 20-85%;	System/AC adapter 100-240V, 50/60 Hz, 250 VA System with cart and peripherals 100-240V, 50/60 Hz, 500 VA, max Operating temperature 10-40° C; relative humidity 15-95%;
Peripherals and Accessories	LAN Picture quality Color Printer, USB flash mobile drive , S-video output, VGA output	LAN, USB thermal Printer, USB flash mobile drive , HDMI video output	LAN, B/W and Color Printer, USB flash mobile drive , SVGA video output

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
- Remote access image management through LAN port
- Supports B (2-D), M, CFM, DPI, PW, Tissue Harmonic Image and combine mode

Intended Use:

InnoSight Diagnostic Ultrasound System is intended for diagnostic ultrasound imaging in B (2D), M-Mode, PW 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, Small Organ (Breast, Thyroid, testes), trans-rectal, trans-vaginal, Other (OB/GYN, Urology, Nerve), Cardiac Adult and Peripheral Vessel. The clinical environments where the system can be used include clinics, hospitals, and clinical point-of-care for diagnosis of patients. 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 C6-2Curved Linear Array 2-6MHz L12-4Linear Array 4-12MHz S4-2Phase Array 64 elements 2-4MHz C9-4vMicro Curved Linear Array 4-9MHz
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 EN60601-2-37 and AIUM UD2/UD3 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
12-100	NEMA UD 3-2004	Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
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))
19-2	AAMI / ANSI / IEC 60601-1-2:2007/(R)2012	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests (Edition 3). (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)