Qisda Corporation
% Mr. Johnson Sheu
Official Correspondent
No.157, Shanying Rd., Shan-Ting Li, Gueishan Dist,
Taoyuan City, 333
TAIWAN

August 27th, 2018

Re: K181313
Trade/Device Name: BenQ Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: July 26, 2018
Received: July 31, 2018

Dear Mr. Sheu:

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.

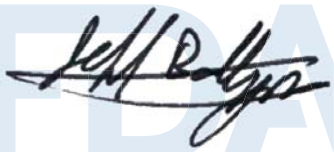
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,



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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K181313

Device Name
BenQ Diagnostic Ultrasound System

Indications for Use *(Describe)*

The system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for ultrasound evaluation/clinical analysis etc. It can be used in non-intrusive applications, including Abdomen, Cardiology, Gynecology, Obstetric, Breast, Thyroid, Musculoskeletal, Vascular (Carotid, Venous, Arterial), Nerve, Renal, and Urology. 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.

The following table provides Diagnostic Ultrasound Indications for Use Forms for the transducers offered with the BenQ Diagnostic Ultrasound System.

| Indications for Use | Supporting Transducers |
|---|---|
| Cardiac Adult | P42B6 |
| Obstetric | C62B |
| Urology | C62B |
| Abdomen | C62B |
| Gynecology | C62B |
| Renal | C62B |
| Musculoskeletal (Conventional) | L154BH |
| Peripheral Vessel (Carotid, Venous, Arterial) | L154BH |
| Small Parts (Breast, Thyroid) | L154BH |
| Nerve | L154BH |

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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*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."*

## Diagnostic Ultrasound Indications for Use Form

**System:** **T3300 Diagnostic Doppler Ultrasound System**
**T3300 Diagnostic Ultrasound Pulsed Echo System**
**T3300 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 | N | N | N | | N | N | Note 1 | N |
| | Abdominal | N | N | N | | N | N | Note 1 | N |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | Small Organ (breast, thyroid, testes) | N | N | N | | N | N | Note 1 | N |
| | Neonatal Cephalic | | | | | | | | |
| | Adult Cephalic | | | | | | | | |
| | Trans-rectal | | | | | | | | |
| | Trans-vaginal | | | | | | | | |
| | Trans-urethral | | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | | |
| | Musculo-skeletal (Conventional) | N | N | N | | N | N | Note 1 | N |
| | Musculo-skeletal (Superficial) | | | | | | | | |
| | Intravascular | | | | | | | | |
| | Other (Ob/GYN, Urology, Nerve) | N | N | N | | N | N | Note 1 | N |
| Cardiac | Cardiac Adult | N | N | N | N | N | N | Note 1 | N |
| | Cardiac Pediatric | | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | | |
| | Intra-cardiac | | | | | | | | |
| | Other (specify) | | | | | | | | |
| Peripheral Vessel | Peripheral vessel | N | N | N | | N | N | Note 1 | N |
| | 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 _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

## Diagnostic Ultrasound Indications for Use Form

Transducer: C62B 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 | N | N | N | N | N | Note1 | N |
| | Abdominal | N | N | N | N | N | Note1 | N |
| | Intra-operative Specify | | | | | | | |
| | Intra-operative Neuro | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | 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, Urology) | N | N | N | N | N | Note1 | N |
| 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: L154BH Linear Array 4-15MHz
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 | N | N | N | N | N | Note1 | N |
| | Intra-operative Specify | | | | | | | |
| | Intra-operative Neuro | | | | | | | |
| | Laparoscopic | | | | | | | |
| | Pediatric | | | | | | | |
| | Small Organ (breast, thyroid, testes) | N | N | N | N | N | Note1 | N |
| | Neonatal Cephalic | | | | | | | |
| | Adult Cephalic | | | | | | | |
| | Trans-rectal | | | | | | | |
| | Trans-vaginal | | | | | | | |
| | Trans-urethral | | | | | | | |
| | Trans-esoph.(non-Card) | | | | | | | |
| | Musculo-skeletal (Conventional) | N | N | N | N | N | Note1 | N |
| | Musculo-skeletal (Superficial) | | | | | | | |
| | Intravascular | | | | | | | |
| | Other (Nerve) | N | N | N | N | N | Note1 | N |
| Cardiac | Cardiac Adult | | | | | | | |
| | Cardiac Pediatric | | | | | | | |
| | Intravascular(Cardiac) | | | | | | | |
| | Trans-esoph.(Cardiac) | | | | | | | |
| | Intra-cardiac | | | | | | | |
| | Other (specify) | | | | | | | |
| Peripheral Vessel | Peripheral vessel | N | N | N | N | N | Note1 | N |
| | 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: P42B6 Phase Array 64 elements 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 | | | | | | | | |
| | Intra-operative Specify | | | | | | | | |
| | Intra-operative Neuro | | | | | | | | |
| | Laparoscopic | | | | | | | | |
| | Pediatric | | | | | | | | |
| | 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 | N | N | N | N | N | N | Note 1 | N |
| | 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)

# 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: BenQ Diagnostic Ultrasound System

Device Model: T3300

Common Name: Diagnostic Ultrasound System

Classification Name: Regulatory Class: II
Review Category: Tier II
Classification Panel: Radiology
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulation Number: 21 CFR 892.1550
Product Code: IYN, IYO, ITX

Primary Predicate Device :

| 510(k) Number | Product Name | Manufacturer name | Regulation Number | Product Code(s) |
|---|---|---|---|---|
| K172056 | InnoSight Diagnostic Ultrasound System | Qisda Corporation | 21 CFR 892.1560 | 90-IYO<br>90-IYN<br>90-ITX |

Registration Number: 3010220244

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

Reason for Submission:
This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

Predicate Device Comparison:
The InnoSight is 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 |
|---|---|---|
| **Product Name** | **InnoSight Diagnostic Ultrasound System** | **BenQ Diagnostic Ultrasound System** |
| **510(k) Number** | **K172056** | **Pending** |
| **Indications for 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 a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for ultrasound evaluation/clinical analysis etc. It can be used in non-intrusive applications, including Abdomen, Cardiology, Gynecology, Obstetric, Breast, Thyroid, Musculoskeletal, Vascular (Carotid, Venous, Arterial), Nerve, Renal, and Urology. The clinical environments where the system can be used include clinics, hospitals, and clinical point of care for diagnosis of patients |
| **Design** | Based on 64 channel full digital beam former. | Based on 64 channel full digital beam former. |
| **Operating Controls** | Autocorrelation for color processing and FFT for pulse and CW Doppler processing.<br>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<br>§ TGC 8 slider, +/- 22.5 dB | Autocorrelation for color processing and FFT for pulse and CW Doppler processing.<br>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<br>§ TGC 8 slider, +/- 22.5 dB |
| | § Depth Range: 1 to 28 cm | § Depth Range: 1 to 28 cm |
| | § Image sector size: 46 lines to full B (256 lines) | § Image sector size: 46 lines to full B (256 lines) |
| | § Image Sector position: Steering within full maximum | § Image Sector position: Steering within full maximum |
| | § B orientation flip: L/R key with marking on the screen | § B orientation flip: L/R key with marking on the screen |
| | § B Dynamic range control: preset 100 levels | § B Dynamic range control: preset 100 levels |
| | § Gray Scale Control: 5 levels | § Gray Scale Control: 5 levels |
| | § Focal Number: 10 focal zone setting | § Focal Number: 10 focal zone setting |
| | § B persistence: 10 levels | § B persistence: 10 levels |
| | § Image Processing: Smoothing, edge enhancement | § Image Processing: Smoothing, edge enhancement |
| | § PW sweeping speed 1,2,4,8 sec over display. | § PW sweeping speed 1,2,4,8 sec over display. |
| | § PW Wall filter setting: 20 levels | § PW Wall filter setting: 20 levels |
| | § PW sample volume: 0.23 to 20 mm | § PW sample volume: 0.23 to 20 mm |
| | § PW/B update: with UPDATE key | § PW/B update: with UPDATE key |
| | § PW cursor steering: Steer key | § PW cursor steering: Steer key |
| | § PW angle correction: - 72,0,72 degree user control | § PW angle correction: - 72,0,72 degree user control |
| | § PW spectrum dynamic range: 8 preset curve over 10-80 dB<br>§ Spectrum baseline shift and invert | § PW spectrum dynamic range: 8 preset curve over 10-80 dB<br>§ Spectrum baseline shift and invert |
| | § M Process: Peak, Mean | § M Process: Peak, Mean |
| | § Color ROI setting: Touch and drag to control size and position<br>§ Color steering on flat probe: +/- 15 | § Color ROI setting: Touch and drag to control size and position<br>§ Color steering on flat probe: +/- 15 |
| | § Color Wall Filter: Color wall filter with 20 settings | § Color Wall Filter: Color wall filter with 20 settings |
| | § Color & B priority: C-B priority Key | § Color & B priority: C-B Reject Key |
| | § Zoom factor: Up to 5x | § Zoom factor: Up to 5x |
| | § Freeze control: Touch freeze key | § Freeze control: Touch freeze key |
| | § Cine control: step, play backward, play continuously | § Cine control: step, play backward, play continuously |

| Qisda | Predicate Device | Submission Device |
|---|---|---|
| **Safety Compliance** | IEC 60601-1 International Electrotechnical Comission; Medical Electrical Equipment – Part 1<br>IEC60601-2 International Electrotechnical Comission; Electromagnetic Compatibility<br>IEC 60601-2-37 International Electrotechnical Comission; Medical Electrical Equipment – Part 2-37 | IEC 60601-1 International Electrotechnical Comission; Medical Electrical Equipment – Part 1<br>IEC60601-2 International Electrotechnical Comission; Electromagnetic Compatibility<br>IEC 60601-2-37 International Electrotechnical Comission; Medical Electrical Equipment – Part 2-37 |
| **Patient Contact Materials** | RTV664+Ultrason S2010 silicon rubber complies with ISO10993-5and ISO10993-10 | Housing: PC/ABS Lens: SILICONE are compliance with ISO 10993-5 and ISO 10993-10 |
| **Operation Mode** | B (2-D), M, CFM, CPA, PW,CW, Tissue Harmonic Image and combine mode | B (2-D), M, Color(CFM), Power(CPA), PW,CW, THI(Tissue Harmonic Image) and combine mode |
| **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/Color/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; touch 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; touch controlled; selective or global erase of the display annotations, body markers with transducer annotations |
| **Display Monitor** | 11.6" LCD Touch Screen | 13.3" LCD Touch Screen |
| **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. |
| **Transducer Types & Connectors** | Convex, Phase array, and Linear array probes; Single-port connector connect 1 transducer | Convex, Phase array, and Linear array probes; Single-port connector connect 1 transducer |
| **Transducer List** | * C6-2<br>* C9-4v<br>* L12-4<br>* S4-2 | * C62B<br>* L154BH<br>* P42B6 |
| **System frequency range** | 1.3 to 14.4 MHz | 1.3 to 14.4 MHz |
| **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. |
| **Users / Sites** | 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 |
| **Dimensions / Weight** | Dimension: Height 223.2 mm Width 319.6 mm Depth 31.8 mm Weight: 2.46 kg | Dimension: Height 238.5 mm, Width 348.2 mm Depth(Thickness): 38.5 mm. Weight: 2.6 kg |
| **Power Requirements** | Power requirements: 100~240 Volts AC, 1.7 Amps<br>Power Consumption: 65 watts max.<br>Operating temperature 10-40° C; relative humidity 20-85%; | Power requirements: 100~240 Volts AC, 1.6A Max.<br>Power Consumption: 65 watts max<br>Operating temperature 10-40° C; relative humidity 20-85%; |
| **Peripherals and Accessories** | LAN, USB thermal Printer, USB flash mobile drive , HDMI video output | LAN, USB thermal Printer, USB flash mobile drive , HDMI video output |

## General Device Description:

The BenQ Diagnostic Ultrasound System (hereinafter called “system”) is an easy-to-use, portable ultrasound imaging instrument intended for use by a qualified operator for ultrasound evaluation and clinical analysis. The user interface is touch screen with 13.3” 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 BenQ diagnostic ultrasound:

- Compact size with 1 transducer sockets. Convertible cart-based system design.
- 2D (B&M mode) with harmonic imaging
- Color Flow Imaging, Pulsed Wave – Spectral Doppler, Steerable Continuous Wave Doppler, Power Doppler
- 13.3" LCD supporting wide-viewing angle with multi-touch
- Support 64 channels, support up to 128 elements probes, and easy maintenance.
- High density transducers with frequency range from 2 to 15 MHz
- Full patient database solutions: DICOM3.0, MP4 /PNG, USB3.0, SSD, PDF report, etc.

Indications for Use:

The system is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for ultrasound evaluation/clinical analysis etc. It can be used in non-intrusive applications, including Abdomen, Cardiology, Gynecology, Obstetric, Breast, Thyroid, Musculoskeletal, Vascular (Carotid, Venous, Arterial), Nerve, Renal, and Urology. 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 | L154BH Linear Array 4-15MHz<br>C62B Curved Linear Array 2-6MHz<br>P42B6 Phased Array 2-4MHz |
| 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<br>• Depth Range: 1 to 28 cm<br>• Image sector size: 46 lines to full B (256 lines)<br>• Image Sector position: moving within full maximum<br>• B orientation flip: L/R key with marking on the screen<br>• B Dynamic range control: preset 100 levels<br>• Gray Scale Control: 5 Settings<br>• Focal Number: up to 10 focal zone setting<br>• B persistence: 10 levels<br>• Image Processing: QScan for smoothing and edge enhancement<br>• PW sweeping speed 1x,1/2x,1/4x,1/8x over display.<br>• PW Wall filter setting: 20 settings<br>• PW sample volume: 0.2 to 20mm<br>• PW/B update: with UPDATE key<br>• PW cursor steering: Steer key<br>• PW angle correction: +/- 72 degree user control<br>• PW spectrum dynamic range: 8 preset curve<br>• Spectrum baseline shift and invert<br>• Color ROI setting: Touch and drag to control size and position<br>• Color steering on flat probe: +/- 15<br>• Color Wall Filter: Color wall filter with 20 settings<br>• Color & B priority: C-B priority key<br>• Color Packet size: preset per Exam range up to 11<br>• Zoom factor: Up to 5x<br>• Freeze control: Touch freeze key<br>• Cine control: step, play continuously |
| Acoustic Output | Conform to IEC 60601-2-37 and AIUM UD2 requirements for all modes of all probes |

Summary of Non-Clinical Test:

The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The T3300 and its applications comply with voluntary standards.

| Recognition Number | Regulations No./Version | Recognition Standard |
|---|---|---|
| 19-4 | ANSI AAMI 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)) |
| 19-1 | IEC 60601-1-2 Edition 3: 2007-03 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests. (General II (ES/EMC) |
| 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 |
| 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)] |
| 12-105 | UD 2-2004 (R2009) | Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3. (Radiology) |
| 13-79 | IEC 62304:2015 | Medical device software - Software life cycle processes |

Summary of Clinical Tests:

The subject of this premarket submission, T3300, is not required clinical studies to support substantial equivalence.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. It is considered that the T3300 to be as safe, as effective and performance is substantially equivalent to the predicate devices. Therefore, it is concluded that this device is safe and effective for its intended use.