April 23, 2025

eSonic Technology (Wuhan) Co., LTD
Wang Jessie
Quality & Regulatory Affairs Director
Floor 7, Building B1, Block B, Phase II, High-Tech Medical Devices Park
No.818 Gaoxin Avenue, East Lake High-Tech Deve
Wuhan, Hubei 430206
CHINA

Re: K250228
Trade/Device Name: eHertz Functional Series Diagnostic Ultrasound System (eHertz C, eHertz E, eHertz R, eHertz S)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 20, 2025
Received: January 27, 2025

Dear Wang Jessie:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

YANNA S. KANG -S

Yanna Kang, Ph.D.
Assistant Director
Mammography and Ultrasound Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250228

Device Name
eHertz Functional Series Diagnostic Ultrasound System (eHertz C, eHertz E, eHertz R, eHertz S)

Indications for Use *(Describe)*
The eHertz Functional Series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), trans-rectal, trans-vaginal, musculoskeletal(conventional, superficial), adult and pediatric cardiac, peripheral vessel and urology exams.
This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.
Modes of operation include: B, M, PWD, CWD, Color Doppler, Combined mode (B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Panoramic Imaging, TDI, Color M, Elastography.

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.

510k Summary (K250228)

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Submitter's name, address, telephone number, contact person

Submitted by:
Manufacturer Name: eSonic Technology (Wuhan) Co., LTD
Address: Floor 7, Building B1, Block B, Phase II, High-tech Medical Devices Park, No.818 Gaoxin Avenue, East Lake High-tech Development Zone, Wuhan, Hubei, China

Primary Correspondent: Jessie Wang/ Quality & Regulatory Affairs Director
E-mail: registration@esonicimage.com
Telephone: (+86)18500469679

Date: 2025.April.16

2. Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Trade/Device Name: eHertz Functional Series Diagnostic Ultrasound System (eHertz C, eHertz E, eHertz R, eHertz S)
Common Name: Diagnostic Ultrasound System
Regulatory Class: II
Review Panel: Radiology

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

3. Predicate Device

M9 Premium Diagnostic Ultrasound System (K230768).

4. Device Description

The proposed eHertz Functional Series Diagnostic Ultrasound System (eHertz C, eHertz E, eHertz R, eHertz S) are portable, laptop-style ultrasound imaging system used to perform diagnostic general purpose ultrasound imaging studies.
The system contains a scan converter and can be coupled to a variety of linear, convex, and phased array transducers to produce images, which are displayed on

a LED monitor.

The eHertz Functional Series is a Track 3 diagnostic ultrasound system. The system includes electronics for transmit and receive of ultrasound data, ultrasound signal processing, software computing, hardware for image storage.

The eHertz Functional Series Diagnostic Ultrasound System's software features include mFlow, eSRI, eTuner, eTissue , Steer angle, and 2B/4B, etc.

- mFlow is a micro blood flow imaging technique. This mode is suitable for higher resolution display of blood flow near the surface of the body compared to C mode.
- eSRI is a post-processing of images to reduce speckles, noise, and enhance image edge without affecting the frame rate. Image quality can be optimized.
- eTuner: Parameters such as B-mode image gain are automatically adjusted to optimize images according to depth and tissue attenuation.
- eTissue: The receiving parameters related to the assumed acoustic speed of ultrasound propagating in the human body can be adjusted. Adjust the acoustic speed parameter to match the tissue type, thereby improving spatial and temporal resolution.
- Steer angle: This function is used to adjust the scan deflection angle.
- 2B/4B: It can switch the display layout of images and support dual or four display. When displaying multiple images, only one image is active, while the others are all frozen images.

5. Intended Use/Indications for Use

The eHertz Functional Series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients.

It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), trans-rectal, trans-vaginal, musculoskeletal(conventional, superficial), adult and pediatric cardiac, peripheral vessel and urology exams.

This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic.

Modes of operation include: B, M, PWD, CWD, Color Doppler, Combined mode (B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Panoramic Imaging, TDI, Color M, Elastography.

6. Summary of the technological characteristics- new device compared to the predicate device

The eHertz Functional Series Diagnostic Ultrasound Systems and its predicate device, M9 Premium Diagnostic Ultrasound System (K230768), have the equivalent intended use, and similar physical characteristics.

Description	**Subject Device** eHertz Functional Series Ultrasound Diagnostic System	**Predicate Device** M9 Premium Diagnostic Ultrasound System **(K230768)**
Indications for use	The eHertz Functional Series Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), trans-rectal, trans-vaginal, musculoskeletal(conventional, superficial), adult and pediatric cardiac, peripheral vessel and urology exams. This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic. Modes of operation include: B, M, PWD, CWD, Color Doppler, Combined mode (B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Panoramic Imaging, TDI, Color M, Elastography.	The Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients. It is intended for use in fetal, abdominal, **Intra-operative, Laparoscopic**, pediatric, small organ (breast, thyroid, testes), **neonatal and adult cephalic**, trans-rectal, trans-vaginal, musculo skeletal(conventional, superficial), adult and pediatric cardiac, **trans-esoph.(Cardiac),** peripheral vessel and urology exams. This device is a general purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid, which is intended to be used in a hospital or medical clinic. Modes of operation include: B, M, PWD, CWD, Color Doppler, **Amplitude Doppler** Combined mode (B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, iScape, TDI, Color M, Elastography, **Contrast imaging (Contrast agent for LVO), Smart**

Description	Subject Device eHertz Functional Series Ultrasound Diagnostic System	Predicate Device M9 Premium Diagnostic Ultrasound System **(K230768)**
		3D, 4D(Real-time 3D), Contrast imaging (Contrast agent for Liver).
User	Qualified and trained healthcare professionals	Qualified and trained healthcare professionals
Environment	Hospital or medical clinic	Hospital or medical clinic
Design	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Curve, Phase array probes.	Autocorrelation for color processing and FFT for pulse Doppler processing. Supporting Linear, Curve, Phase array probes.
Patient Contact Materials	Material meet ISO 10993-1 and FDA guidance	Material meet ISO 10993-1 and FDA guidance
Mode of operation	Modes of operation include: B, M, PWD, CWD, Color Doppler Combined modes (B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, Panoramic imaging, TDI, Color M, Elastography.	Modes of operation include: B, M, PWD, CWD, Color Doppler, **Amplitude Doppler** Combined mode (B+M, PW+B, Color+B, Power+B, PW+Color+B, Power+PW+B), Tissue Harmonic Imaging, iScape, TDI, Color M, Elastography, **Contrast imaging (Contrast agent for LVO), Smart 3D, 4D(Real-time 3D), Contrast imaging (Contrast agent for Liver).**

Description	Subject Device eHertz Functional Series Ultrasound Diagnostic System	Predicate Device M9 Premium Diagnostic Ultrasound System **(K230768)**
Functions	➢ Tissue Harmonic Imaging (THI) ➢ Expand (FOV) ➢ Panoramic imaging ➢ Spatial compound imaging ➢ Strain Elastography ➢ TDI (TVI, TVD) ➢ Power Doppler imaging (PDI, dPDI) ➢ Anatomical M ➢ *mFlow* ➢ *eSRI* ➢ *eTuner (Auto Image Optimization)* ➢ *Steer Angle* ➢ *eTissue* ➢ *2B/4B* ➢ Cine ➢ Body mark ➢ Annotation ➢ Network(wired) ➢ DICOM ➢ USB Storage ➢ HDMI port ➢ Printing ➢ Report	➢ **Biopsy guide and iNeedle** ➢ Tissue Harmonic Imaging (THI) ➢ FOV ➢ iScape View (Panoramic imaging) ➢ iBeam (Spatial compound imaging) ➢ Strain Elastography ➢ TDI(TVI,TVD,**TEI,TVM**) ➢ Power Doppler imaging (PDI, dPDI) ➢ Anatomical M ➢ *HR Flow* ➢ *iClear* ➢ *iTouch (Auto Image Optimization)* ➢ *Steer* ➢ *TSI (Tissue Specific Imaging)* ➢ *Dual-split/ Quad-split* ➢ Cine ➢ Body mark ➢ Comment ➢ Network(wired and **wireless**) ➢ DICOM ➢ **CD/DVD** or USB Storage ➢ HDMI port ➢ Printing ➢ Report ➢ **Contrast Imaging** ➢ **3D,4D** ➢ **Stress Echo** ➢ **ECG** ➢ **iWork** ➢ **Touch screen** ➢ **Barcode reader**

Description	Subject Device eHertz Functional Series Ultrasound Diagnostic System	Predicate Device M9 Premium Diagnostic Ultrasound System **(K230768)**
		➢ **iScanHelper** ➢ **iVision**
Measurements	**Basic measurement:** Distance, Area, Circumference, Volume, Velocity, Time **Measurement package:** ➢ Abdomen measurement package ➢ Gynecology measurement package ➢ Obstetric measurement package ➢ Cardiac measurement package ➢ Vascular measurement package ➢ Urology measurement package ➢ Small organ measurement package	**Basic measurement:** Distance, Area, Circumference, Volume, Velocity, Time **Measurement package:** ➢ Abdomen measurement package ➢ Gynecology measurement package ➢ Obstetric measurement package ➢ Cardiac measurement package ➢ Vascular measurement package ➢ Urology measurement package ➢ Small organ measurement package ➢ **Pediatrics measurement package** ➢ **Emergency measurement package**

Description	**Subject Device** eHertz Functional Series Ultrasound Diagnostic System	**Predicate Device** M9 Premium Diagnostic Ultrasound System **(K230768)**
Transducer Types	Convex array Phased array Linear array Micro convex array	Convex array Phased array Linear array Micro convex array
Acoustic Output within FDA guidelines	Track 3; Ispta.3 ≤ 720 mW/cm2 MI ≤ 1.9 TI ≤ 6.0	Track 3; Ispta.3 ≤ 720 mW/cm2 MI ≤ 1.9 TI ≤ 6.0
general safety and effectiveness information	ANSI/AAMI ES60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1
Labeling	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801
Accessories	➢ Foot switch ➢ Cart (mechanical) ➢ Three-port probe unit	➢ Foot switch ➢ Trolley ➢ Probe extension module ➢ **Biopsy needle guides** ➢ **Audio/Video Extend Module** ➢ **ECG lead and cable** ➢ **USB to LAN Adapter** ➢ **Keyboard** ➢ **Barcode reader** ➢ **Printer** ➢ **Microphone**

Technology:

The eHertz Functional Series Ultrasound Diagnostic System employs the same fundamental scientific technology as its predicate device.

Determination of substantial equivalence:

The Proposed eHertz Functional Series Ultrasound Diagnostic System are substantially equivalent to the predicate M9 Premium Diagnostic Ultrasound

System (K230768) with regards to intended use, indication for use, image capabilities, technological characteristics, image mode.
The following is an overview of the differences between the proposed eHertz Functional Series Ultrasound Diagnostic System and its predicate device.

Comparison Analysis:

Note 1: Indications for use

The Indication for use of subject device does not support application of Intra-operative, Laparoscopic, neonatal and adult cephalic, trans-esoph.(Cardiac), and not support operation Modes of Amplitude Doppler, also not support Combined mode of Contrast imaging (Contrast agent for LVO), Smart 3D, 4D(Real-time 3D), Contrast imaging (Contrast agent for Liver). As the subject device does not support specific application and mode of operation or combined mode, it is less than Predicate device. And also Panoramic Imaging of subject device is equivalent as iScape of Predicate device, just different name. They can demonstrate substantial equivalence with predicate device.

Note 2: Patient Contact Materials.

The Patient Contact Materials of probes is equivalent to the predicate device, both the subject and predicate device probe material meet ISO 10993-1 and FDA guidance requirement. They can demonstrate substantial equivalence with predicate device.

Note 3: Functions

- The subject device does not support functions of Biopsy guide and iNeedle, TDI(TEI,TVM), Network(wireless), CD/DVD storage, Contrast Imaging, 3D,4D, Stress Echo, ECG , iWork, Touch screen, Barcode reader, iScanHelper, iVision. As the subject device does not support specific functions, it is less than Predicate device. And also functions mFlow, eSRI, eTuner (Auto Image Optimization), Steer Angle, eTissue, 2B/4B of subject device is equivalent as HR Flow, iClear, iTouch (Auto Image Optimization), Steer, TSI (Tissue Specific Imaging), Dual-split/ Quad-split of Predicate device respectively, just different name.

They can demonstrate substantial equivalence with predicate device.

Note 4: Measurements

The subject device does not support Pediatrics measurement package and Emergency measurement package. As the subject device functions is less than Predicate device. They can demonstrate substantial equivalence with predicate device.

Note 5: Accessories
The subject device does not support Accessories of Biopsy needle guides, Audio/Video Extend Module, ECG lead and cable, USB to LAN Adapter, Keyboard, Barcode reader, Printer, Microphone. As the subject device Accessories is less than Predicate device. They can demonstrate substantial equivalence with predicate device.

The eHertz Functional Series Ultrasound Diagnostic System employs the same fundamental scientific technology as its predicate device. The Proposed eHertz Functional Series Ultrasound Diagnostic System are substantially equivalent to the predicate M9 Premium Diagnostic Ultrasound System (K230768) with regards to intended use, indication for use, image capabilities, technological characteristics, image mode. The Patient Contact Materials, functions demonstrate substantial equivalent with predicate device.

7. A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence

Summary of Non-clinical test:
The eHertz Functional Series Ultrasound Diagnostic System were evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as performance tests, thermal, electrical, electromagnetic, and mechanical safety, and have been found to comply with applicable medical device safety standard, The eHertz Functional Series Ultrasound Diagnostic System complies with voluntary standards:

(1) ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
(2) IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
(3) IEC/TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
(4) 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

(5) IEC62359, Ultrasonics-Field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.

(6) ISO10993-1 Fifth edition 2018-08 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

(7) ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

(8) ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

(9) ISO10993-23 First edition 2021-01 Biological evaluation of medical devices - Part 23: Tests for irritation

(10) ISO14971 Third Edition 2019-12 Medical devices - Application of risk management to medical devices

(11) NEMA PS 3.1 - 3.20 2023e Digital Imaging and Communications in Medicine (DICOM) Set.

(12) IEC60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

(13) IEC62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION Medical devices - Part 1: Application of usability engineering to medical devices

(14) IEC62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes

(15) ISTA 3B 2017 Packaged-Products for Less-Than-Truckload (LTL) Shipment

(16) IEC 62133-2:2017+AMD1:2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

The above testing confirmed that eHertz Functional Series Diagnostic Ultrasound System perform according to the stated intended use. All data fell within pre-determined product specifications and external standard requirements. Results of non-clinical testing confirmed the substantial equivalence of the eHertz Functional Series Diagnostic Ultrasound System to the predicate device.

The performance tests of the eHertz Functional Series Diagnostic Ultrasound System demonstrate substantial equivalence (SE) to the predicate device.

8. A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of

substantial equivalence

Not Applicable. The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

9. Conclusion

For testing, all pre-determined acceptance criteria were met. Results of these tests show that the proposed eHertz Functional Series Diagnostic Ultrasound System (models: eHertz C, eHertz E, eHertz R, eHertz S) meet their intended use.

The proposed eHertz Functional Series Diagnostic Ultrasound System is similar to the predicate M9 Premium Diagnostic Ultrasound System (K230768) in terms of indications for use, design, technological characteristics, modes of operations. eSonic considers the eHertz Functional Series Diagnostic Ultrasound System to be substantially equivalent, with respect to safety and effectiveness, to the predicate device.