Samsung Medison Co., Ltd.
Dayoung Choi
Regulatory Affairs Specialist
3366, Hanseo-Ro, Nam-Myeon
Hongcheon-Gun, Gangwon-do 25108
Republic Of Korea

July 28, 2026

Re: K261412
Trade/Device Name: V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System; V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System; V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System; V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System; V4/XV4/XH4/H4/cV4 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, LLZ, QIH
Dated: July 6, 2026
Received: July 6, 2026

Dear Dayoung Choi:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara - S
Date: 2026.07.28 10:35:07 -04'00'

For

Yanna Kang
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261412

Please provide the device trade name(s).

V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System; V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System; V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System; V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System; V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System;

Please provide your Indications for Use below.

For V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System:
The diagnostic ultrasound system and probes are designed to obtain ultrasound images and analyze body fluids.
The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Thoracic, Ophthalmic, Trans-esophageal (Cardiac) and Peripheral vessel.
It is intended for use by, or by the order of, and under the supervision of, an appropriately trained healthcare professional who is qualified for direct use of medical devices. It can be used in hospitals, private practices, clinics and similar care environment for clinical diagnosis of patients.
Modes of Operation: 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, MV-Flow mode, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode.

For V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System:
The diagnostic ultrasound system and probes are designed to obtain ultrasound images and analyze body fluids.
The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Thoracic, Trans-esophageal (Cardiac), Peripheral vessel and Dermatology.
It is intended for use by, or by the order of, and under the supervision of, an appropriately trained healthcare professional who is qualified for direct use of medical devices. It can be used in hospitals, private practices, clinics and similar care environment for clinical diagnosis of patients.
Modes of Operation: 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, MV-Flow Mode, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.	☒ Neonates/Newborns (Birth to < 29 days old) ☒ Infants (29 days old to < 2 years old) ☒ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(K) Summary: K261412

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

1. Date Prepared – April 30th , 2026

2. Manufacturer
   SAMSUNG MEDISON CO., LTD.
   3366, Hanseo-ro, Nam-myeon, Hongcheon-gun, Gangwon-do 25108, Republic of Korea

3. Contact Person
   Da-young Choi
   Regulatory Affairs Specialist
   Phone: +82.2.2194.1407
   Fax: +82. 2.2194.0273
   Email: dy1217.choi@samsung.com

4. Secondary Contact Person
   Ninad Gujar
   Vice President
   Phone: +1.978.564.8632
   Fax: +1.978.564.8677 Email: ngujar@samsunghme.com

5. Proposed Device
   - Common/Usual Name : Diagnostic Ultrasound System and Accessories
   - Proprietary Name :
     V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System;
     V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System;
     V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System;
     V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System;
     V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System;
   - Regulation Name : Ultrasonic pulsed doppler imaging system
   - Regulatory Class : Class II
   - Product Code : IYN, IYO, ITX, LLZ, QIH
   - Regulation Number : 21 CFR 892.1550, 892.1560, 892.1570, 892.2050

6. Predicate / Reference Device
   - Predicate device
     - V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 Diagnostic Ultrasound System (K250999)
   - Reference Device
     - HERA Z20, HERA Z20e, HERA Z20s, R20, HERA Z30, R30 Diagnostic Ultrasound System (K252018)

- RS85 Diagnostic Ultrasound System (K240516)
- EVO Q30/EVO Q20/EVO Q10/ EVO XQ30/EVO XQ20/EVO XQ10/EVO QH30/ EVO QH20/EVO QH10 Diagnostic Ultrasound System (K254099)

7. Device Description

■ V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System:

The V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System are general purpose, mobile, software controlled, diagnostic ultrasound systems. Its function is to acquire ultrasound data and to display the data as 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, MV-Flow Mode, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode. The V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System also give the operator the ability to measure anatomical structures and offers analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System have real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

■ V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System:

The V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System are general purpose, mobile, software controlled, diagnostic ultrasound systems. Its function is to acquire ultrasound data and to display the data as 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, MVFlow Mode. Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode. The V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System also give the operator the ability to measure anatomical structures and offer analysis packages that provide information that is used to make a diagnosis by competent health care professionals. The V5/XV5/XH5/H5/cV5

Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System have a real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

8. Intended Use

- V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System:
  The diagnostic ultrasound system and probes are designed to obtain ultrasound images and analyze body fluids.
  The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Thoracic, Ophthalmic, Trans-esophageal (Cardiac), and Peripheral vessel.
  It is intended for use by, or by the order of, and under the supervision of, an appropriately trained healthcare professional who is qualified for direct use of medical devices. It can be used in hospitals, private practices, clinics and similar care environment for clinical diagnosis of patients.
  Modes of Operation: 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, MV-Flow Mode, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode.

- V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System:
  The diagnostic ultrasound system and probes are designed to obtain ultrasound images and analyze body fluids.
  The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Intra-operative, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Thoracic, Trans-esophageal (Cardiac), Dermatology, and Peripheral vessel.
  It is intended for use by, or by the order of, and under the supervision of, an appropriately trained healthcare professional who is qualified for direct use of medical devices. It can be used in hospitals, private practices, clinics and similar care environment for clinical diagnosis of patients.
  Modes of Operation: 2D mode, Color Doppler mode, Power Doppler (PD) mode, M mode, Pulsed Wave (PW) Doppler mode, Continuous Wave (CW) Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan Mode, MV-Flow Mode, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode.

9. Technological Comparison to Predicate Device
   The V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6

ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System employ the same fundamental scientific technology as its predicate device V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 Diagnostic Ultrasound System (K250999).

10. Determination of Substantial Equivalence

Comparison to Predicate: The V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System, V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, and V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System are substantially equivalent to the predicate device with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System:
  - The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
  - The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System and the predicate V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 Diagnostic Ultrasound System (K250999) have the same intended use, and modes of operation.
  - The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System have introduced a clinical application for ophthalmic use.
  - The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System have been updated to Windows 11 operating system.
  - The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7

ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System have migrated the following software features from the reference device HERA Z20, HERA Z20e, HERA Z20s, R20, HERA Z30, R30 Diagnostic Ultrasound System (K252018): Voice Command, IOTA-SRrisk, EzStructure, EzFlow, EzCheck, PortraitVue, IDEA, IETA, EzPictogram, Luminant, Slice A, Live Q-Scan, 3D Printing.

- The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System have included a new transducer, BCC2-13.

- The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System have migrated transducers PA2-9S, CA2-13M from the reference device HERA Z20, HERA Z20e, HERA Z20s, R20, HERA Z30, R30 Diagnostic Ultrasound System (K252018).

- The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System have migrated Prostate Fusion, a sub-function of the previously cleared S-Fusion in the reference device RS85 Diagnostic Ultrasound System (K240516).

- For marketing purposes, we've included the following product names for the XV, XH, H, cV, V ONE, XV ONE, XH ONE, H ONE, cV ONE series: (XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE, XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE, XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE), which have the same specifications as the V series (V8, V7 and V6).

- The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System and the primary predicate device V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 Diagnostic Ultrasound System (K250999) have been designed in compliance with approved electrical and physical safety standards.

- The proposed V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, and V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System and the primary predicate device V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 Diagnostic Ultrasound System (K250999) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

- The system is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.

- The system has acoustic power levels which are below the applicable FDA level.

■ V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System:

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.

- The proposed V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System and the predicate V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 Diagnostic Ultrasound System (K250999) have the same intended use, and modes of operation.

- The proposed V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System have been updated to Windows 11 operating system.

- The proposed V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System have migrated the following software features from the reference device HERA Z20, HERA Z20e, HERA Z20s, R20, HERA Z30, R30 Diagnostic Ultrasound System (K252018): A-Focus, Voice Command, IOTA-SRrisk, EzStructure, EzFlow, EzCheck, PortraitVue, IDEA, IETA, EzPictogram, Luminant, Slice A, 3D Printing.

- The proposed V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System have migrated transducer PA2-9S from the reference device HERA Z20, HERA Z20e, HERA Z20s, R20, HERA Z30, R30 Diagnostic Ultrasound System (K252018), and the PA1-5AED from the reference device EVO Q30/EVO Q20/EVO Q10/EVO XQ30/EVO XQ20/EVO XQ10/EVO QH30/ EVO QH20/EVO QH10 Diagnostic Ultrasound System (K254099).

- For marketing purposes, we've included the following product names for the XV, XH, H, cV series: (XV5/XH5/H5/cV5, XV4/XH4/H4/cV4), which have the same specifications as the V series (V5, V4).

- The proposed V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound and the primary predicate device V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 Diagnostic Ultrasound System (K250999) have been designed in compliance with approved electrical and physical safety standards.

- The proposed V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound and the primary predicate device V8/cV8, V7/cV7, V6/cV6, V5/cV5, V4/cV4 Diagnostic Ultrasound System (K250999) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

- The system is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.

- The system has acoustic power levels which are below the applicable FDA levels.

11. Summary of Non-Clinical Testing

The device has been evaluated for acoustic output, biocompatibility, software function, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable FDA guidances and medical device safety standards. The V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System, V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, and V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System and its applications comply with the following FDA-recognized standards.

Reference No.	Title
IEC 60601-1	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
IEC 60601-1-2	IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020
IEC 60601-2-37	IEC 60601-2-37:2024
IEC 60601-4-2	IEC TS 60601-4-2:2024
ISO10993-1	ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO14971	ISO 14971:2019, Medical devices - Application of risk management to medical devices

NEMA UD 2-2004	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

All software tests met the acceptance criteria for verification and validation testing.

12. Summary of Clinical Tests

    The proposed device V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System, V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, and V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System did not require clinical studies to demonstrate substantial equivalence.

13. Conclusion

    Since the predicate device and the proposed device have a similar intended use and key technological features, the non-clinical data support the safety of the device and demonstrate that the V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System, V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System, V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System, V5/XV5/XH5/H5/cV5 Diagnostic Ultrasound System, and V4/XV4/XH4/H4/cV4 Diagnostic Ultrasound System should perform as intended in the specified use conditions. Therefore, SAMSUNG MEDISON CO., LTD. considers the proposed device to be as safe, as effective, and substantially equivalent in performance to the predicate device that is currently marketed for the same intended use.

- END of 510(k) Summary -