February 12, 2025

Samsung Medison Co., Ltd.
Yujin Kim
Regulatory Affairs Specialist
3366, Hanseo-ro, Nam-myeon
Hongcheon-gun, Gangwon-do 25108
REPUBLIC OF KOREA

Re: K243702
Trade/Device Name: V8 Diagnostic Ultrasound System; cV8 Diagnostic Ultrasound System; V7 Diagnostic Ultrasound System; cV7 Diagnostic Ultrasound System; V6 Diagnostic Ultrasound System; cV6 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: November 29, 2024
Received: November 29, 2024

Dear Yujin Kim:

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,

Marjan Nabili -S for

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.

Submission Number *(if known)*

K243702

Device Name

V8 Diagnostic Ultrasound System; cV8 Diagnostic Ultrasound System; V7 Diagnostic Ultrasound System; cV7 Diagnostic Ultrasound System; V6 Diagnostic Ultrasound System; cV6 Diagnostic Ultrasound System

Indications for Use *(Describe)*

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) 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, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode.

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.

K243702

510(K) Summary:

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

1. Date Prepared – November 29th, 2024

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

3. Primary Contact Person
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4. Secondary Contact Person
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   Vice President
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5. Proposed Device
   - Common/Usual Name : Diagnostic Ultrasound System and Accessories
   - Proprietary Name : V8 Diagnostic Ultrasound System
     cV8 Diagnostic Ultrasound System
     V7 Diagnostic Ultrasound System
     cV7 Diagnostic Ultrasound System
     V6 Diagnostic Ultrasound System
     cV6 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 Devices
   - V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 Diagnostic Ultrasound System (K240631) – Primary
   - RS85 Diagnostic Ultrasound System (K240516) – Reference

7. Device Description
   The V8/cV8, V7/cV7, V6/cV6 are a general purpose, mobile, software controlled, diagnostic ultrasound system. Their 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, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode. The V8/cV8, V7/cV7, V6/cV6 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 V8/cV8, V7/cV7, V6/cV6 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

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) 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, Combined modes, Multi-Image mode(Dual, Quad), 3D/4D mode.

9. Technological Comparison to Predicate Devices

The V8/cV8, V7/cV7, V6/cV6 employ the same fundamental scientific technology as its predicate devices V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631) and RS85 (K240516).

10. Determination of Substantial Equivalence

Comparison to Predicate: The V8/cV8, V7/cV7, V6/cV6 are substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

- The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.
- The proposed V8/cV8, V7/cV7, V6/cV6 and the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631) have the same intended use.
- The proposed V8/cV8, V7/cV7, V6/cV6 and the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631) have the same imaging modes and modes of operation.
- The proposed V8/cV8, V7/cV7, V6/cV6 have included ‘EzNerveMeasure’ previously cleared in the predicate RS85 (K240516), as a sub-function of NerveTrack based on AI technology.
- The proposed V8/cV8, V7/cV7, V6/cV6 have included ‘RFA Viewer’. This

function displays information in real-time, such as total ablation time and total energy, generated by the RFA Generator.

- The proposed V8/cV8, V7/cV7, V6/cV6 have updated 'Strain+', a cleared function in the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631). It has expanded 'left atrium(LA), and right ventricle(RV)' measurement items.
- The proposed V8/cV8, V7/cV7, V6/cV6 have updated 'AutoEF', a cleared function in the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631). It has expanded a 'Global Longitudinal Strain(GLS)' measurement item.
- The proposed V8/cV8, V7/cV7, V6/cV6 have included a new transducer BCL2-14. Biocompatibility test has been conducted for the new transducer, and image performance test has been conducted for the new transducer.
- The proposed V8/cV8, V7/cV7, V6/cV6 and the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed V8/cV8, V7/cV7, V6/cV6 and the primary predicate V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 (K240631) have been designed in compliance with approved electrical and physical safety standards.
- 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 limits.

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/cV8, V7/cV7, V6/cV6 and its applications comply with the following FDA-recognized standards.

Reference No.	Title
IEC 60601-1	AAMI ANSI 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)
IEC 60601-1-2	IEC60601-1-2:2014 [Including AMD 1:2021] , Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - EMC
IEC 60601-2-37	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
IEC 60601-4-2	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
ISO10993-1	AAMI / ANSI / 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.

[The validation for EzNerveMeasure of NerveTrack based on AI]

▣ Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance. We tested on the flattening ratio (FR) and cross-sectional area (CSA) of NerveTrack EzNerveMeasure.

☐ A deep learning-based segmentation algorithm was validated using 100 median nerve images collected at a hospital.

☐ FR and CSA measure test

◌ The average error rate of FR was 8.31% (95% Confidence Interval: [7.29, 9.34]), and the average error rate of CSA was 13.12% (95% Confidence Interval: [10.90, 15.34]). The standard deviation error rate of FR was 5.22, and the standard deviation error rate of CSA was 11.33. Error Rate (%) is calculated as follows: (GT Value - Measured Value) / GT Value x 100.

▣ The number of individual patients, images were collected from:

☐ A total of 10 cases acquired from ten individual patients at Seoul National University were used.

☐ Ten static images from each case are randomly selected and used for the validation dataset.

▣ The number of samples, if different from above, and the relationship between the two:

☐ Each individual contributed at ten static images. In other words, the ten static images from a 2D sequence data acquired from an individual were used for validation.

☐ Validation dataset includes a total of 100 static images.

▣ Demographic distribution:

☐ Gender: Female

☐ Age: 38–68 (mean: 45.8)

☐ BMI: 16.0–27.1 (mean: 20.53)

☐ Ethnicity/Country: Koreans

▣ Information about clinical subgroups and confounders present in the dataset:

☐ We divided the nerve ultrasound images, depending on clinical need, into median nerves for wrist.

▣ Information about equipment and protocols used to collect images

☐ We acquired the dataset with SAMSUNG MEDISON's ultrasound systems in order to secure diversity of the data set: Mix of data from retrospective data collection and prospective data collection in clinical practice.

▣ Information about how the reference standard was derived from the dataset (i.e. the "Truthing" process):

☐ The GT data were built by three participating experts. Nerve areas in all acquired images for training, tuning and validation were manually drawn by an anesthesiologist with more than 10 years of experience in pain management. The doctors who scanned the ultrasound were directly involved for the construction of GT data. Drawn GT rectangles covered the nerve region perfectly.

☐ For verification of GT, other doctors with more than 10 years of experience checked every frame of each scanned sequences. If they did not agree on median nerve locations, necessary corrections were made to make the final GT.

▣ Description of how the independence of test data from training data was ensured:

☐ Data used for training, tuning and validation purpose are completely separated from the ones during training process, and there is no overlap among the three.

12. Summary of Clinical Tests

The proposed device V8/cV8, V7/cV7, V6/cV6 Ultrasound System did not require clinical studies to demonstrate substantial equivalence.

13. Conclusion

Since the predicate devices and the subject 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/cV8, V7/cV7, V6/cV6 Ultrasound System should perform as intended in the specified use conditions. Therefore, SAMSUNG MEDISON CO., LTD. considers the subject device to be as safe, as effective, and performance is substantially equivalent to the primary predicate device that is currently marketed for the same intended use.

- END of 510(k) Summary -