June 21, 2024

Samsung Medison Co., Ltd.
% Jee Young Ju
Regulatory Affairs Specialist
3366, Hanseo-ro, Nam-myeon
Hongcheon-gun, Gangwon-do 25108
REPUBLIC OF KOREA

Re: K240631
Trade/Device Name: V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 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
Dated: March 6, 2024
Received: May 22, 2024

Dear Jee Young Ju:

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.

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

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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)*

K240631

Device Name

V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 Diagnostic Ultrasound System

Indications for Use *(Describe)*

The diagnostic ultrasound system and transducers 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.

K240631

510(k) Summary:

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

1. Date Prepared – March 6th, 2024

2. Manufacturer
   SAMSUNG MEDISON CO., LTD.
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   Gangwon-do, Republic of Korea

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5. Proposed Device
   - Common/Usual Name : Diagnostic Ultrasound System and Accessories
   - Proprietary Name : V8/XV8/XH8 Diagnostic Ultrasound System
     V7/XV7/XH7 Diagnostic Ultrasound System
     V6/XV6/XH6 Diagnostic Ultrasound System
   - Regulation Name : Ultrasonic pulsed doppler imaging system
   - Regulatory Class : Class II
   - Product Code : IYN, IYO, ITX
   - Regulation Number : 21 CFR 892.1550, 892.1560, 892.1570

6. Predicate Devices
   - V8/H8, V7/H7, V6/H6 Diagnostic Ultrasound System (K231772) – Primary
   - Collaboration Live (K212777) – Reference

7. Device Description
   The V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system 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/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 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 V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 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. Indication for Use

The diagnostic ultrasound system and transducers 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/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system employ the same fundamental scientific technology as its predicate devices V8/H8, V7/H7, V6/H6 (K231772) diagnostic ultrasound system and Collaboration Live (K212777).

10. Determination of Substantial Equivalence

Comparison to Predicate: The V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system is 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/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system and the primary predicate V8/H8, V7/H7, V6/H6(K231772) diagnostic ultrasound system have the same clinical intended use.
- The proposed V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system and the primary predicate V8/H8, V7/H7, V6/H6(K231772) diagnostic ultrasound system have the same imaging modes and modes of operation.
- The proposed V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system has expanded the applications of NerveTrack Segmentation previously cleared in the predicate V8/H8, V7/H7, V6/H6(K231772) diagnostic ultrasound system based on AI technology.

- The proposed V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system have included one new transducer TA2-9. Biocompatibility test has been conducted for the new transducer, and image performance test has been conducted for the new transducer.
- The proposed V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system have included the 27-inch OLED monitor.
- The proposed V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system have updated SonoSync, a cleared function in the primary predicate V8/H8, V7/H7, V6/H6 diagnostic ultrasound system(K231772), for diagnostic image viewing and review as similar indications for use as Collaboration Live (K212777).
- The proposed V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system and primary predicate V8/H8, V7/H7, V6/H6 diagnostic ultrasound system (K231772) have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system and primary predicate V8/H8, V7/H7, V6/H6 diagnostic ultrasound system (K231772) have been designed in compliance with approved electrical and physical safety standards.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have 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/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic ultrasound system and its applications comply with the following FDA-recognized standards.

Reference No.	Title
IEC 60601-1	AAMI ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2	IEC60601-1-2: 2020-09(4.1 Edition) , Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - EMC
IEC 60601-2-37	IEC 60601-2-37 Edition 2.0 2007, 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 10993-1:2009/(R)2013, 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

[The Summary of Testing for AI based NerveTrack]

These are the details on validation of the AI algorithm used for all the new and improved AI-based features that includes expansion of the use of NerveTrack feature and the information about the dataset the device was tested on.

Acceptance Criteria:

Validation Type	Definition	Acceptance Criteria
Accuracy (%)	$\frac{\text{Number of correctly detected frames}}{\text{Total number of frames with nerve}} \times 100$	$\geq 80\%$
Speed (FPS)	$\frac{1000}{\text{Average latency time of each frame (msec)}}$	≥ 2 FPS

Summary Performance data, Standard Deviations & Confidence Intervals:

Validation Type	Average	Standard Deviation	95% CI
Accuracy (%)	90.3	4.88	87.28 to 93.33
Speed (FPS)	3.66	0.25	3.51 to 3.82

The standalone performance of NerveTrack was evaluated for BMI (Body Mass Index) subgroups, which are potential subject and image confounder. For subgroup analysis, we divided BMI values into four groups according to the CDC (Centers for Disease Control and Prevention) definition for adult overweight & obesity. They are underweight (BMI < 18.5), healthy weight (18.5 ≤ BMI < 25), overweight (25 ≤ BMI < 30), and obesity (BMI ≥ 30).

We evaluated the performance for the four groups and observed very good generalizability for BMI, because the average accuracy of all subgroups is included within the confidence interval of the accuracy for the full dataset. The depth range was set 2.5cm to 4.5cm, and the maximum depth of the detected nerve was 3.31 cm from skin. When we calculate the relationship between BMI and the maximum depth of nerves, it illustrates a low correlation and no significant difference of NerveTrack performance according to the patient's BMI information. Therefore, we believe that our model is robust even if the cases with various BMI information exist.

When collecting scan data, the speed of the transducer varies approximately from 1cm to 5cm per second. The orientation of the transducer was short-axis imaging and perpendicular

to the skin, obtained by sliding the transducer in both the proximal and distal directions. All the nerve data were acquired on Samsung ultrasound devices including V8.

Twelve anesthesiologists and five sonographers with over ten years' experience participated in establishing the ground truth (GT) for the locations of twelve different types of nerves. For each dataset, the doctors who performed the ultrasound scans directly drew the GT of the nerve locations, which were then reviewed and verified as accurate by at least two additional anesthesiologists and sonographers. Any errors or discrepancies identified during the reviews were corrected until satisfactory results were achieved.

The training data used for the training of the NerveTrack algorithm are independent of the data used to test the NerveTrack algorithm.

Contour segmentation for nine kinds of nerves (ISBP: interscalene brachial plexus, AxBP: axillary brachial plexus, GON: Greater Occipital Nerve, SSN: Suprascapular Nerve, ICN: Intercostal Nerve, LFCN: Lateral Femoral Cutaneous Nerve, SLGN: Superior Lateral Genicular Nerve, SMGN: Superior Medial Genicular Nerve, and IMGN: Inferior Medial Genicular Nerve) and surrounding structures in the body was added to display boundary of each region. Contours were displayed with different colors: nerve with yellow, bone with blue, blood vessel with red, muscle with green, and ligament with orange. With the following acceptance criteria of nerve segmentation, performance was summarized as follows:

Acceptance Criteria for Segmentation:

Validation Type	Definition	Acceptance Criteria
Accuracy (%)	$\frac{\text{Number of correctly segmented frames}}{\text{Total number of frames with nerve}} \times 100$	≥ 80%
Speed (FPS)	$\frac{1000}{\text{Average latency time of each frame (msec)}}$	≥ 2 FPS

Summary Performance data, Standard Deviations & Confidence Intervals for Segmentation:

Validation Type	Average	Standard Deviation	95% CI
Accuracy (%)	98.42	3.99	97.13 to 99.71
Speed (FPS)	3.64	0.40	3.48 to 3.80

The accuracy was measured by comparing the segmented outputs of NerveTrack and ground truth made by anesthesiologists. Measurement using the test images was repeated three times, and the average values were calculated.

Twelve anesthesiologists and five sonographers with over ten years' experience participated in establishing the ground truth (GT) for the locations of nine different types of nerves. For each dataset, the doctors who performed the ultrasound scans directly drew the GT of the nerve locations, which were then reviewed and verified as accurate by at least two additional anesthesiologists and sonographers. Any errors or discrepancies identified during the reviews were corrected until satisfactory results were achieved.

The training data used for the training of the NerveTrack algorithm are independent of the

data used to test the NerveTrack algorithm.

[The validation for SonoSync]

Pre-determined criteria were utilized in validation tests to assess whether remote viewing and reviewing with SonoSync matched the performance of local ultrasound systems. Labeling materials is provided to inform users about the necessary specifications for safely and effectively conducting remote diagnostic reviews and viewing.

12. Summary of Clinical Tests

The proposed device V8/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic 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/XV8/XH8, V7/XV7/XH7, V6/XV6/XH6 diagnostic 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**