



August 22, 2022

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

Re: K221599

Trade/Device Name: HS40 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: August 2, 2022
Received: August 10, 2022

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 (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <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,

For

Michael D. O'Hara, Ph.D.
Deputy Director
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

510(k) Number (if known)
K221599

Device Name
HS40 Diagnostic Ultrasound System

Indications for Use (Describe)

The HS40 diagnostic ultrasound system and probes are designed to obtain ultrasound images and analyze body fluids.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric 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.

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510(k) Premarket Notification – Traditional

K221599

5. 510(K) Summary

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

1. Date Prepared – May 31, 2022
2. Manufacturer
SAMSUNG MEDISON CO., LTD.
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Hongcheon-gun, Gangwon-do 25108,
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5. Proposed Device
 - Proprietary Name: HS40 Diagnostic Ultrasound System
 - Common Name : System, Imaging, Pulsed Doppler, Ultrasonic System, Imaging, Pulsed Echo, Ultrasonic Transducer, Ultrasonic, Diagnostic
 - Classification: 21 CFR 892.1550 Ultrasonic pulsed doppler imaging system
21 CFR 892.1560 Ultrasonic pulsed echo imaging system
21 CFR 892.1570 Diagnostic ultrasonic transducer
 - Product Code(s): IYN, IYO, ITX
6. Predicate Device

HS40 Diagnostic Ultrasound System (K210426)	– Primary Predicate
HM70 EVO Diagnostic Ultrasound System (K220269)	– Reference
V8 Diagnostic Ultrasound System (K211945)	– Reference
7. Device Description
The HS40 is a general purpose, mobile, software controlled, diagnostic ultrasound system. Its function is to acquire ultrasound data and to display the data as 2D mode, M mode, Color Doppler imaging, Power Doppler imaging (including Directional Power Doppler mode; S-Flow), PW Spectral Doppler mode, CW Spectral Doppler mode, Harmonic imaging(S-

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Harmonic), Tissue Doppler imaging, Tissue Doppler Wave, Panoramic Imaging, Freehand 3D, 3D imaging mode (real-time 4D imaging mode), Elastoscans Mode or as a combination of these modes. The HS40 also gives 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 HS40 has 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 HS40 diagnostic ultrasound system and probes are designed to obtain ultrasound images and analyze body fluids.

The clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal (Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric 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. Technology

The HS40 employs the same fundamental scientific technology as its predicate device(s).

10. Determination of Substantial Equivalence

Comparison to Predicate: The HS40 is substantially equivalent to the predicate device(s) 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 HS40 and predicate HS40(K210426) have the same clinical intended use.
- The proposed HS40 and predicate HS40(K210426) have the same imaging modes and modes of operation.
- The proposed HS40 has added the UterineAssist based on AI already cleared in the predicate device V8(K211945) and expanded the detection nerve type (Elbow : MN, UN, RN / Neck&Shoulder : ISBP, SCBP, AxBP) of NerveTrack based on AI in the

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previously cleared HS40(K210426).

- The proposed HS40 has added the LA2-9S, PA3-9B, PA1-5A and CA1-7AD transducers from already cleared in predicate device HM70 EVO(K220269).
- The proposed HS40 has changed the housing material of EV2-10A transducer and specification of caster (4 locking or 3 locking + 1 non-locking type).
- 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.
- The proposed HS40 and predicate HS40 (K210426) have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed HS40 and predicate have been designed in compliance with approved electrical and physical safety standards.

11. Summary of Non-Clinical Test

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 guidance and medical device safety standards. The HS40 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: 2014(4th 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
ISO10993-1	ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO14971	ISO 14971:2007, 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

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[The validation for expansion of the detection nerve of NerveTrack based on AI]

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)	$\frac{1000}{\text{Average latency time of each frame (msec)}}$	$\geq 2 \text{ FPS}$

Summary Performance data, Standard Deviations & Confidence Intervals:

Validation Type	Average	Standard Deviation	95% CI
Accuracy (%)	91.7	5.6	89.5 to 93.9
Speed (FPS)	7.93	1.11	7.04 to 8.82

Testing Data Information:

	Females	Males	Total
Number of Subjects	13	5	18
Number of Images	1,168	978	2,146
Age range	32~68	22~50	22~68
Average age	45.7	35.0	42.7
BMI range	16~27.1	31.5	16~31.5
Average BMI	20.5	31.5	21.5
Ethnicity	All Koreans		

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 ($18.5 \leq \text{BMI} < 25$), overweight ($25 \leq \text{BMI} < 30$), 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 are 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 shows a low correlation and no significant difference of NerveTrack performance according to the patient's BMI information. So, we believe that our model is robust even if the cases with various BMI information exist.

When collecting scan data, the speed of the probe varies from about 1cm to 5cm per second.

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The orientation of the probe was short-axis imaging and perpendicular to the skin, obtained by sliding the probe in both the proximal and distal directions. All the nerve data were acquired on Samsung ultrasound devices including HS40.

Ten anesthesiologists and five sonographers with more than 10 years of experience participated to establish the ground truth (GT) for the location of 8 different kinds of nerves. One anesthesiologist who scanned the ultrasound directly drew the GT of nerve location, and two or more other anesthesiologists and sonographers reviewed and confirmed that it was correct. If there was any mistake during the review, it was revised again.

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

[The Summary of Testing for UterineAssist]

- Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance.

We tested on three areas : image segmentation, feature points extraction and size measurement.

- Segmentation test

- A deep learning based segmentation algorithm was validated using 450 sagittal uterus images and 150 transverse uterus images collected at three hospitals.
- The average dice-score of uterus is 96%
- The average dice-score of endometrium is 92%

- Feature points extraction test

- We acquired, in addition, 45 sagittal and 41 transverse plane images of uterus collected at three hospitals.
- The errors of uterus feature points are 5.8 mm or less
- The errors of endometrium feature points are 4.3 mm or less

- Size measurement test

- We use same data set of Feature points extraction test
- The errors of Measurements performance are 2.0 mm or less

- Demographic distribution:

- Gender : Female

- Age : Reproductive age, specific age not collected

- Ethnicity/Country : All Koreans

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- Information about clinical subgroups and confounders present in the dataset:
 - We divided the sagittal uterus images, depending on the shape of the endometrium, into 4 phases : early proliferative, peri-ovulatory, secretory, and post-menopause.
 - During testing, a differentiation is made between good image quality and challenging image quality data set.

- Information about equipment and protocols used to collect images
 - We acquired the data set with 4 SAMSUNG MEDISON’s ultrasound systems and probes 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) :
 - Segmentation of the ground truth was generated by three participating OB/GYN experts with more than 10 years’ experience.
 - The set of images (uterus and endometrium) were divided into 3 subsets and the three participating OB/GYN experts each drew the ground truths for one of the subsets.
 - The ground truths drawn by an expert were cross-checked by the other two experts. Any images that do not meet the inclusion/exclusion criteria were excluded from the set of images.

- Description of how the independence of test data from training data was ensured:
 - Data used for test/training validation purpose are completely separated from the ones during training process and there is no overlap between the two.

12. Summary of Clinical Tests

The subject of this premarket submission, HS40, does not require clinical studies to support substantial equivalence.

13. Conclusion

Since the predicate device(s) and 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 HS40 Ultrasound System should perform as intended in the specified use conditions. Therefore, SAMSUNG MEDISON CO., LTD. concludes that the performance of the subject device is as safe and effective, and is therefore substantially equivalent, to the predicate device(s) that are currently marketed for the same intended use.

- **END of 510(K) Summary**