October 30, 2020

Samsung Medison Co., LTD
℅ Ji Yea Lee
Regulatory Affairs Specialist
3366, Hanseo-ro, Nam-myeon,
Hongcheon-gun, Gangwon-do 25108
REPUBLIC OF KOREA

Re: K202556
Trade/Device Name: HS30 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 31, 2020
Received: September 3, 2020

Dear Ji Yea Lee:

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202556

Device Name
HS30 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, 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.

5. 510(K) Summary: K202556

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

1. Date Prepared – August 31, 2020

2. Manufacturer
   SAMSUNG MEDISON CO., LTD.
   3366, Hanseo-ro, Nam-myeon,
   Hongcheon-gun, Gangwon-do 25108,
   REPUBLIC OF KOREA

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5. Proposed Device
   - Common/Usual Name: Diagnostic Ultrasound System and Accessories
   - Proprietary Name: HS30 Diagnostic Ultrasound System
   - Common Name: Diagnostic Ultrasound System
   - Classification Names: system, imaging, pulsed doppler, ultrasonic
   - Product Code: IYN, IYO, ITX
   - Regulation: 21 CFR 892.1550, 892.1560, 892.1570

6. Predicates
   - HS30 Diagnostic Ultrasound System (K182632) - Primary
   - HS40 Diagnostic Ultrasound System (K200339)

7. Device Description
   The HS30 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-Harmonic), Tissue Doppler imaging, Tissue Doppler Wave, Panoramic Imaging, Freehand 3D, Elastoscan Mode or as a combination of these modes. The HS30 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 HS30 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 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 HS30 employs the same fundamental scientific technology as the predicates.

10. Determination of Substantial Equivalence
The HS30 is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

Feature	**HS30 (Under Review)**	**HS30 (K182632) Primary**	**HS40 (K200339)**
Indication for Use	- Fetal/Obstetrics - Abdominal - Gynecology - Pediatric - Small Organ - Neonatal Cephalic - Adult Cephalic - Trans-rectal - Trans-vaginal - Musculo-skel. (Conventional) - Musculo-skel. (Superficial) - Urology - Cardiac Adult - Cardiac Pediatric - Peripheral vessel	- Fetal/Obstetrics - Abdominal - Gynecology - Pediatric - Small Organ - Neonatal Cephalic - Adult Cephalic - Trans-rectal - Trans-vaginal - Musculo-skel. (Conventional) - Musculo-skel. (Superficial) - Urology - Cardiac Adult - Cardiac Pediatric - Peripheral vessel	- Fetal/Obstetrics - Abdominal - Gynecology - Pediatric - Small Organ - Neonatal Cephalic - Adult Cephalic - Trans-rectal - Trans-vaginal - Musculo-skel. (Conventional) - Musculo-skel. (Superficial) - Urology - Cardiac Adult - Cardiac Pediatric Peripheral vessel
Scanhead Types:	- Linear Array - Curved Linear Array - Endocavity - Phased Array - Static Probes	- Linear Array - Curved Linear Array - Endocavity - Phased Array - Static Probes	- Linear Array - Curved Linear Array - Endocavity - Phased Array - Static Probes
Scanhead Frequency	1.0 ~ 20.0 MHz	1.0 ~ 20.0 MHz	1.0 ~ 20.0 MHz

Feature	HS30 (Under Review)	HS30 (K182632) Primary	HS40 (K200339)
Acoustic Output Display & FDA Limits:	- Display Feature for Higher Output–Track3 - MI Output Display - TI Output Display	- Display Feature for Higher Output–Track3 - MI Output Display - TI Output Display	- Display Feature for Higher Output–Track3 - MI Output Display TI Output Display
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	- 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)	- 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
510(k) Track	Track 3	Track 3	Track 3
System Characteristics:	- Mobile cart - LED Monitor - 256 gray shades on monitor - 100-120V, 60 Hz; - 200-240V, 50 Hz	- Mobile cart - LED Monitor - 256 gray shades on monitor - 100-120V, 60 Hz; - 200-240V, 50 Hz	- Mobile cart - LED Monitor - 256 gray shades on monitor - 100-120V, 60 Hz; - 200-240V, 50 Hz
Product Safety Certification	- IEC 60601-1 - IEC60601-2-37	- IEC 60601-1 - IEC60601-2-37	- IEC 60601-1 - IEC60601-2-37
EMC Compliance	IEC60601-1-2	IEC60601-1-2	IEC60601-1-2
Functionality	- DICOM - Quick Scan (QScan) - ClearVision - MultiVision - Auto IMT+ - Elastoscan - Panoramic - Needle Mate+ - Strain + - EzExam+ - 3D Imaging (Freehand 3D) - 3D Rendering (MPR)	- DICOM - Quick Scan (QScan) - ClearVision - MultiVision - Auto IMT+ - Elastoscan - Panoramic - Needle Mate+ - Strain + - EzExam+ - 3D Imaging (Freehand 3D) - 3D Rendering (MPR)	- DICOM - Quick Scan (QScan) - ClearVision - MultiVision - Auto IMT+ - Elastoscan - Panoramic - Needle Mate+ - Strain + - EzExam+ - 3D Imaging (Freehand 3D) - 3D Rendering (MPR)

Feature	HS30 (Under Review)	HS30 (K182632) Primary	HS40 (K200339)
	- 3D MagiCut - 3D XI(MSV, Oblique View, XI VOCAL) - XI STIC - 2D NT - BiometryAssist - LaborAssist	- 3D MagiCut -	- 3D MagiCut - 3D XI (MSV, Oblique View, XI VOCAL) - XI STIC - 2D NT - BiometryAssist - LaborAssist
Transducers	[Linear array] -LN5-12 -L5-12/50	[Linear array] -LN5-12 -L5-12/50	[Linear array] -LA3-16AD -LN5-12 -L5-12/50 -L4-7 -LS6-15
	[Curved array] -CF4-9 -C2-8 -C2-5 -CA2-6BM	[Curved array] -CF4-9 -C2-8 -C2-5	[Curved array] CA2-8AD -CF4-9 -C2-8 -C2-5 -CA2-6BM
	[Endo Cavity] -EVN4-9 -ER4-9	[Endo Cavity] -EVN4-9 -ER4-9	[Endo Cavity] -EVN4-9 -ER4-9
	[Phased array] -PN2-4 -SP3-8	[Phased array] PN2-4	[Phased array] -PN2-4 -SP3-8
	[3D] -VN4-8 -EV2-10A		[3D] -VN4-8 -V5-9 -EV2-10A
	[CW] DP2B	[CW] DP2B	[CW] -DP2B -DP8B
Biopsy Guides	- BP-KIT-024 - BP-KIT-035 [BP-KIT-035-NG] - BP-KIT-040 [BP-KIT-040-NG] - BP-KIT-045 [BP-KIT-045-NG] - BP-KIT-047 [BP-KIT-047-NG] - BP-KIT-049 [BP-KIT-049-NG] - BP-KIT-061 - BP-KIT-085 - BP-KIT-086	- BP-KIT-024 - BP-KIT-035 [BP-KIT-035-NG] - BP-KIT-040 [BP-KIT-040-NG] - BP-KIT-045 [BP-KIT-045-NG] - BP-KIT-047 [BP-KIT-047-NG] - BP-KIT-061	- BP-KIT-024 - BP-KIT-029 - BP-KIT-054 [BP-KIT-054-NG] - BP-KIT-055 [BP-KIT-055-NG] - BP-KIT-049 [BP-KIT-049-NG] - BP-KIT-060 - BP-KIT-061 - BP-KIT-068 [BP-KIT-068-NG] - BP-KIT-043 - BP-KIT-085 - BP-KIT-086

Feature	HS30 (Under Review)	HS30 (K182632) Primary	HS40 (K200339)
optional devices	- Digital B/W Video Printer - Digital Color Video Printer - USB Printer DVD recorder (DVR)	- Digital B/W Video Printer - Digital Color Video Printer - USB Printer DVD recorder (DVR)	- Digital B/W Video Printer - Digital Color Video Printer - USB Printer DVD recorder (DVR)
Accessories	- Foot Switch - ECG Gel Warmer	- Foot Switch - ECG Gel Warmer	- Foot Switch - ECG Gel Warmer

11. Summary of Non-Clinical Test
The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic and mechanical safety, and has been found to conform with applicable medical device safety standards. The HS30 and its applications comply with voluntary standards.

Reference No.	Title
IEC 60601-1	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010 /(R)2012 Medical Electrical Equipment - Part 1: General Requirements for basic safety and essential performance.
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	IEC60601-2-37:2007 + A1:2015, Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
ISO10993-1	ISO 10993-1, 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

12. Summary of Clinical Tests
The subject of this premarket submission, HS30 is not required clinical studies to support substantial equivalence.

13. Conclusion
Intended uses and other key features are consistent with traditional clinical practices and FDA guidelines. The design, development and quality process of the manufacturer confirms with 21 CFR 820 and ISO 13485. The device is designed to conform to applicable medical device safety standards and compliance. Therefore, SAMSUNG MEDISON CO., LTD. considers the HS30 to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

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