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

May 7, 2020

Re: K200699
Trade/Device Name: HS70A 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 13, 2020
Received: March 17, 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,

For

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200699

Device Name
HS70A Diagnostic Ultrasound System

Indications for Use *(Describe)*
The Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.

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, Trans-esophageal(Cardiac) and Peripheral vessel.

The Diagnostic Ultrasound System is intended for use by, or by the order of, and under the supervision of, a licensed physician 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.

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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5. 510(K) Summary: K200699

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

1. **Date Prepared** – March 13, 2020

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

3. **Contact Person**
   Primary contact
   Ji Yea Lee
   Regulatory Affairs Specialist
   Phone: +82.2.2194.1594
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   Secondary Contact
   Ninad Gujar
   Director of Regulatory & Quality
   Phone: +1.978.564.8632
   Fax: +1.978.564.8677
   Email: ngujar@neurologica.com

4. **Proposed Device**
   - Common/Usual Name: Diagnostic Ultrasound System and Accessories
   - Proprietary Name: HS70A Diagnostic Ultrasound System
   - Regulation Name: Ultrasound pulsed Doppler imaging system
   - Panel/ Regulatory Class: Radiology / II
   - Product Code: IYN, IYO, ITX
   - Regulation : 21 CFR 892.1550, 892.1560, 892.1570

5. **Predicate Device:** HS70A Diagnostic Ultrasound System (K173713)
   Second Predicate Device:
   HERA W9/HERA W10 Diagnostic Ultrasound System (K192319)

6. **Device Description**
   The HS70A 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, 3D imaging mode (real-time 4D imaging mode), Elastoscan Mode or as a combination of these modes. The HS70A 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 HS70A has real time acoustic output display with two basic indices, a mechanical index and a thermal index, which are both automatically displayed.

7. **Indications for Use**
   The Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound

imaging and fluid analysis of the human body.
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, Trans-esophageal(Cardiac) and Peripheral vessel.

The Diagnostic Ultrasound System is intended for use by, or by the order of, and under the supervision of, a licensed physician 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.

8. Technology

The HS70A employs the same fundamental scientific technology as its predicate devices.

9. Determination of Substantial Equivalence

The proposed HS70A is similar to the predicate device with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.
A comparison of the proposed device to the currently marketed predicates is provided in the table below.

<Change List>

<table>
<tr><th>HS70A</th><th>Addition of V2.02</th><th>Remarks</th></tr>
<tr><td>Clinical application</td><td>- No addition</td><td></td></tr>
<tr><td>Operation of modes</td><td>- No addition</td><td></td></tr>
<tr><td>Applied transducers</td><td>- EV2-10A</td><td><table><tr><th>Transducer</th><th>510(k) Clearance</th></tr><tr><td>EV2-10A</td><td>K192319</td></tr></table></td></tr>
<tr><td>SW Features</td><td>- Addition of predicate S/W features
: IOTA-ADNEX, BiometryAssist, 5D Heart, CrystalVue Flow

- Improvement of cleared S/W functions
: Measurement, Setup&Preferences, Utility, DICOM, 5D Follicle, Sonoview</td><td><table><tr><th>SW Features</th><th>510(k) clearance</th></tr><tr><td>IOTA-ADNEX</td><td>K192319</td></tr><tr><td>BiometryAssist</td><td>K192319</td></tr><tr><td>5D Heart</td><td>K192319</td></tr><tr><td>CrystalVue Flow</td><td>K192319</td></tr></table></td></tr>
<tr><td>HW Features</td><td>- 23.8 inch Monitor</td><td></td></tr>
</table>

<Comparison Table>

Device name	HS70A (Under Review) The subject device	HS70A (K173713) Primary Predicate	HERA W9/HERA W10 (K192319) Second Predicate	Note
Manufacturer	SAMSUNG MEDISON.	SAMSUNG MEDISON.	SAMSUNG MEDISON.	Same to predicate
Regulation No.	892.1550 892.1560 892.1570	892.1550 892.1560 892.1570	892.1550 892.1560 892.1570	
Product Code	IYN, IYO, ITX	IYN, IYO, ITX	IYN, IYO, ITX	
Intended Use	The Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.	The Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.	The Diagnostic Ultrasound System and transducers are intended for diagnostic ultrasound imaging and fluid analysis of the human body.	
clinical Application	- Fetal/Obstetrics	- Fetal/Obstetrics	Fetal/Obstetrics	Same to predicate
	- Abdominal	- Abdominal	Abdominal	Same to predicate
	- Gynecology	- Gynecology	Gynecology	Same to predicate
	- Intra-operative	- Intra-operative		Same to predicate
	- Pediatric	- Pediatric	Pediatric	Same to predicate
	- Small Organ	- Small Organ	Small Organ	Same to predicate
	- Neonatal Cephalic	- Neonatal Cephalic	Neonatal Cephalic	Same to predicate
	- Adult Cephalic	- Adult Cephalic	Adult Cephalic	Same to predicate
	- Trans-rectal	- Trans-rectal	Trans-rectal	Same to predicate
	- Trans-vaginal	- Trans-vaginal	Trans-vaginal	Same to predicate
	- Trans-esophageal (Cardiac)	- Trans-esophageal (Cardiac)		Same to predicate
	- Muscular-Skeletal (Conventional, Superficial)	- Muscular-Skeletal (Conventional, Superficial)	Muscular-Skeletal (Conventional, Superficial)	Same to predicate
	- Urology	- Urology	Urology	Same to predicate
	- Cardiac Adult	- Cardiac Adult	Cardiac Adult	Same to predicate
	- Cardiac Pediatric	- Cardiac Pediatric	Cardiac Pediatric	Same to predicate
	- Peripheral vessel	- Peripheral vessel	Peripheral vessel	Same to predicate
Scanhead Types	- Linear Array	- Linear Array	Linear Array	Same to predicate

Device name	HS70A (Under Review) The subject device	HS70A (K173713) Primary Predicate	HERA W9/HERA W10 (K192319) Second Predicate	Note
	- Curved Linear Array	- Curved Linear Array	Curved Linear Array	Same to predicate
	- Endocavity	- Endocavity	Endocavity	Same to predicate
	- Phased Array	- Phased Array	Phased Array	Same to predicate
	- Static Probes	- Static Probes	Static Probes	Same to predicate
Scanhead Frequency	1.0 ~ 20.0 MHz	1.0 ~ 20.0 MHz	1.0 ~ 20.0 MHz	Same to predicate
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	Same to predicate
Modes of Operation	- B-mode	- B-mode	B-mode	Same to predicate
	- M-mode	- M-mode	M-mode	Same to predicate
	- Pulsed wave (PW) Doppler	- Pulsed wave (PW) Doppler	Pulsed wave (PW) Doppler	Same to predicate
	- Continuous wave (CW) Doppler	- Continuous wave (CW) Doppler	Continuous wave (CW) Doppler	Same to predicate
	- Color Doppler	- Color Doppler	Color Doppler	Same to predicate
	- Power Amplitude Doppler	- Power Amplitude Doppler	Power Amplitude Doppler	Same to predicate
	- Pulse Inversion Harmonic Imaging (S-Harmonic)	- Pulse Inversion Harmonic Imaging (S-Harmonic)	Pulse Inversion Harmonic Imaging (S-Harmonic)	Same to predicate
	- 3D imaging mode	- 3D imaging mode	3D imaging mode	Same to predicate
	- ElastoScan Mode	- ElastoScan Mode	ElastoScan Mode	Same to predicate
	- Combined modes	- Combined modes	Combined modes	Same to predicate
#Transmit Channels	192	192	192	Same to predicate
#Receive Channels	192	192	192	Same to predicate
System Characteristics :	- Beamformer 192	- Beamformer 192	Beamformer 192	Same to predicate
	- Mobile cart	- Mobile cart	Mobile cart	Same to predicate
	- LCD Monitor (LED Backlight unit):	- LCD Monitor (LED Backlight unit):	- LCD Monitor (LED Backlight unit):	Same to predicate

Device name	HS70A (Under Review) The subject device	HS70A (K173713) Primary Predicate	HERA W9/HERA W10 (K192319) Second Predicate	Note
	23inch, 23.8inch	23inch	23inch	
	- 256 gray shades on monitor	- 256 gray shades on monitor	256 gray shades on monitor	Same to predicate
	- 100-240VAC, 1100VA,	- 100-240VAC, 1100VA,	100-240VAC, 1100VA,	Same to predicate
	- 50/60Hz	- 50/60Hz	50/60Hz	Same to predicate
Product Safety Certification	- IEC 60601-1	- IEC 60601-1	IEC 60601-1	Same to predicate
	- CSA C22.2 No.601.1	- CSA C22.2 No.601.1	CSA C22.2 No.601.1	Same to predicate
	- IEC 60601-2-37	- IEC 60601-2-37	IEC 60601-2-37	Same to predicate
EMC Compliance	- IEC 60601-1-2	- IEC 60601-1-2	IEC 60601-1-2	Same to predicate
Acoustic Output Display Standard	Track 3	Track 3	Track 3	Same to predicate
Biocompatibility Compliance	ISO10993-1	ISO10993-1	ISO10993-1	Same to predicate
Software Functionality	- Q Scan	- Q Scan	- Q Scan	Same to predicate
	- ClearVision	- ClearVision	- ClearVision	Same to predicate
	- MultiVision	- MultiVision	- MultiVision	Same to predicate
	- Panoramic	- Panoramic	- Panoramic	Same to predicate
	- Needle Mate+	- Needle Mate	- Needle Mate+	Same to predicate
	- Auto IMT+	- Auto IMT+	- Auto IMT+	Same to predicate
	- Strain+	- Strain+		Same to predicate
	- Stress Echo	- Stress Echo		Same to predicate
	- E-Strain	- E-Strain	E-Strain	Same to predicate
	- S-Shearwave	- S-Shearwave		Same to predicate
	- S-Detect for Breast	- S-Detect for Breast	S-Detect for Breast	Same to predicate

Device name	HS70A (Under Review) The subject device	HS70A (K173713) Primary Predicate	HERA W9/HERA W10 (K192319) Second Predicate	Note
	- S-Detect for Thyroid	- S-Detect for Thyroid	- S-Detect for Thyroid	Same to predicate
	- ADVR	- ADVR	- ADVR	Same to predicate
	- 3D Imaging (Volume Data Acquisition)	- 3D Imaging (Volume Data Acquisition)	- 3D Imaging (Volume Data Acquisition)	Same to predicate
	- 3D Imaging presentation (3D Cine/4D Cine/5D Cine)	- 3D Imaging presentation (3D Cine/4D Cine/5D Cine)	- 3D Imaging presentation (3D Cine/4D Cine/5D Cine)	Same to predicate
	-3D Rendering (MPR)	-3D Rendering (MPR)	-3D Rendering (MPR)	Same to predicate
	-3D XI (MSV/Oblique View)	-3D XI (MSV/Oblique View)	-3D XI (MSV/Oblique View)	Same to predicate
	-3D MXI (Volume Slice, Mirror View)	-3D MXI (Volume Slice, Mirror View)	-3D MXI (Volume Slice, Mirror View)	Same to predicate
	- XI Volume CT (Volume CT)	- XI Volume CT (Volume CT)	- XI Volume CT (Volume CT)	Same to predicate
	-3D MagiCut	-3D MagiCut	-3D MagiCut	Same to predicate
	-Volume Calculation (VOCAL, XI VOCAL)	-Volume Calculation (VOCAL, XI VOCAL)	-Volume Calculation (VOCAL, XI VOCAL)	Same to predicate
	- XI STIC	- XI STIC	- XI STIC	Same to predicate
	- HDVI	- HDVI	- HDVI	Same to predicate
	- RealisticVue	- RealisticVue	- RealisticVue	Same to predicate
	- CEUS+	- CEUS+	- CEUS+	Same to predicate
	- 5D Follicle	- 5D Follicle		Same to predicate
	- HDVI	- HDVI		Same to predicate
	- 5D NT	- 5D NT	- 5D NT	Same to predicate
	- 5D LB	- 5D LB	- 5D LB	Same to predicate
	- 5D CNS	- 5D CNS	- 5D CNS	Same to predicate
	- Auto NT (Old Name: 2D NT)	- Auto NT (Old Name: 2D NT)	- Auto NT (Old Name: 2D NT)	Same to predicate
	- ElastoScan	- ElastoScan	- ElastoScan+	Same to predicate
	- E-Thyroid	- E-Thyroid	- E-Thyroid	Same to predicate
	- E-Breast	- E-Breast	- E-Breast	Same to predicate

Device name	HS70A (Under Review) The subject device	HS70A (K173713) Primary Predicate	HERA W9/HERA W10 (K192319) Second Predicate	Note
	- ArterialAnalysis	- ArterialAnalysis		Same to predicate
	- IOTA-ADNEX		- IOTA-ADNEX	Same; refer to SE analysis 1
	- BiometryAssist		- BiometryAssist	Same; refer to SE analysis 2
	- CrystalVueFlow		- CrystalVueFlow	SE; refer to SE analysis 3
	- 5D Heart		- 5D Heart	SE; refer to SE analysis 4
Transducer	- CA1-7A	- CA1-7A	CA1-7A	Same to predicate
	- CA2-8A	- CA2-8A		Same to predicate
	- CF4-9	- CF4-9	CF4-9	Same to predicate
	- E3-12A	- E3-12A	E3-12A	Same to predicate
	- VR5-9	- VR5-9		Same to predicate
	- CA2-9A	- CA2-9A		Same to predicate
	- CA3-10A	- CA3-10A	CA3-10A	Same to predicate
	- EA2-11B	- EA2-11B	EA2-11B	Same to predicate
	- L3-12A	- L3-12A	L3-12A	Same to predicate
	- LA3-16A	- LA3-16A		Same to predicate
	- LA3-16AI	- LA3-16AI		Same to predicate
	- LA2-9A	- LA2-9A	LA2-9A	Same to predicate
	- LA4-18B	- LA4-18B	LA4-18B	Same to predicate
	- LM4-15B	- LM4-15B		Same to predicate
	- PE2-4	- PE2-4		Same to predicate
	- PA3-8B	- PA3-8B	PA3-8B	Same to predicate
	- P4-12B	- P4-12B		Same to predicate
	- PA1-5A	- PA1-5A		Same to predicate
	- MMPT3-7	- MMPT3-7		Same to predicate
	- CV1-8A	- CV1-8A	CV1-8A	Same to predicate
	- V5-9	- V5-9		Same to predicate

Device name	HS70A (Under Review) The subject device	HS70A (K173713) Primary Predicate	HERA W9/HERA W10 (K192319) Second Predicate	Note
	- LV3-14A	- LV3-14A		Same to predicate
	- CW4.0	- CW4.0		Same to predicate
	- CW6.0	- CW6.0		Same to predicate
	- DP2B	- DP2B		Same to predicate
	- DP8B	- DP8B		Same to predicate
	- EV2-10A	-	- EV2-10A	Same; refer to SE analysis 5
Compatible Biopsy Guide	- BP-KIT-029	- BP-KIT-029	- BP-KIT-029	510(k) Exempt
	- BP-KIT-030	- BP-KIT-030		510(k) Exempt
	- BP-KIT-041	- BP-KIT-041	- BP-KIT-041	510(k) Exempt
	- BP-KIT-043	- BP-KIT-043	- BP-KIT-043	510(k) Exempt
	- BP-KIT-053	- BP-KIT-053		510(k) Exempt
	- BP-KIT-054	- BP-KIT-054	- BP-KIT-054	510(k) Exempt
	- BP-KIT-055	- BP-KIT-055		510(k) Exempt
	- BP-KIT-057	- BP-KIT-057	- BP-KIT-057	510(k) Exempt
	- BP-KIT-058	- BP-KIT-058	- BP-KIT-058	510(k) Exempt
	- BP-KIT-059	- BP-KIT-059	- BP-KIT-059	510(k) Exempt
	- BP-KIT-060	- BP-KIT-060	- BP-KIT-060	510(k) Exempt
	- BP-KIT-065	- BP-KIT-065	- BP-KIT-065	510(k) Exempt
	- BP-KIT-066	- BP-KIT-066	- BP-KIT-066	510(k) Exempt
	- BP-KIT-068	- BP-KIT-068		510(k) Exempt
	- BP-KIT-069	- BP-KIT-069	- BP-KIT-069	510(k) Exempt
	- BP-KIT-071	- BP-KIT-071	- BP-KIT-071	510(k) Exempt
	- BP-KIT-075	- BP-KIT-075		510(k) Exempt
	- BP-KIT-083	-		510(k) Exempt
	- BP-KIT-085	-	- BP-KIT-085	510(k) Exempt
	- BP-KIT-086	-	- BP-KIT-086	510(k) Exempt
Digital Storage/Transfer	- Foot Switch - ECG (defibrillation proof)	- Foot Switch - ECG (defibrillation proof)	- Foot Switch - ECG (defibrillation proof)	Same to predicate

Device name	HS70A (Under Review) The subject device	HS70A (K173713) Primary Predicate	HERA W9/HERA W10 (K192319) Second Predicate	Note
Station	- Gel Warmer - Clear Track/ Virtual Track System Stand WLAN Card	- Gel Warmer - Clear Track/ Virtual Track System Stand - WLAN Card	- Gel Warmer - Clear Track/ Virtual Track System Stand WLAN Card	

10. 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 HS70A and its applications comply with voluntary standards.

Test	Standards and FDA Guidance
Risk Management	ISO 14971 Second edition 2007 Medical devices - Application of risk management to medical devices
Electrical Safety	The HS70A Ultrasound System with defibrillation-proof ECG electrode was evaluated per the following standards. 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.
Electromagnetic Compatibility	IEC60601-1-2: 2014(4th Edition) Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
Biocompatibility	ISO 10993-1 Fourth edition 2009-10-15 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
Reprocessing Medical Devices	FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling issued on March 17, 2015, revised June 9, 2017.
Software/Firmware-driven Functionality	All migrated software functionality was evaluated using the same test criteria as the predicates for all applicable imaging modes to ensure that migration into a new system design did not compromise image quality with respect to the intended use of each feature. Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2005
Ultrasound Safety	Marketing Clearance of Diagnostic Ultrasound Systems and Transducers issued June 27, 2019
	IEC60601-2-37:2007 + A1:2015, Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment
	NEMA UD 2-2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3

11. Summary of Clinical Tests
    The subject of this premarket submission, HS70A, is not required clinical studies to support substantial equivalence.

12. Conclusion
    SAMSUNG MEDISON CO., LTD. considers the HS70A to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

-END of 510(K) Summary