



September 25, 2026

Samsung Medison Co., Ltd.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K263182

Trade/Device Name: EVO X30 Diagnostic Ultrasound System; EVO X20 Diagnostic Ultrasound System; EVO X10 Diagnostic Ultrasound System; EVO XP30 Diagnostic Ultrasound System; EVO XP20 Diagnostic Ultrasound System; EVO XP10 Diagnostic Ultrasound System; EVO XC30 Diagnostic Ultrasound System; EVO XC20 Diagnostic Ultrasound System; EVO XC10 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

Dated: September 11, 2026

Received: September 11, 2026

Dear Prithul Bom:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D.

O'hara -S

Date: 2026.09.25 08:48:18 -04'00'

For

Yanna Kang, PhD

Assistant 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K263182

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Please provide the device trade name(s).

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EVO X30 Diagnostic Ultrasound System; EVO X20 Diagnostic Ultrasound System; EVO X10 Diagnostic Ultrasound System; EVO XP30 Diagnostic Ultrasound System; EVO XP20 Diagnostic Ultrasound System; EVO XP10 Diagnostic Ultrasound System; EVO XC30 Diagnostic Ultrasound System; EVO XC20 Diagnostic Ultrasound System; EVO XC10 Diagnostic Ultrasound System

Please provide your Indications for Use below.

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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, Dermatology, Trans-esophageal(Cardiac), Ophthalmic 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 (including emergency rooms), 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) Spectral Doppler mode, Continuous Wave (CW) Spectral Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan+ Mode, Combined modes, MV-Flow mode, Multi-Image mode(Dual, Quad).

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use ([21 CFR 801 Subpart D](#))

☐ Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

☒ Neonates/Newborns (Birth to < 29 days old)

☒ Infants (29 days old to < 2 years old)

☒ Children (2 years old to < 12 years old)

☒ Adolescents (12 years old to < 22 years old)

☒ Adults (22 years old and greater)

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510(k) Summary:

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

1. Date Prepared – Jul 31, 2026
2. Manufacturer
SAMSUNG MEDISON CO., LTD.
3366, Hanseo-ro, Nam-myeon, Hongcheon-gun,
Gangwon-do, Republic of Korea
3. Primary Contact Person
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Regulatory Affairs Specialist
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4. Secondary Contact Person
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Vice President
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Fax: +1.978.564.8677
Email: ngujar@samsunghme.com
5. Proposed Device
 - Common/Usual Name : Diagnostic Ultrasound System and Accessories
 - Proprietary Name : EVO X30 Diagnostic Ultrasound System
EVO X20 Diagnostic Ultrasound System
EVO X10 Diagnostic Ultrasound System
EVO XP30 Diagnostic Ultrasound System
EVO XP20 Diagnostic Ultrasound System
EVO XP10 Diagnostic Ultrasound System
EVO XC30 Diagnostic Ultrasound System
EVO XC20 Diagnostic Ultrasound System
EVO XC10 Diagnostic Ultrasound System
 - Regulation Name : Ultrasonic pulsed doppler imaging system
 - Regulatory Class : Class II
 - Product Code : IYN, IYO, ITX, LLZ
 - Regulation Number : 21 CFR 892.1550, 892.1560, 892.1570, 892.2050
6. Predicate/ Reference Devices
 - Primary Predicate device: EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound System (K254099)
 - Predicate device: V8/XV8/XH8/H8/cV8/V8 ONE/XV8 ONE/XH8 ONE/H8 ONE/cV8 ONE Diagnostic Ultrasound System; V7/XV7/XH7/H7/cV7/V7 ONE/XV7 ONE/H7 ONE/XH7 ONE/cV7 ONE Diagnostic Ultrasound System; V6/XV6/XH6/H6/cV6/V6 ONE/XV6 ONE/H6 ONE/XH6 ONE/cV6 ONE Diagnostic Ultrasound System; (K261412)
 - Reference device: Venue; Venue Go; Venue Fit; Venue Sprint (K251322)

7. Device Description

EVO X30, EVO X 20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems are general purpose, mobile, software controlled, diagnostic ultrasound systems. Its 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, MV-Flow mode, Multi-Image mode(Dual, Quad).

EVO X30, EVO X 20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems 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.

EVO X30, EVO X 20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems 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 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, Dermatology, Trans-esophageal(Cardiac), Ophthalmic 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 (including emergency rooms), 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) Spectral Doppler mode, Continuous Wave (CW) Spectral Doppler mode, Tissue Doppler Imaging (TDI) mode, Tissue Doppler Wave (TDW) mode, ElastoScan+ Mode, Combined modes, MV-Flow mode, Multi-Image mode(Dual, Quad).

9. Technological Comparison to Predicate Devices

EVO X30, EVO X 20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems employ the same fundamental scientific technology as the predicate device EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound Systems (K254099).

10. Determination of Substantial Equivalence

Comparison to Predicate: EVO X30, EVO X 20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems are substantially equivalent to the predicate device 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 EVO X30, EVO X 20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems and predicate devices have the same clinical intended use.
- The proposed EVO X30, EVO X20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems and the predicate device EVO Q30, EVO Q20, EVO Q10, EVO XQ30, EVO XQ20, EVO XQ10, EVO QH30, EVO QH20, EVO QH10 Diagnostic Ultrasound Systems (K254099) have the same imaging modes and modes of operation, with the exception that the proposed devices do not support 3D/4D mode
- The proposed EVO X30/EVO X20/EVO X10/EVO XP30/EVO XP20/EVO XP10/EVO XC30/EVO XC20/EVO XC10 Diagnostic Ultrasound Systems have migrated their software features from the cleared predicate device EVO Q30/EVO Q20/EVO Q10/EVO XQ30/EVO XQ20/EVO XQ10/EVO QH30/EVO QH20/EVO QH10 Diagnostic Ultrasound Systems (K254099).
- The proposed EVO X30/EVO X20/EVO X10/EVO XP30/EVO XP20/EVO XP10/EVO XC30/EVO XC20/EVO XC10 Diagnostic Ultrasound Systems include 21 transducers, all of which are migrated from the predicate devices.
- The proposed EVO X30, EVO X20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems have included WLAN, supporting Wi-Fi and Bluetooth modules.
- The proposed EVO X30, EVO X20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems and the predicate devices have the same capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The proposed EVO X30, EVO X20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems and the predicate devices 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 level.

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. EVO X30, EVO X20, EVO X10, EVO XP30, EVO XP20,

EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems and their 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) [Including Amendment 2 (2021)]
IEC 60601-1-2	ANSI AAMI IEC 60601-1-2:2014 [Including AMD 1:2021], Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests [Including Amendment 1 (2021)]
IEC 60601-2-18	IEC 60601-2-18:2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
IEC 60601-2-37	IEC 60601-2-37:2024, 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
ISO 10993-1	ANSI AAMI 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 14971	ANSI AAMI 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

12. Summary of Clinical Tests

The proposed device EVO X30, EVO X20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems do 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 EVO X30, EVO X20, EVO X10, EVO XP30, EVO XP20, EVO XP10, EVO XC30, EVO XC20, EVO XC10 Diagnostic Ultrasound Systems 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