August 23, 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: K241302
Trade/Device Name: SonoSync
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, IYN, IYO
Dated: July 12, 2024
Received: July 12, 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,

Marjan Bakhtiari-nejad -S For

Yanna Kang, Ph.D.
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

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)*

K241302

Device Name

SonoSync

Indications for Use *(Describe)*

SonoSync is a software solution for live streaming images acquired through ultrasound systems to healthcare professionals for diagnostic image viewing, remote access, review, consultation, guidance, support and education in real time.

It is required to follow the technical and operator requirements in the User Manual.

As users of this remote solution, the healthcare professionals take responsibility for ensuring that image quality, display contrast and ambient light conditions meet the generally accepted practices of the ultrasound imaging.

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.

510(K) Summary:

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

1. Date Prepared – May 9, 2024

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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5. Proposed Device
   - Common/Usual Name : System, Image Processing, Radiological.
   - Proprietary Name : SonoSync
   - Regulation Name : Medical image management and processing system.
   - Regulatory Class : Class II
   - Product Code : LLZ(Primary), IYN, IYO
   - Regulation Number : 21 CFR 892.2050(Primary), 892.1550, 892.1560

6. Predicate Devices
   - Collaboration Live (K212777) – Primary

7. Device Description
   SonoSync is a software solution that allows medical professionals to stream ultrasound images live, providing real-time access to diagnostic imaging, remote viewing, reviewing, consulting, guiding, supporting, and educating.

   SonoSync supports four main features: remote diagnostic viewing and guiding, remote clinical training and education, collaboration, and remote service support.

   With permission from the person operating the ultrasound equipment, a remote user can control the ultrasound equipment using a virtual remote touch panel and remote control panel.
   Furthermore, under the technical, operational, and environmental conditions described in

the manual, healthcare professionals can provide clinical diagnostics at a remote location as if directly using the ultrasound equipment.

8. Indication for Use

SonoSync is a software solution for live streaming images acquired through ultrasound systems to healthcare professionals for diagnostic image viewing, remote access, review, consultation, guidance, support and education in real time.

It is required to follow the technical and operator requirements in the User Manual.

As users of this remote solution, the healthcare professionals take responsibility for ensuring that image quality, display contrast and ambient light conditions meet the generally accepted practices of the ultrasound imaging.

9. Comparison of Technological Characteristics with the Predicate Device

Attribute	SonoSync (Subject Device)	Collaboration Live K212777 (Predicate Device)	Comparison
Regulation Name	Medical image management and processing system	Medical image management and processing system	Identical
Product Code(s)	Primary: LLZ Secondary: IYN, IYO	Primary: LLZ Secondary: IYN, IYO	Identical
Indications for Use	SonoSync is a software solution for live streaming images acquired through ultrasound systems to healthcare professionals for diagnostic image viewing, remote access, review, consultation, guidance, support and education in real time. It is required to follow the technical and operator requirements in the User Manual. As users of this remote solution, the healthcare professionals take responsibility for ensuring that image quality, display contrast and ambient light conditions meet the generally accepted practices of the ultrasound imaging.	Collaboration Live is indicated for remote console access of the Philips ultrasound system for diagnostic image viewing and review, consultation, guidance, support, and education in real time. Access must be granted by the healthcare professionals operating the ultrasound system. Compliance with the technical and operator requirements specified in the User Manual is required. It is the responsibility of the healthcare professionals at the remote client to ensure image quality , display contrast, and ambient light conditions are consistent with the generally accepted standards of the clinical application.	Identical

Features	- Streaming - Text Chat - Voice Chat - Video Chat - Image Sharing - Remote Control - Marking - Remote Image Quality - Invitation	- Image viewing and review - Text Chat - Voice Calling - Video Calling - Remote Asset Sharing - Remote Control - Network Indicator - Remote Image Quality - Remote User Measurement	Identical
Remote System Hardware	Commercially available off- the-shelf computer hardware	Commercially available off- the-shelf computer hardware	Identical
Supported Imaging Modalities	Ultrasound	Ultrasound	Identical
Intended Users	Qualified healthcare professionals	Qualified healthcare professionals	Identical
Remote-client Use Environment	Clinical environment with ambient light condition consistent with the generally accepted standards of the clinical application.	Clinical environment with ambient light condition consistent with the generally accepted standards of the clinical application.	Identical
Remote Diagnostic Use	Image visualized for diagnostic review and viewing on Chrome compliant Browser	Image visualized for diagnostic review and viewing on remote-client Reacts	Identical

10. Summary of Non-Clinical Testing

Pre-set criteria were utilized in validation tests to assess whether remote viewing and reviewing with SonoSync matched the performance of local ultrasound systems.
Specifications for remote displays and required network bandwidth to ensure diagnostic image quality were identified. Labeling materials have been prepared to inform users about the necessary specifications for safely and effectively conducting remote diagnostic reviews and viewing.

11. Conclusion

Since the predicate device 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 SonoSync 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 indication for use.

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