Samsung Medison Co., Ltd.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
BUFFALO MN 55313

May 15, 2018

Re: K180883
Trade/Device Name: 5D Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 9, 2018
Received: May 10, 2018

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K180883

Device Name
5D Viewer

Indications for Use *(Describe)*
5D Viewer is a software application for the display and 3D visualization of US Volume Data measured by an ultrasound system.
This application is designed to allow the user to examine and analyze images based on volume data received from the specified ultrasound diagnostic system. It may also be used to search, analyze, edit, measure, and store the volume data.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information:

SAMSUNG MEDISON CO., LTD.
145, Pangyoyeok-ro, Bundang-gu, Seongnam-si, Gyeonggi-do, 13530, Korea

1.1. Contact Person

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Data Prepared: November 15, 2017

2. Name of the device:

Common/Usual Name:

Picture Archiving Communications System

Proprietary Name:

5D Viewer

Classification Names:	FR Number	Product Code
Picture Archiving Communications System	892.2050	LLZ

3. Identification of the predicate or legally marketed device:

- 5D Viewer (K161955)
- WS80A Diagnostic Ultrasound System (K171070)

4. Device Description:

5D Viewer is standalone software that can be installed in laptops/PCs with Microsoft Windows 7.

This product lets users use their computers to review, analyze, edit, and measure the volume data exported from ultrasound equipment via storage media such as USB drive.

Since this product reads 3D volume data, users can review the test results of patients more quickly and

easily. This function allows them to check 3D image results without using an ultrasound system, helping them conduct more tests with the ultrasound system.

5D Viewer only supports the DICOM files containing the volume data created by Samsung Medison's Diagnostic Ultrasound Systems. In other words, you only use the volume data in DICOM files. 5D Viewer is not compatible with the DICOM files from third parties.

Main operational functions

- Display and edit volume data set
- Save data (video and volume data)
- Support simple caliper (Distance, Ellipse, or 3 Distance Volume)

Functions that require a USB-type dongle

- HDVI
- 5D Heart

5D Viewer uses the volume data of Samsung Medison's WS80A, RS80A, and HS70A Ultrasound systems.

The Volume Data contains the raw data obtained during the scan as well as the information required for rendering (e.g., Geometry, View mode, etc.). The patient information is not relevant to the rendering, so it is not included in the Volume Data.

5. Intended Uses:

5D Viewer is a software application for the display and 3D visualization of Ultrasound volume data derived from Ultrasound system. It is designed to allow the user to observe images and perform analysis using the volume data acquired with specified diagnostic ultrasound systems. It is intended to be used for viewing, analyzing, editing, measuring and storing of volume data.

6. Technological Characteristics:

5D Viewer is substantially equivalent with respect to safety, effectiveness, and functionality primarily to the 5D Viewer (K161955) and WS80A Diagnostic Ultrasound System (K171070) as a reference. The device is a software application and does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets volume data being displayed. It is designed to allow the user to observe images and perform analysis using the volume data acquired with specified diagnostic ultrasound systems. It is intended to be used for viewing, analyzing, editing, measuring and storing of volume data.

These are described in detail in the technological characteristics comparison table as below.

<Technological Characteristics Comparison Table>

Feature	Subject Device	The Primary predicate device	The Reference predicate devices
	5D Viewer (Under Review)	5D Viewer (K161955)	WS80A (K171070)
Indications for Use	5D Viewer is a software application for the display and 3D visualization of US Volume Data measured by an ultrasound system. This application is designed to allow the user to examine and analyze images based on volume data received from the specified ultrasound diagnostic system. It may also be used to search, analyze, edit, measure, and store the volume data.	5D Viewer is a software application for the display and 3D visualization of US Volume Data measured by an ultrasound system. This application is designed to allow the user to examine and analyze images based on volume data received from the specified ultrasound diagnostic system. It may also be used to search, analyze, edit, measure, and store the volume data.	The WS80A 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, Pediatric, Small Organ, Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Muscular-Skeletal(Conventional, Superficial), Urology, Cardiac Adult, Cardiac Pediatric, Peripheral vessel and Intra-operative.
Computer platform (minimum requirements)	- CPU: Intel Core i5 - VGA: Nvidia graphic card supporting Shader Model 3.0 with 1GB Video Memory - Resolution: 1280x720 - Memory: 4GB	- CPU: Intel Core i5 - VGA: Nvidia graphic card supporting Shader Model 3.0 with 1GB Video Memory - Resolution: 1280x720 - Memory: 4GB	Not applicable
Computer Operating System	Windows 7	Windows 7	Not applicable
Opening and saving files	*.mvl, *.sty, *.dcm ※ 5D Viewer only supports the DICOM files containing the volume data created by Samsung Medison. In other words, you only use the volume data in DICOM files. 5D Viewer is not compatible with the DICOM files from third parties.	*.mvl, *.sty, *.dcm ※ 5D Viewer only supports the DICOM files containing the volume data created by Samsung Medison. In other words, you only use the volume data in DICOM files. 5D Viewer is not compatible with the DICOM files from third parties.	*.mvl, *.sty
Functionality	(Similarity) Functionality of 5D Viewer is same with the previously cleared 510(k) submission 5D Viewer (K161955) and WS80A (K171070) that there is not difference in functionality between them. (Difference) In the 5D Viewer, some functionality (Crystal Vue Flow) that was previously cleared on WS80A (K171070) has been added with 5D Viewer. It doesn't impact on device safety and effectiveness. It is substantially equivalent with respect to safety, effectiveness, and functionality to the **5D Viewer (K161955)** and **WS80A (K171070)** in		

Feature	Subject Device	The Primary predicate device	The Reference predicate devices
	5D Viewer (Under Review)	5D Viewer (K161955)	WS80A (K171070)
	regards to the device with **5D Viewer.**		
- MPR			
Slub 3D	Yes	Yes	Yes
Accept ROI	Yes	Yes	Yes
FAD	Yes	Yes	Yes
Curved ROI	Yes	Yes	Yes
- Mirror View	Yes	Yes	Yes
- MagiCut			
Smooth Cut	Yes	Yes	Yes
- Volume Slice	Yes	Yes	Yes
- MSV	Yes	Yes	Yes
- Oblique View	Yes	Yes	Yes
- Volume CT	Yes	Yes	Yes
- VOCAL	Yes	Yes	Yes
- XI VOCAL	Yes	Yes	Yes
- Cine View			
3D Cine	Yes	Yes	Yes
4D Cine	Yes	Yes	Yes
- 5D Functions			
5D NT	Yes	Yes	Yes
5D CNS+ (old name: 5D CNS)	Yes	Yes	Yes
5D Follicle	Yes	Yes	Yes
5D LB	Yes	Yes	Yes
5D Heart	Yes	Yes	Yes
5D Limb Vol	Yes	No	Yes
- Measurement			
Distance	Yes	Yes	Yes
Ellipse	Yes	Yes	Yes
3 Distance Volume	Yes	Yes	Yes
- Render Setup functions			
Realistic Vue	Yes	Yes	Yes
VSI	Yes	Yes	Yes
ClearVision	Yes	No	Yes
Crystal Vue	Yes	No	Yes
Crystal Vue Flow	Yes	No	Yes
Natural Vue	Yes	No	No
- Post Processing functions			
Post Gain	Yes	Yes	Yes

Feature	Subject Device	The Primary predicate device	The Reference predicate devices
	5D Viewer (Under Review)	5D Viewer (K161955)	WS80A (K171070)
Clear SFVI	Yes	Yes	Yes
Detailed SFVI	Yes	Yes	Yes
HDVI	Yes	Yes	Yes
- Chroma map function	Yes	Yes	Yes

<Change list>

5D Viewer	Addition of V2.00	Remarks
Model Name	N/A	
SW Features	• Adding the predicate S/W features : Crystal Vue Flow • Improving the S/W feature that was previously cleared in 5D Viewer (K161955) : 5D Follicle	Description of S/W Features • Crystal Vue Flow: This feature is to display rendered images in Crystal Vue with Color Doppler.

SW Features	The previously cleared SW Features
Crystal Vue Flow	K171070

7. A brief discussion of the non-clinical and clinical tests conducted on the subject device

The device has been evaluated to conform to applicable voluntary standards.

- IEC 62304 Medical device software - Software life-cycle processes
- ISO 14971 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
- HIPAA COMPLIANCE - 5D Viewer is in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
- SAMSUNG MEDISON Software Development Procedure (DXQ2-0030K)

Summary of Clinical Tests:

Not applicable. The subject of this submission, 5D Viewer, did not require clinical studies to support substantial equivalence.

8. Conclusion

SAMSUNG MEDISON CO., LTD. considers the 5D Viewer to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

- The 510(k) Pre-Market Notification for the 5D Viewer contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device.
- The device will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
- The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

END of 510(K) Summary