



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

August 10, 2016

Re: K161955
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: July 14, 2016
Received: July 18, 2016

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large watermark of the letters "FDA".

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

Indications for Use

510(k) Number (if known)

K161955

Device Name

5D Viewer

Indications for Use (Describe)

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 ultrasound volume data acquired with specified diagnostic ultrasound systems. It is intended to be used for viewing, analyzing, editing, measuring and storing of volume data. Typical users of this system are trained professionals, including physicians, nurses, and technicians.

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.

42, Teheran-ro 108-gil, Gangnam-gu, Seoul, Korea

Contact Person:

Kyeong-Mi, Park

Regulatory Affairs Manager

Telephone: 82.2.2194.1373

Facsimile: 82.2.556.3974

Data Prepared: June 3, 2016

2. Name of the device:

Common/Usual Name:

Picture Archiving Communications System

Proprietary Name:

5D Viewer

Classification Names:

Picture Archiving Communications System

FR Number

892.2050

Product Code

LLZ

3. Identification of the predicate or legally marketed device:

- 3D/5D Viewer (K151808)
- WS80A Diagnostic Ultrasound System (K153529)
- RS80A Diagnostic Ultrasound System (K151663)

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 to the 3D/5D Viewer (K151808), WS80A Diagnostic Ultrasound System (K143089) and RS80A Diagnostic Ultrasound

System (K151663).

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 devices	The predicate devices	
	5D Viewer	3D/5D Viewer (K151808)	WS80A (K153529)	RS80A (K151663)
Computer Operating System - Windows 7	Yes	Yes	Not applicable	Not applicable
Opening and saving files - *.mvl - *.sty - *.dcm	Yes Yes Yes	Yes Yes No	Yes Yes Yes	Yes Yes Yes
- MPR Slub 3D Accept ROI FAD Curved ROI	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes
- Mirror View	Yes	Yes	Yes	Yes
- MagiCut Smooth Cut	Yes	Yes	Yes	Yes
- Volume Slice	Yes	Yes	Yes	Yes
- MSV	Yes	Yes	Yes	Yes
- Oblique View	Yes	Yes	Yes	Yes
- Volume CT	Yes	Yes	Yes	Yes
- VOCAL	Yes	Yes	Yes	Yes
- XI VOCAL	Yes	Yes	Yes	Yes
- Cine View 3D Cine 4D Cine	Yes Yes	Yes Yes	Yes Yes	Yes Yes
- 5D Functions 5D NT 5D CNS+ (old name: 5D CNS) 5D Follicle 5D LB	Yes Yes Yes Yes	Yes Yes Yes Yes	Yes Yes Yes Yes	No No No No

Feature	Subject Device	The Primary predicate devices	The predicate devices	
	5D Viewer	3D/5D Viewer (K151808)	WS80A (K153529)	RS80A (K151663)
5D Heart	Yes	Yes	Yes	No
5D Limb Vol	Yes	No	Yes	No
- Measurement				
Distance	Yes	Yes	Yes	Yes
Ellipse 3	Yes	Yes	Yes	Yes
Distance	Yes	Yes	Yes	Yes
Volume				
- Render Setup functions				
Realistic	Yes	Yes	Yes	Yes
Vue VSI	Yes	Yes	Yes	Yes
ClearVision	Yes	No	Yes	Yes
Crystal Vue	Yes	No	Yes	No
Natural Vue	Yes	No	No	No
- Post Processing functions				
Post Gain	Yes	Yes	Yes	Yes
Clear SFVI	Yes	Yes	Yes	Yes
Detailed SFVI	Yes	Yes	Yes	Yes
HDVI	Yes	Yes	Yes	Yes
- Chroma map function	Yes	Yes	Yes	Yes

<Change list>

5D Viewer	Addition of V1.01	Remarks				
Model Name	<ul style="list-style-type: none"> Change of model name in the V1.01 (3D/5D Viewer → 5DViewer) 					
SW Features	<ul style="list-style-type: none"> Adding the predicate S/W features : ClearVision, Natural Vue, Crystal Vue and 5D Limb Vol. Improving the S/W feature that was previously cleared in 3D/5D Viewer (K151808) : 5D CNS+ Changing the S/W feature's name - 5D CNS → 5D CNS+ <table border="1" style="margin-left: 20px;"> <tr> <td>SW Features</td> <td>The previously cleared SW Features</td> </tr> <tr> <td>ClearVision</td> <td>K153529</td> </tr> </table>	SW Features	The previously cleared SW Features	ClearVision	K153529	<p>Description of S/W Features</p> <ul style="list-style-type: none"> ClearVision: It provides the function of removing the noise in images and intensifies boundary lines to make more vivid. Natural Vue: It shows the reflected light on the object surface by the light source to improve realism and representation of shape Crystal Vue: This feature is the volume rendering technology that visualizing interior and exterior structures of 3D volume data. 5D Limb Vol: This feature allows you to detect fractional limb contour and to measure semi-automatically the volume of
SW Features	The previously cleared SW Features					
ClearVision	K153529					

5D Viewer	Addition of V1.01		Remarks
	Natural Vue	K151663	fractional limb.
	Crystal Vue	K153529	
	5D Limb Vol	K153529	

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