



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

July 29, 2015

Re: K151808
Trade/Device Name: 3D/5D Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 1, 2015
Received: July 2, 2015

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,

 For

Robert Ochs, Ph.D.
Acting 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)

K151808

Device Name

3D/5D Viewer

Indications for Use (Describe)

3D/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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

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:

Jiyoung, Kim
Regulatory Affairs Manager
Telephone: 82.2.2194.1299
Facsimile: 82.2.556.3974

Data Prepared: April 27, 2015

2. Name of the device:

Common/Usual Name:

Picture Archiving Communications System

Proprietary Name:

3D/5D Viewer

Classification Names:

Picture Archiving Communications System

FR Number

892.2050

Product Code

LLZ

3. Identification of the predicate or legally marketed device:

- SonoView Pro™ (K031886)
- WS80A Diagnostic Ultrasound System (K143089)

4. Device Description:

3D/5D Viewer is a standalone software product, which can be installed on a laptop/PC with Microsoft Windows XP and 7. It allows the user to use their computer to review, analyze, edit, and measure the volume data exported from ultrasound equipment via storage media such as a USB drive. As the 3D/5D Viewer software reads 3D volume data, the users can review test results of patients more quickly and easily. This function allows them to check 3D image results without using an ultrasound system, which helps them conduct more tests with the ultrasound system.

Primary operating functions are:

- Display and editing of Volume data sets
- Data storage (image, volume data)
- Support simple Caliper (distance, Ellipse, 3 Distance volume)

Some functions that it need to USB dongle are:

- HDVI
- 5D Heart

5. Intended Uses:

3D/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:

3D/5D Viewer is substantially equivalent with respect to safety, effectiveness, and functionality to the SonoView Pro™ (K031886) and WS80A Diagnostic Ultrasound System (K143089).

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
	3D/5D Viewer	SonoView Pro™ (K031886)	WS80A (K143089)
Computer Operating System			
- Windows XP, 7	Yes	Yes	Not applicable
Opening and saving files			
- Type of file			
*.mvl	Yes	Yes	Yes
*.sty	Yes	No	Yes
Functionality			
- MPR			
Slub 3D	Yes	Yes	Yes
Accept ROI	Yes	Yes	Yes
FAD	Yes	No	Yes
Curved ROI	Yes	No	Yes
- Mirror View	Yes	Yes	Yes
- MagiCut			
Smooth Cut	Yes	No	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	No	Yes
5D CNS	Yes	No	Yes
5D Follicle	Yes	No	Yes
5D LB	Yes	No	Yes
5D Heart	Yes	No	Yes
- Measurement			
Distance	Yes	No	Yes
Ellipse	Yes	No	Yes
3 Distance Volume	Yes	No	Yes
- Render Setup functions			
Realistic Vue	Yes	No	Yes
VSI	Yes	No	Yes
- Post Processing functions			
Post Gain	Yes	No	Yes
Clear SFVI	Yes	No	Yes
Detailed SFVI	Yes	No	Yes
HDVI	Yes	No	Yes
- Chroma map function	Yes	Yes	Yes

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 - 3D/5D Viewer is in compliance with the Health Insurance Portability and

Accountability Act of 1996 (HIPAA).

- SAMSUNG MEDISON Software Development Procedure (DXQ2-0035K)

Summary of Clinical Tests:

Not applicable. The subject of this submission, 3D/5D Viewer, did not require clinical studies to support substantial equivalence.

8. Conclusion

SAMSUNG MEDISON CO., LTD. considers the 3D/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 3D/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