SAMSUNG ELECTRONICS Co., Ltd.

510(k) Premarket Notification - Traditional

MAY 2 9 2014

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted accordance with requirements of 21 CFR 807.92

1. **Date:** 2014. Feb. 06
2. **Submitter**
   A. Company Name: SAMSUNG ELECTRONICS Co., Ltd.
   B. Address: 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 443-742, Republic of Korea

3. **Primary Contact Person**
   A. Name: Donald D. Fickett
   B. Title: Vice President Regulatory & Quality Assurance
   C. Phone Number: 978-564-8523
   D. FAX Number: 978-750-6677
   E. E-Mail: dfickett@samsungneurologica.com

4. **Secondary Contact Person**
   A. Name: Ha, Aeyoung
   B. Title: Regulatory Affairs Manager
   C. Phone Number: +82-31-200-1537
   D. FAX Number: +82-31-200-1199
   E. E-Mail: ay.ha@samsung.com

5. **Device**
   A. Trade Name: XGEO GF50
   B. Common Name: Digital Diagnostic X-ray System
   C. Classification Name: System, X-Ray, Stationary
   D. Product Code: KPR

6. **Predicate Device**
   A. Manufacturer: SAMSUNG ELECTRONICS Co., Ltd.
   B. Trade Name: XGEO GC80
   C. 510(k) Number: K123098

7. Device Description

This system is used to capture images by transmitting X-ray to a patient's body.

The X-ray passing through a patient's body is sent to the detector and then converted into electrical signals. These signals go through the process of amplification and digital data conversion in the signal process device before being sent to the XGEO Station (Operation Software) and saved in DICOM file, a standard for medical imaging. The captured images are sent to the Picture Archiving & Communication System (PACS) server, and can be used for reading images.

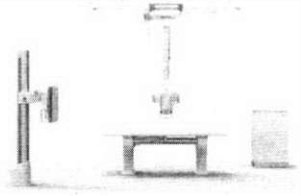
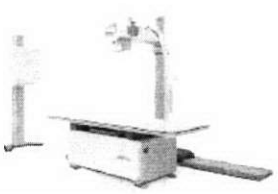
The XGEO GF50 is intended to be used for capturing digital X-ray images of various parts of the body including the head, chest, spine, abdomen, joints, hands, feet and other organs.

8. Intended Use

The XGEO GF50 Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

9. Summary of Technological characteristic of the proposed device compared with the predicate device

The XGEO GF50 does not have significant change in materials, energy source or technological characteristics compared to the predicate device. Comparisons of the following technological characteristics were assessed and the results demonstrate the substantial equivalence to the predicates.

Specification	Predicate Device	Proposed Device	Discussion
Device Name	XGEO GC80	XGEO GF50	
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	
510(k) Number	K123098	N/A	
Appearances			Equivalent (1)

Intended Use	The XGEO GC80 digital X-ray imaging system is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	The XGEO GF50 digital X-ray imaging system is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.	Same
Configuration	Ceiling type	Floor-mounted or Floor-ceiling type	Equivalent (1)

Manufacturer Contents		XGEO GC80	XGEO GF50	Discussion
(1)High Voltage Generator				
Type		High Frequency	High Frequency	Same
Max. Power		80kW	52kW	Equivalent (2)
Output RANGE	Tube Voltage	40-150kV	40-150kV	
	Tube Current	10-1000mA	10-640mA	
	Exposure Time	1msec-2sec	1msec-10sec	
AEC (Automatic Exposure Control)		Yes	Yes	Same
APR (Anatomically Programmed Radiography)		Yes	Yes	Same
(2)Ceiling Suspension				
Moving Range (mm)	Longitudinal	1350 ~ 3350 (Varies with room size)	2100(Floor-mounted) 2500(Floor ceiling)	Equivalent (3)
	Lateral	770 ~ 2770 (Varies with room size)	220	
	Vertical	1800	1330	
Vertical Tube Moving method		Motorized/ Manual	Manual	Equivalent
Tube Assembly Rotation		-157 ~ +183	±135	Equivalent (4)
Brake locking Method		Electromagnetic	Electromagnetic	Same
Moving Rail Type		Al Extrusion	Steel plate	Equivalent (5)
Image Preview		O	O	Same
Display Type		Color LCD	Color LCD	
Control Switch Type		Button + Touch Screen	Button + Touch Screen	

Manufacturer Contents			XGEO GC80	XGEO GF50	Discussion
(3) Wall Stand					
Vertical Movement		Mechanism	Motorized/ Manual	Manual	Equivalent
		Range(mm)	400~1,800	420~1770	Equivalent
Detector	Tilting	Mechanism	Motorized	N/A	Equivalent (6)
		Range	-20~+90		
AEC			Conventional	Conventional	Same
Grid		Lines/cm	84.6	84.6	Same
		Grid mechanism	Stationary	Stationary	Same
		Removability	Removable	Removable	Same
Detector Support Mounting			Floor	Floor	Same
Patient Support Device			Patient handgrips, lateral support bar	Patient handgrips, lateral support bar	Same
(4)Patient Table					
Table Top	Size(mm)		2433 X 806	2200 X 750(4way) 2200 X 810(6way)	Equivalent (7)
	Range (mm)	Lateral	±140	±125	
		Longitudinal	±480	±500	
Table height	Mechanism		DC Motor, Ball screw	DC Motor (6way)	Equivalent
	Range(mm)		545 ~ 900	565 ~ 850	Equivalent
Horizontal range of detector(mm)			590	590	Same
AEC			Conventional	Conventional	Same
Grid	Lines/cm		84.6	84.6	Same
	Grid mechanism		Stationary	Stationary	Same
	Removability		Removable	Removable	Same
Vertical Sync.			O	O	Same
Control Switch Type			Foot switch	Foot switch	Same
Maximum Patient Weight(kg)			350 (Static, Center load)	250 (Static, Center load)	Equivalent
(5)Collimator					
Overall Size(mm)			H212 X W300 X D179	H185 X W213 X D180	Equivalent
Beam Limiting Blade Moving Method			Motorized /Manual	Manual	Equivalent
Manual Operation Method			Volume	Volume	Same
Collimator Rotation			±45	±90	Equivalent

Manufacturer Contents	XGEO GC80	XGEO GF50	Discussion
			(8)
Beam Light Source	LED	Halogen Lamp	Equivalent (9)
Light Field Indicator Timer	O	O	Same
Side Lamp	O	O	Same
	Laser Module	Laser Module	Same
Field Size / SID Display	Color LCD	Color LCD	Same

Manufacturer Contents	XGEO GC80		XGEO GF50	Discussion
(6) Detector				
Name	SDX-4336CP	SDX-4343CS	S4335-W	
Detector Type	CsI	CsI	CsI	Same
	Indirect	Indirect	Indirect	Same
Detector Area	14"X17" (351mmX423mm)	17"X17" (429mmX429mm)	14"X17" (345mmX425mm)	Equivalent
Number of pixels	2340X2820	3000X3000	2466X3040	Equivalent (10)
Pixel Pitch(um)	150	143	140	
High Contrast Limiting Resolution (LP/mm)	3.3	3.5	3.5	
Communication	Wired		Wired / Wireless	Equivalent (11)

No.	Description	Explanation
(1)	Configuration	Predicate device is a ceiling type digital x-ray imaging system and the proposed device is a Floor-mounted or Floor ceiling type digital x-ray imaging system. The difference of THU location doesn't affect the fundamental scientific characteristic of x-ray operation.
(2)	High Voltage Generator	The proposed device has the lower output power and tube current specification than the predicate device. The wider time range of proposed device makes the equivalent mAs range to predicate device.
(3)	Moving range	Due to the nature of Floor-mounted device, it has less flexibility of moving range than ceiling type device. This is a matter of convenience to use. Therefore proposed device is equivalent to predicate device.
(4)	Tube Assembly Rotation	Predicate device has wider range of the tube assembly rotation than proposed device. The rotation range of proposed device, ± 135, can operate the most of procedure intended for use in general radiography which makes equivalence of the proposed device to predicate device.

(5)	Moving Rail Type	The moving rail type of predicate and proposed device is designed suitable for each type of device, ceiling and floor mounted type. As the XGEO GF50 is complied with IEC60601-1, the fundamental mechanical safety is equivalent to the predicate device.
(6)	Detector Tilt	Proposed device doesn't provide detector tilt function. As detector tilt function is an optional function and not an essential requirement for safety and effectiveness of the system, it doesn't affect to the safety and effectiveness.
(7)	Table size and moving range	Proposed device has 2 types of the patient tables provides option to physicians for their convenience. The patient tables are complied with IEC60601-1 for basic electrical and mechanical safety. Therefore, it is equivalent to the predicate device.
(8)	Collimator Rotation	Proposed device has more collimator rotation angle than predicate device which gives more flexibility to the collimator positioning for patient.
(9)	Beam light source	Predicate device used LED lamp and proposed device uses Halogen lamp for beam light source. Halogen lamp is the one generally used light source before LED lamp was used. It is equivalent to the predicate device.
(10)	Resolution of detector	Proposed detector has better resolution than predicated. In the specification sheet, to compare with the same size detector (SDX-4336CP), proposed detector shows more number of pixels, short pixel pitch and higher contrast limiting resolution. In non-clinical data, the propose detector shows better curves and measurements of MTF and DQE than predicate device. In clinical data, the radiologists evaluate the image of XGEO GF50 is substantially equivalent to predicate device.
(11)	Communication	Proposed device supports wireless connection and wired connection by tether, while PD only supports wired connection. To ensure the safety and effectiveness of wireless communication between detector and workstation, the wireless function is tested by EN 301 489-1, EN 301 489-17, 47 CFR Part 15C, 47 CFR Part 15E, wireless specification and performance in testing lab and actual environment and evaluated under the risk management followed by a guidance, Radio frequency Wireless Technology in Medical Devices.

10. Safety, EMC and Performance Data:

Electrical, mechanical, environmental safety and performance testing according to standard ES 60601-1(2012), 21CFR1020.30 and 21CFR1020.31 were performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2007). Wireless function was tested and verified followed by guidance, Radio frequency Wireless Technology in Medical Devices. All test results were satisfied.

11. Non-clinical data

Non clinical test was conducted for imaging performance of the proposed detector. Both of the predicate device and proposed device are based on a-Si TFT photodiode arrays with a scintillator designed for general radiography. MTF and DQE were tested and measured by IEC 62220-1. MTF curves and measurements from the two detectors were compared and it shows that the propose detector perform better than the predicate in terms of the resolution at all spatial frequencies tested. In DQE, the propose device also has better DQE performance at all spatial frequencies tested because scintillator deposition method is different. Therefore, in non-clinical data review, the XGEO GF50 is substantially equivalent with the predicate device.

12. Clinical data

According to the CDRH guidance for the submission of 510(k)'s for Solid State X-ray Imaging Devices, concurrence study was conducted. The evaluation of the qualified radiologists in the study shows that XGEO GF50 provides images of equivalent diagnostic capability to the predicate device. It demonstrates that XGEO GF50 is substantially equivalent with the predicate device.

13. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Samsung Electronics Co., Ltd. concludes that The XGEO GF50 is safe and effective and substantially equivalent to predicate devices as described herein.

14. Samsung Electronics Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2014

SAMSUNG ELECTRONICS Co., Ltd.
% Jeongpyo Hong
Assistant Manager, Regulatory Affairs
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do, 443-742
REPUBLIC OF KOREA

Re: K140326
Trade/Device Name: XGEO GF50
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: April 28, 2014
Received: April 29, 2014

Dear Jeongpyo Hong:

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.

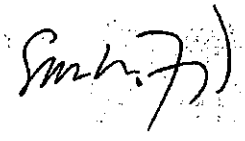
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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" (21CFR 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

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: XGEO GF50

Indications for Use:

The XGEO GF50 Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.

Prescription Use___X_____	AND/OR	Over-The-Counter Use____
(Part 21 CFR 801 Subpart D)		(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)