DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 9, 2015

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

Re: K143029
Trade/Device Name: Digital Diagnostic X-ray System (GC80)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: January 6, 2015
Received: January 8, 2015

Dear Chulsin Kim:

This letter corrects our substantially equivalent letter of February 4, 2015.

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,

Robert A Ochs

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143029

Device Name
GC80

Indications for Use *(Describe)*
The GC80 Series 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.

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.

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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:** January 6, 2015
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**
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   E-Mail: chulsin.kim@samsung.com

4. **Secondary 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-Mail: dfickett@samsungneurologica.com

5. **Identification Device**
   A. Trade Name: GC80
   B. Device Name: GC80
   C. Common Name: Digital Diagnostic X-ray System
   D. Classification Name: System, X-ray, Stationary
   E. Product Code: KPR
   F. Regulation: 21 CFR 892.1680

6. **Predicate Device**
   A. Manufacturer: SAMSUNG ELECTRONICS Co., Ltd.

B. Trade Name: XGEO GC80

C. Classification Name: System, X-ray, Stationary

D. Product Code: KPR

E. 510(k) Number: K140334

F. 510(k) Decision Date: May 28, 2014

7. Device Description

The GC80 digital X-ray imaging system consists of High voltage generator (HVG), Ceiling Suspension, X-ray tube, Collimator, Detector, AEC, DAP, CIB(Control Interface Box), Wall Stand, Patient Table, Collimator, Detector, Remote controller, Grid, Foot switch, Barcode scanner and Auto-stitching stand.

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 S-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.

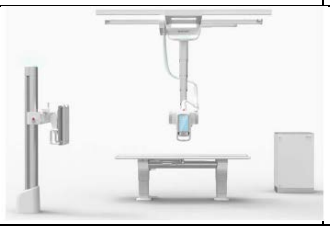
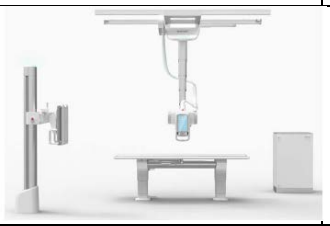
8. Intended Use

The 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.

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

The GC80 adds new detectors to the predicate device, and it does not have significant change in materials, energy source or technological characteristics compared to the predicate device, XGEO GC80 (K140334). 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	GC80	
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	

510(k) Number	K140334	N/A	
Appearances			Same
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 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.	Same

Manufacturer Contents		XGEO GC80 (K140334)	GC80	Discussion
(1)High Voltage Generator				
Type		High Frequency	High Frequency	Same
Max. Power		80kW	80kW	Same
Output RANGE	Tube Voltage	40-150kV	40-150kV	Same
	Tube Current	10-1000mA	10-1000mA	Same
	Exposure Time	1msec-6.3sec	1msec-6.3sec	Same
AEC (Automatic Exposure Control)		Yes	Yes	Same
APR (Anatomically Programmed Radiography)		Yes	Yes	Same

Manufacturer Contents		XGEO GC80 (K140334)	GC80	Discussion
(2)Ceiling Suspension				
Moving Range (mm)	Longitudinal	1680~4180 (Varies with room size)	1680~4180 (Varies with room size)	Same
	Lateral	1030~3030 (Varies with room size)	1030~3030 (Varies with room size)	Same

Manufacturer Contents		XGEO GC80 (K140334)	GC80	Discussion
	Vertical	1840	1840	Same
Vertical Tube Moving method		Motorized	Motorized	Same
Tube Assembly Rotation		-157 ~ +183	-157 ~ +183	Same
Brake locking Method		Electromagnetic	Electromagnetic	Same
Automatic Centering		O	O	Same
Moving Rail Type		Al Extrusion	Al Extrusion	Same
Image Preview		O	O	Same
Display Type		Color LCD	Color LCD	Same
Control Switch Type		Button + Touch Screen	Button + Touch Screen	Same
Vertical Sync.	With Table	O	O	Same
	With Stand	O	O	Same

Manufacturer Contents			XGEO GC80 (K140334)	GC80	Discussion
(3) Wall Stand					
Vertical Movement		Mechanism	Motorized/ Manual	Motorized/ Manual	Same
		Range(mm)	400~1800	400~1800	Same
Detector/tube servo coupling			Yes	Yes	Same
Detecto r	Tilting	Mechanism	Motorized	Manual	Same
		Range	-20~+90	-20~+90	Same
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

Manufacturer Contents		XGEO GC80 (K140334)	GC80	Discussion
(4)Patient Table				
Table Top	Size(mm)	2410 X 812	2410 X 812	Same

Manufacturer Contents			XGEO GC80 (K140334)	GC80	Discussion
	Range (mm)	Lateral	±140	±140	Same
		Longitudinal	±480	±480	Same
Table height	Mechanism		DC Motor, Ball screw	DC Motor, Ball screw	Same
	Range(mm)		545 ~ 900	545 ~ 900	Same
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)	350 (Static, Center load)	Same

Manufacturer Contents	XGEO GC80 (K140334)	GC80	Discussion
(5)Collimator			
Overall Size(mm)	H212 X W300 X D179	H212 X W300 X D179	Same
Beam Limiting Blade Moving Method	Motorized /Manual	Motorized /Manual	Same
Manual Operation Method	Volume	Volume	Same
Collimator Rotation	±45	±45	Same
Beam Light Source	LED	LED	Same
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 (K140334)	GC80	Discussion
*NOTE: S3025-W detector as an option is added in the list of detectors used for XGEO GC80 (K140334)			

Manufacturer Contents	XGEO GC80 (K140334)		GC80	Discussion
(6) Detector				
Name	S4335-W	S4343-W	S3025-W	
Detector Type	CsI	CsI	CsI	Same
	Indirect	Indirect	Indirect	Same
Detector Area	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10"X12" (245mmX295mm)	Difference(1)
Number of pixels	2466X3040	3036X3040	1750X2108	Difference(2)
Pixel Pitch(um)	140	140	140	
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	3.57	
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same

No	Differences	Explanation
(1)	Detector Area	Proposed medical device's detector has smaller area than the predicate device's detectors while technical specification is identical among them such as type & pixel pitch, and the smaller area does not contribute any adverse impacts to the predicate device's safety and performance.
(2)	Number of pixels Resolution and pixel pitch of detector	Proposed medical device's detector has smaller detector area. Therefore, the proposed medical device's numbers of pixels is smaller than the predicate device's detectors while pixel pitch is identical among them, and the smaller number of pixels does not contribute any adverse impacts to the predicate device's safety and performance.

In non-clinical data, the propose detector shows curves and measurements of MTF and DQE that do not differ from the predicate device.

In clinical data, the radiologists evaluate the image of GC80 is substantially equivalent, and superior in some images to the predicate device.

10. Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing according to standard ES 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-54, ISO14971, 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 satisfying the standards.

11. Non-clinical data

In non-clinical data, MTF and DQE were tested and measured by IEC 62220-1. The proposed device shows no different curves and measurements of MTF and DQE from the predicate device.

12. Clinical data

Clinical images were provided; these images were not necessary to establish substantial equivalence but they provide further evidence in addition to the laboratory performance data to show that the whole system works as intended.

13. Conclusions

The non-clinical and clinical data demonstrates that the proposed device is as safe, as effective, and performs as well as the legally marketed device identified in paragraph 6.

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