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

December 7, 2016

SAMSUNG ELECTRONICS Co., Ltd.
% Mr. Chulsin Kim
Regulatory Affairs Manager
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do 16677
REPUBLIC OF KOREA

Re: K163115
Trade/Device Name: GC70
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: October 31, 2016
Received: November 7, 2016

Dear Mr. Kim:

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.
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)*

K163115

Device Name
GC70

Indications for Use *(Describe)*

The GC70 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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Section 5: 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:** Oct 31, 2016

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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4. **Secondary Contact Person**
   A. Name: Ninad Gujar
   B. Title: Director of Regulatory Affairs
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   D. FAX Number: 978-750-6677
   E-Mail: ngujar@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: GC70
   B. Device Name: GC70
   C. Common Name: Digital Diagnostic X-ray System
   D. Classification Name: Stationary x-ray system
   E. Product Code: KPR
   F. Regulation: 21 CFR 892.1680

6. **Predicate Devices**
   A. Trade Name: GC85A
   B. Device Name: GC85A
   C. Common Name: Digital Diagnostic X-ray System
   D. Classification Name: Stationary x-ray system
   E. Product Code: KPR
   F. Regulation: 21 CFR 892.1680
   G. 510(k): K160997

7. **Device Description**
   The GC70 digital X-ray imaging 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.

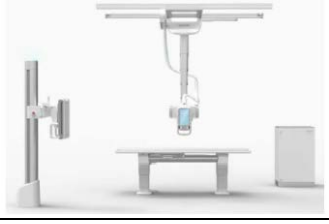
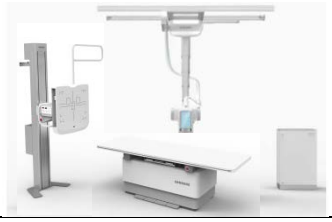
8. Intended Use

The GC70 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 devices

The proposed device, GC70, has same detectors and image processing as the predicate device so it does not have significant changes in imaging performance in comparison to the predicate device, and has few configuration options more as HVG(High Voltage Generator), Wall Stand and Patient Table are added.

A. Comparing with Predicate Device

Specification	Predicate Device	Proposed Device	Discussion
Device Name	GC85A	GC70	
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	Same
510(k) Number	K160997	None	
Appearances			Difference(1)
Intended Use	The GC85A 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 GC70 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	GC85A (K160997)	GC70	Discussion
(1)High Voltage Generator			

Manufacturer Contents		GC85A (K160997)	GC70		Discussion
Max. Power		82kW	82kW	52kW	Same & Differences(2)
Output RANGE	Tube Voltage	40-150kV	40-150kV	40-150kV	Same
	Tube Current	10-1000mA	10-1000mA	10-640mA	Same & Differences(3)
	Exposure Time	1msec-10sec	1msec-10sec	1msec-10sec	Same

Manufacturer Contents			GC85A (K160997)	GC70	Discussion
(3) Wall Stand					
Vertical Movement		Mechanism	Motorized	Motorized	Same
		Range(mm)	280~1850	412~1838	Differences(4)
Detector	Tilting	Motorized	Motorized	Motorized	Same
		-20~+90	-20~+90	-30~+90	Differences(5)

Manufacturer Contents			GC85A (K160997)	GC70		Discussion
(4)Patient Table						
Table Top	Size(mm)		2410 X 812	2410 X 812	2200 X 810	Same
	Range (mm)	Lateral	±140	±140	±125	Same & Differences(6)
		Longitudinal	±480	±480	±500	Same & Differences(7)
Table height	Mechanism		DC Motor, Ball screw	DC Motor, Ball screw	DC Motor, Ball screw	Same
	Range(mm)		545 ~ 900	545 ~ 900	565 ~ 850	Same & Differences(8)
Horizontal range of detector(mm)			688	688	290	Same & Differences(9)
Maximum Patient Weight(kg)			350 (Static, Center load)	350 (Static, Center load)	300 (Static, Center load)	Same & Differences(10)

Manufacturer Contents	GC85A (K160997)			GC70			Discussion
(6) Detector (already cleared with K160997)							
Name	S4335-W	S4343-W	S3025-W	S4335-W	S4343-W	S3025-W	Same
MTF	84% (0.5 lp/mm, Typical)	85 % (0.5 lp/mm, Typical)	86% (0.5 lp/mm, Typical)	84% (0.5 lp/mm, Typical)	85 % (0.5 lp/mm, Typical)	86% (0.5 lp/mm Typical)	Same
DQE	73% (0.1 lp/mm, Typical)	80 % (0.1 lp/mm, Typical)	78% (0.1 lp/mm, Typical)	73% (0.1 lp/mm, Typical)	80 % (0.1 lp/mm, Typical)	78% (0.1 lp/mm, Typical)	Same

Manufacturer Contents	GC85A (K160997)	GC70	Discussion
(8) Software Features (already cleared with K160997)			
Feature Names	SimGrid	SimGrid	Same
	Bone Suppression Image	Bone Suppression Image	Same
Description			
The SimGrid is an additional image processing software option which is able to compensate the contrast loss due to scatter radiations, primarily acquisitions without a physical anti-scatter grid. The Bone Suppression Software features that will be made to Samsung Digital X-ray imaging Systems are adding Samsung's new post image processing algorithm. This SW can provide companion images to assist diagnosis in addition to the images obtained from normal diagnosis protocol. The Bone Suppression software option suppresses bone anatomy to enhance visualization of chest pathology in a companion image that is delivered in addition to the original diagnostic image.			

B. **Difference Table**

No	Differences	Explanation
(1)	Appearance	The table and stand of the proposed device is a basic model in comparison with the predicate device's one, which does not contribute any adverse impacts to the device's safety and performance and image quality.
(2)	Max. Power	The difference of max power rate does not contribute any adverse impacts to the device's safety and performance and image quality.
(3)	Tube Current	The difference of tube current does not contribute any adverse impacts to the device's safety and performance and image quality.
(4)	Vertical Movement - Range	The difference of vertical Moving range does not contribute any adverse impacts to the device's safety and performance and image quality.
(5)	Detector – Tilting	The difference of Detector – Tilting does not contribute any adverse impacts to the device's safety and performance and image quality.
(6)	Table Top - Lateral	The difference of lateral moving range does not contribute any adverse impacts to the device's safety and performance and image quality.
(7)	Table Top - Longitudinal	The difference of table top longitudinal moving range does not contribute any adverse impacts to the device's safety and performance and image quality.
(8)	Table Height - range	The difference of Table Height - range does not contribute any adverse impacts to the device's safety and performance and image quality.
(9)	Horizontal range of detector.	The difference of horizontal range of detector does not contribute any adverse impacts to the device's safety and performance and image quality.
(10)	Maximum Patient Weight	The difference of maximum patient weight does not contribute any adverse impacts to the device's safety and performance and image quality.

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. 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

Non-clinical testing data was provided in conformance to the FDA “Guidance for the Submission of 510(k)’s for Solid-State X-ray Imaging Devices”, which includes MTF and DQE measurements as tested by IEC 62220-1.

The proposed device shows no difference in non-clinical testing data such as MTF and DQE measurements from the predicate device.

The software contained in the proposed device has been developed & tested in the S/W development procedure on IEC62304, and the Guidance for Content of Premarket Submissions for Software Contained in Medical Devices.

The dosimetry performance has been evaluated with IEC60601-1, and the recommened exposure chart is provided in the user manual.

12. Clinical data

In clinical data, phantom image evaluations were performed in accordance with FDA guidance for the submission of 510(k)’s for Solid State X-ray Imaging Devices. They were evaluated by a professional radiologist and found to be equivalent to the predicate device.

13. Conclusions

The non-clinical and clinical data demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed devices.