DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 6, 2016

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

Re: K160997
Trade/Device Name: GC85A
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: April 7, 2016
Received: April 11, 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)*
K160997

Device Name
GC85A

Indications for Use *(Describe)*
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.

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:** April 07, 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

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4. **Secondary Contact Person**
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   B. Title: Regulatory Affairs Manager
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   D. FAX Number: 978-750-6677
   E-Mail: ngujar@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: GC85A
   B. Device Name: GC85A
   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 Devices**

	Predicate Device #1	Predicate Device #2	Predicate Device #3
Device Name	GC85A	FDR D-EVO FLAT PANEL DETECTOR SYSTEM	DRX-EVOLUTION
Classification Name	Stationary X-ray System	Stationary x-ray system.	Stationary x-ray system.
Product Code	KPR	MQB	KPR
Regulation	21 CFR 892.1680	21 CFR 892.1680	21 CFR 892.1680
510(K)#	K150165	K141765	K141837
510(K)	April 02, 2015	October 03, 2014	March 11, 2015

Decision Date			

7. Device Description

The GC85A 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.

The SimGrid is a post-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 Image (BSI) is a post-image processing software option which provides companion images to assist diagnosis in addition to the images obtained from normal diagnosis protocol. The BSI 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.
The SimGrid and BSI are available as options to be exclusively installed in S-station, which is a Samsung Digital X-ray operation S/W, since this post-image processing software does not depend on how the image is acquired, or with what acquisition device.

8. Intended Use

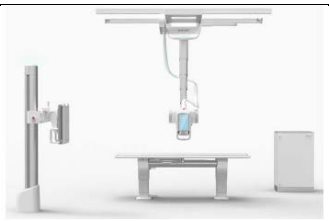
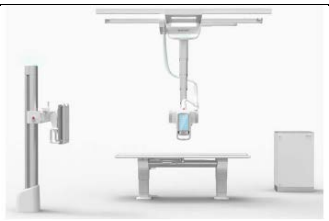
The GC85A Digital X-ray Imaging System is intended for use in generating radiographic images of human anatomy by a qualified/trained doctor or technician. This device is not intended for mammographic applications.
The SimGrid is a technology that enhances the visibility of major clinical equipment by compensating for the decrease in contrast that is caused by scatter radiation when the portable grid is not used for portable images.
Bone Suppression is a technology that helps to create images with good lung field visibility by removing part of the ribs and clavicle with S/W algorithms. It is used as diagnosis assistance for areas that the image reader is interested in, such as soft tissues and lesions in the lung field.

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

The proposed device, GC85A, has the same technological characteristics as its original predicate device, GC85A (K150165), and adds two post-image processing software features, SimGrid and BSI(Bone Suppression Image), and other minor software features such as S-Align & S-Guide, and hardware such as a collimator and a weight distribution cap. All features do not have significant change in materials, energy source or technological characteristics compared to the predicate devices #1, 2 & 3.

A. Comparing with Predicate Device #1

Specification	Predicate Device #1	Proposed Device	Discussion

Device Name	GC85A	GC85A		-
Manufacturer	SAMSUNG ELECTRONICS co., ltd.	SAMSUNG ELECTRONICS co., ltd.		-
510(k) Number	K150165	None		-
Appearances				Same
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 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.		Same
Collimator	*NOTE: SDR-OGCL80U was cleared with K150165			
Model Names	SDR-OGCL80U	SDR-OGCL80U	SDR-OGCL83U	Difference(1)
Overall size(mm)	H212 X W300 X D179	H212 X W300 X D179	H212 X W306 X D179	Difference(1)
Weight Distribution Cap				
Model Name	None	SDR-OGWD80U W x L x H(mm): 505x553x37.4		Difference(2)
Software Features				
Feature Names	None	S-Align & S-Guide		Difference(3)

No	Differences	Explanation
(1)	Collimator Overall Size	The new SDR-OGCL83U collimator has 6mm wider width than the predicate device‘s collimator. It does not contribute adverse impacts to the device safety and performance.
(2)	Weight Distribution Cap	As an accessory, it is introduced to prevent the detector from being damaged by excessive force, which does not contribute adverse impacts to the device safety and performance.
(3)	S-Align & S-Guide	S-Align is to display the tilt angle of the portable detector, and S-guide is to display the values (stitching areas) required for image capturing. Both don’t contribute adverse impacts to the device safety and performance.

B. Comparing with Predicate Device #2

Specification	Predicate Device #2	Proposed Device	Discussion
Device Name	FDR D-EVO FLAT PANEL DETECTOR SYSTEM	GC85A	-
Manufacturer	FUJIFILM Medical Systems U.S.A Inc.	SAMSUNG ELECTRONICS co., ltd.	-
510(k) Number	K141765	None	-
Intended Use	The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film/screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.	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.	Difference(1)
S/W Feature Name	Virtual Grid Software	SimGrid	-
S/W description	The Virtual Grid Software is designed to improve image contrast in general radiographic images by reducing the effects of scatter radiation, primarily for exams acquired without a grid.	The SimGrid is a technology that enhances the visibility of major clinical equipment by compensating for the decrease in contrast that is caused by scatter radiation when the portable grid is not used for portable images.	Same

No	Differences	Explanation
(1)	Intended Use	The intended use of both devices is different, but the s/w feature's application is same as the post-image processing software, which does not contribute adverse impacts to the device safety and performance.

C. Comparing with Predicate Device #3

Specification	Predicate Device #3	Proposed Device	Discussion
Device Name	DRX-EVOLUTION	GC85A	-

Manufacturer	FUJIFILM Medical Systems U.S.A Inc.	SAMSUNG ELECTRONICS co., ltd.	-
510(k) Number	K141837	None	-
Intended Use	The device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging including tomography. The tomography feature is not to be used for imaging pediatric patients.	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.	Difference(1)
S/W Feature Name	Bone Suppression	Bone Suppression Image	-
S/W description	Bone Suppression can improve visibility of lung nodules and other pathology by suppressing the appearance of posterior ribs and clavicles.	Bone Suppression is a technology that helps to create images with good lung field visibility by removing part of the ribs and clavicle with S/W algorithms. It is used as diagnosis assistance for areas that the image reader is interested in, such as soft tissues and lesions in the lung field.	Same

No	Differences	Explanation
(1)	Intended Use	The intended use of both devices is different, but the s/w feature's application is same as the post-image processing software, which does not contribute adverse impacts to the device safety and performance.

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 #1.

SimGrid software was evaluated with various phantoms at various exposure conditions to demonstrate that SimGrid processing gives the better local contrast than images acquired without a grid. The qualitative side including usefulness was validated by a radiographer using clinical images which was proved in 'Clinical data' section.

12. Clinical data

In clinical data, clinical 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 devices.

BSI software was evaluated with various kinds of clinical images, such as with various sizes of patients at various exposure conditions, by a professional radiologist. Overall quality of the bone suppressed images was found to be useful as diagnosis assistance for areas that the reader is interested in, such as soft tissues and lesions in the lung field.

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.