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

November 15, 2016

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

Re: K162278
Trade/Device Name: GM85
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL, MQB
Dated: October 24, 2016
Received: October 26, 2016

Dear Chulsin 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)*
K162278

Device Name
GM85

Indications for Use *(Describe)*
The GM85 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

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:** August 10, 2016

2. **Submitter**
   A. Company Name: SAMSUNG ELECTRONICS Co., Ltd.
   B. Address: 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16677, Republic of Korea

3. **Primary Contact Person**
   A. Name: KIM, CHULSIN
   B. Title: Regulatory Affairs Manager
   C. Phone Number: +82-31-200-7661
   D. FAX Number: +82-31-200-1199
   E-Mail:chulsin.kim@samsung.com

4. **Secondary Contact Person**
   A. Name: Ninad Gujar
   B. Title: Director, Regulatory & Quality
   C. Phone Number: 978-564-8503
   D. FAX Number: 978-750-6677
   E-Mail: ngujar@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: GM85
   B. Device Name: GM85
   C. Common Name: Digital Diagnostic Mobile X-ray System
   D. Classification Name: Mobile X-ray System
   E. Product Code: IZL & MQB
   F. Regulation: 21 CFR 892.1720

6. **Predicate Devices**

	Predicate Device #1	Predicate Device #2	Predicate Device #3
Device Name	GM60A-32S, GM60A-40S	GC85A	ClearRead +Confirm
Classification Name	MobileX-ray system.	Stationary X-ray System	System, Image Processing, Radiological
Product Code	IZL	KPR	LLZ
Regulation	21 CFR 892.1720	21 CFR 892.1680	21CFR 892.2050
510(K)#	K150097	K160997	K123526
510(K) Decision Date	February 19, 2015	April 02, 2015	December 27, 2012

7. Device Description

The GM85 Digital Mobile X-ray imaging System is the equipment that captures 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 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 of all kinds of anatomical regions.
The SimGrid is available as options to be exclusively installed in S-station, which is a Samsung Digital X-ray operation S/W, while this post-image processing software does not depend on how the image is acquired, or with what acquisition device.

The Tube & Line Enhancement (TLE) is that after generating a normal post processing image, pressing the TLE button will create a companion view. For making a better tube & line look in chest radiography, input raw image is processed by using stronger contrast and detail enhancement algorithm. This supports clearer visibility of tube & lines than normal post processing image.
TLE is available as options to be exclusively installed in S-station, which is a Samsung Digital X-ray operation S/W, while this post-image processing software does not depend on how the image is acquired, or with what acquisition device.

The Pediatric Exposure Management provides subdivided patient size and exposure conditions of chest and abdomen radiographs specially optimized for pediatric patients. It helps an optimal dose for radiographic procedures of pediatric patients by providing guidance of optimized exposure conditions according to patient's weight and procedures.

8. Intended Use

The GM85 Digital Mobile 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 of all kinds of anatomical regions.

The Tube & Line Enhancement enhances the visibility of tube and line to support radiologists or ICU clinicians who may need to find tubes and line on chest radiographs by trained professionals, such as physician, radiologists, and technicians.

The Pediatric Exposure Management support radiologists to select suitable patient's size or take steps to serve an optimal exposure conditions to the lowest possible levels

especially for the pediatric patients.

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

The proposed device, GM85, has same detectors and image processing as predicate devices so it does not have significant changes in image characteristics compare to the predicate device #1 & #2, GM60A and GC85A.

SimGrid, optional post-image processing software, has same image processing technology as SimGrid of predicate device, SimGrid technology is possible to applying to all kinds of anatomical regions where scatter radiation cause the contrast decrease. Specific description is added to make it clear with the non-clinical data, because the description of the predicate device was not mentioned about the target anatomical regions specifically.

Tube & Line Enhancement (TLE) and ClearRead +Confirm (K123526) are the same kind of function in that both include software with the ability to enhance visibility of tube and line. These are also provided in addition to the application and used to assistant tool for radiologist.

Pediatric Exposure Management is subdivided patient size and exposure conditions especially for pediatric patients based on weight and protocols. It follows same methodologies to define preset of patient size compare to preset of standard patient size from predicate device but specially optimized for pediatric patients.

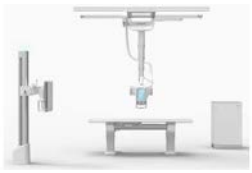
The gantry of GM85 is newly designed to enhance coverage of tube head and usability but it has same structures of battery powered system, wheel based movable body, built-in console, rotational collapsible column, extractable arm and rotational tube head as predicate device #1 GM60A so it does not have significant changes in acquiring radiographic images compare to predicate device #1 GM60A.

Comparisons of the following technological characteristics were assessed and the results demonstrate the substantial equivalence to the predicates.

A. Comparing with Predicate Device #1 and #2

The proposed device is shown as its parts are identical or equivalent with predicate device #1 or #2 while some differences are made as below, which does not show significant difference in safety and effectiveness.

Specification	Predicate Device #2	Proposed Device	Predicate Device #1	Discussion
Device Name	GC85A	GM85	GM60A-32S, 40S	
Manufacturer	SAMSUNG ELECTRONICS co., ltd.	SAMSUNG ELECTRONICS co., ltd.	SAMSUNG ELECTRONICS co., ltd.	
510(k) Number	K160997	-	K150097	

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 GM85 Digital Mobile 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 GM60A Digital Mobile 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		Predicate Device #2		GM85	Predicate Device #1		Discussion
(2)Tube assembly							
Moving Range	Horizontal	1680~4180mm		793~1355mm	700~1250mm		Difference(2)
	Vertical	1030~3030mm		550~2030mm	550~2020mm		Difference(2)
Tube	Target Angle	12°		14°	12°	16°	Difference(3)
Collimator		SDR-OGCL80U 212X300X179mm	SDR-OGCL83U 212X306X179mm	SDR-OGCL40U 212 X 306 X 179mm	RALCO R221 DHHS		Difference(4)

Manufacturer Contents	Predicate Device #2	GM85	Predicate Device #1	Discussion
(6) Software Feature				
SimGrid	SimGrid	SimGrid	-	Difference(5)
Tube & Line Enhancement(TLE)	-	TLE	-	Difference(6)
Pediatric Exposure Management(PEM)	-	PEM	-	Difference(7)
S-Align	S-Align	S-Align	-	Difference(8)

No	Differences	Explanation
(1)	Appearance	The gantry of GM85 is newly designed to enhance coverage of tube head and usability but it has same structures of battery powered system, wheel based movable body, built-in console, rotational collapsible column, extractable arm and rotational tube head as predicate device #1 GM60A. So it does not have significant changes in acquiring radiographic images compare to predicate device #1, GM60A.

(2)	Moving Range	Extended coverage of proposed device GM85 can be more helpful to set position than predicate device #1, GM60A.
(3)	Tube Target Angle	Tube target angle is maximized while focal spot is maintained 0.6/1.2mm for proposed device GM85. Larger target angle increases X-ray beam coverage and enhances usability. Tube target angle 14° of proposed device GM85 does not have significant changes in image characteristics compare to tube target angle between 12° and 16° of predicate device #1 GM60A.
(4)	Collimator	Collimator (SDR-OGCL40U) of proposed device, GM85 has same design compare to collimator (SDR-OGCL80U) of predicate device #2, GC85A but collimator(SDR-OGCL40U) of proposed device, GM85 has some mechanical changes to mount sub display unit on it from predicate device #2 GC85A. So it does not have significant changes in performance compare to predicate device #2 GC85A.
(5)	SimGrid	SimGrid, optional post-image processing software, has same image processing technology as SimGrid of predicate device #2 GC85A. SimGrid technology is possible to applying to all kinds of anatomical regions where scatter radiation cause the contrast decrease. Specific description is added to make it clear with the non-clinical data, because the description of the predicate device #2 was not mentioned about the target anatomical regions specifically.
(6)	Tube & Line Enhancement (TLE)	Tube & Line Enhancement (TLE) is optional software to make an additional image with enhanced tube and line besides original post processing image. It focused on enhancement of tubes and lines regardless of patient size and should be used only as an assistant tool. (Refer to the comparing with predicate device #3)
(7)	Pediatric Exposure Management (PEM)	Pediatric Exposure Management is subdivided patient size and exposure conditions especially for pediatric patients based on weight and protocols. It follows same methodologies to define preset of patient size compare to preset of standard patient size from predicate device but specially optimized for pediatric patients.
(8)	S-Align	S-Align of proposed device GM85 has same design but GM85 is operated only in manual compare to predicate device GC85A and it doesn't contribute adverse impacts to the device safety and performance.

B. Comparing with Predicate Device #3

Specification	Predicate Device #3	Proposed Device	Discussion
Device Name	ClearRead +Confirm	GM85	-
Manufacturer	Riverain Technologies, LLC	SAMSUNG ELECTRONICS co., ltd.	-
510(k) Number	K123526	None	-
S/W Feature Name	ClearRead +Confirm 1.0	Tube & Line Enhancement	-
Intended Use	ClearRead +Confirnm is intended to generate an enhanced secondary digital radiographic image of the chest to facilitate confirmation of line/tubes. The enhanced AP or PA image of the chest provides improved visibility of lines and tubes. The ClearRead +Confirm image provides adjunctive information and is not	Tube & Line Enhancement (TLE) software generates a companion image which can provide clear visibility of tubes and lines in addition to the original chest radiograph. Since the image generated by TLE is intended to be used to assist diagnosis, the TLE image should be	Difference(6)

	a substitute for the original PA/AP image. This device is intended to be used by trained professionals, such as physicians, radiologists, and technicians, on patients with lines and tubes and is not intended to be used on pediatric patients.	provided with the original diagnostic chest radiograph. TLE software is intended to be used by qualified/ trained doctors or technicians on patients with tubes and lines.	

No	Differences	Explanation
(6)	Intended Use	Since TLE software amplify specific frequencies suitable for tubes and lines partially, it does not depend on the size of patients. Therefore TLE software can be used for all patients including the pediatric patient. So it does not have significant changes in performance compare to predicate device #3.

C. 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.

D. 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 has same detectors so it shows no difference in non-clinical testing data such as MTF and DQE measurements from the predicate device #1 and #2.

SimGrid software, 510(k) cleared before with predicate device #2 was evaluated with various phantoms at various exposure conditions demonstrating that SimGrid processing gives the better local contrast than images acquired without a grid at expanded anatomical regions.

Tube & Line Enhancement(TLE) was evaluated with the phantom. After input image is acquired with chest phantom which is inserted tube line, the normal post image and TLE image are created. Then, the three images are compared in terms of the tube & line contrast. This evaluation proves that TLE processing gives the better tube and line visibility than original post processing.

E. 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 devices. Evaluated 30case of phantom image includes eight parts of the body.

F. 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 predicate devices #1, #2 and #3.