July 20, 2018

Samsung Electronics Co., Ltd.
% Jaesang Noh
Senior Professional, Regulatory Affairs
129, Samsung-ro, Yeongtong-gu,
Suwon-si, Gyeonggi-do 16677
REPUBLIC OF KOREA

Re: K181631
Trade/Device Name: GR40CW
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: June 15, 2018
Received: June 20, 2018

Dear Jaesang Noh:

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.
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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K181631

Device Name
GR40CW

Indications for Use *(Describe)*

The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. 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.

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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:** June 15, 2018

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: JAESANG NOH & CHUNSIN KIM
   B. Title: Regulatory Affairs, Senior Professional
   C. Phone Number: +82-2-2193-2444 & +82-2-2193-2437
   D. FAX Number: +82-31-200-6401
   E. E-Mail: jaesang.noh@samsung.com & chulsin.kim@samsung.com

4. **Secondary Contact Person**
   A. Name: Genci Omari
   B. Title: Manager, Regulatory Affairs
   C. Phone Number: 978-564-8602
   D. FAX Number: 978-560-0602
   E. E-Mail: gomari@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: GR40CW
   B. Device Name: GR40CW
   C. Common Name: Retrofit Kit
   D. Regulation Name: Stationary x-ray system
   E. Product Code: MQB
   F. Regulation: 21 CFR 892.1680

6. **Predicate Devices**

	Predicate Device #1	Predicate Device #2
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.
Device Name	GR40CW	GM85
Common Name	Retrofit Kit	Digital Diagnostic Mobile X-ray System
Regulation Name	Stationary x-ray system	Mobile X-ray System
Product Code	MQB	IZL
Regulation	21 CFR 892.1680	21 CFR 892.1720
510(k) Number	K180543	K171119
510(k) Decision Date	May 24, 2018	May, 12, 2017

7. Device Description

The GR40CW digital X-ray imaging system consists of Detector, Power supply box, Battery pack, Battery charger, Access point, CIB(Control Interface Box), Workstation, Barcode scanner, Main cable and software for image acquisition and image processing and does not include the X-ray generator. 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.

The GR40CW digital X-ray imaging system was previously cleared with K180543, and through this premarket notification, we would like to add more configurations in the previously cleared GR40CW as three detectors are newly added, and some software features called as SimGrid, S-Enhance, BSI (Bone Suppression Image), Remote View and manual Stitching are newly added as stated below.

SimGrid software option, cleared with K171119, is able to compensate the contrast loss due to scatter radiations, primarily acquisitions without a physical anti-scatter grid.

BSI software option suppresses bone anatomy and S-Enhance is renamed from Tube & Line Enhancement (TLE), which was cleared before with the predicate device GM85 at K171119, to enhance visibility of tubes and lines and provide enhanced images separately from original images. In this submission, the scope of S-Enhance is expanded from tubes and lines on chest images to foreign body (e.g. tubes, lines and needles) and urinary stones on chest, abdomen, and L-spine. And Manual Stitching to capture a body part that is larger than the detector's by capturing multiple images and Remote View function to remote access to view the current image on the workstation through a web browser. It was determined that the level of concern for the software contained in the GR40CW digital X-ray imaging system was Moderate in accordance with the FDA guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Device".

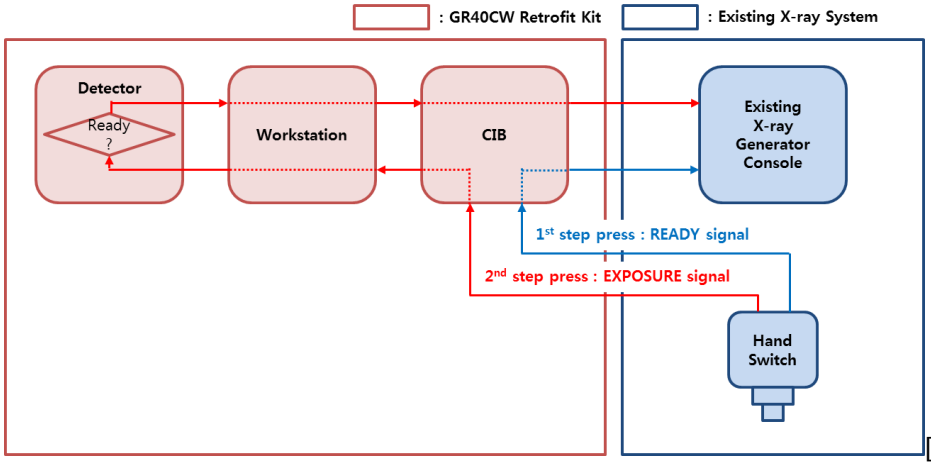
Integration Information

This is a retrofit system consisting of Detectors, Power supply box, Battery pack, Battery charger, Access point, CIB (Control Interface Box), Workstation, Barcode scanner and Main cable. This retrofit system is designed to generate a digital image while using the current analogue X-ray system by upgrading only the part of an analogue cassette film to the digital panel(detector), and does not get involved in controlling X-ray radiation related parameters, which is still controlled by the existing X-ray system.

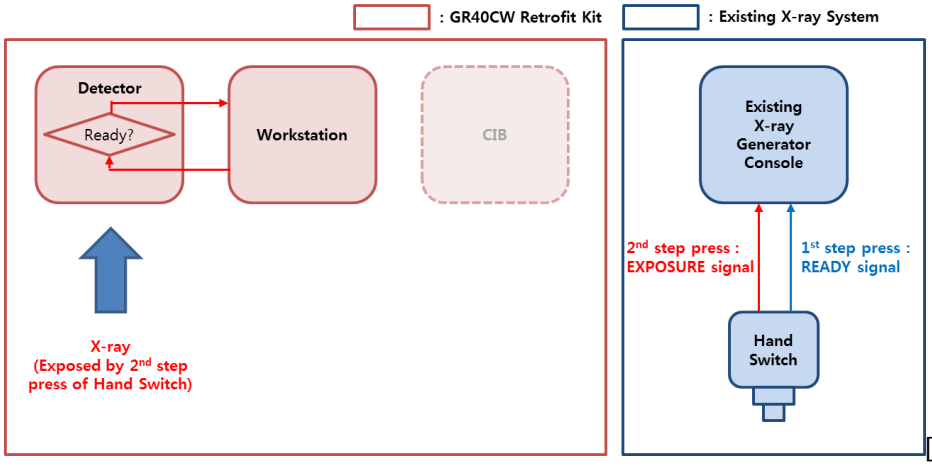
The GR40CW retrofit system can be applied to the existing analogue X-ray system by two ways (CIB and AED modes). 1) In CIB mode, CIB is only connected to a signal line of a hand switch for passively detecting the signal, as On or Off, coming out from the hand switch to the X-ray Generator Console, to make the digital detector ready to active or inactive to receive X-ray radiation. 2) In AED (Automatic Exposure Detection) mode, without CIB, the detector is sensing of radiation exposure. Once it recognizes the exposure, it become active right away to receive X-ray radiation. This whole process is independently operated from the existing

analogue X-ray system.

[Integration Diagram]



[CIB mode]



[AED mode]

In conclusion, this retrofit kit does not either require a modification / alteration or control in the part of X-ray radiation control of the current X-ray system in anyway.

8. Intended Use

The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. This device is not intended for mammographic applications.

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

The proposed device GR40CW apply the software feature as S-Enhance, which were cleared with K171119, to GR40CW product which was cleared with K180543 without changes in technical characteristics, materials, energy sources and biocompatibility such as X-ray Tube Assembly except of detector. Optional three detectors which were improved durability and dust/water-resistance are added to GR40CW.

Comparisons of technological characteristics were executed and demonstrate the substantial equivalence to the predicate.

A. Comparing with Predicate Device

Specification	Predicate Device #1	Proposed Device	Predicate Device #2	Discussion
Device Name	GR40CW	GR40CW	GM85	
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG ELECTRONICS Co., Ltd.	
510(k) Number	K180543	None	K171119	
Appearances				Same as PD#1
Intended Use	The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. This device is not intended for mammographic applications.	The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. 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.	Same as PD#1

Manufacturer Contents	GR40CW (K180543)			GR40CW			GM85 (K171119)		Discussion
(1) Detector									
Name	S4335-WV S4335-W S4343-W S3025-W			S4335-WV S4335-W S4343-W S3025-W S4335-AWV S4335-AW S4343-AW			S4335-W S4343-W S3025-W		Difference(1)
	S4335-W	S4335-WV	S4343-W	S4335-AW	S4335-AW	S4343-AW	S4335-W	S4343-W	

Manufacturer Contents	GR40CW (K180543)			GR40CW			GM85 (K171119)		Discussion
					V				
Detector Type	CsI	Gd_2O_2S	CsI	CsI	Gd_2O_2S	CsI	CsI	CsI	Same as PD#1
	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Indirect	Same as PD#1
Detector Area	14"X17"(345mmX425mm)	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	14"X17"(345mmX425mm)	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	14"X17"(345mmX425mm)	17"X17"(425mmX425mm)	Same as PD#1
Number of pixels	2466X3040	2466X3040	3036X3040	2466X3040	2466X3040	3036X3040	2466X3040	3036X3040	Same as PD#1
Pixel Pitch(um)	140	140	140	140	140	140	140	140	Same as PD#1
High Contrast Limiting Resolution (LP/mm)	3.57	3.5	3.57	3.57	3.5	3.57	3.57	3.57	Same as PD#1
Communication	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Wired / Wireless	Same as PD#1
Dust/Water-resistance	IPx1			IP54			IPx1		Difference(1)-1
Max.load capacity	150 kg for uniform load, 100 kg for local load (40 mm in diameter disk at the center)			400 kg for uniform load, 200 kg for local load (40 mm in diameter disk at the center)			150 kg for uniform load, 100 kg for local load (40 mm in diameter disk at the center)		Difference(1)-2

Manufacturer Contents	GR40CW (K180543)	GR40CW	GM85 (K171119)	Discussion
(2) Software Features				
Feature Names	-	SimGrid	SimGrid	Same as PD#2
	-	S-Enhance	TLE	Difference(2)
	S-Share	S-Share	S-Share	Same
	-	BSI	BSI	Same as PD#2
	-	Remote View	-	Difference(3)

Manufacturer Contents	GR40CW (K180543)	GR40CW	GM85 (K171119)	Discussion
	-	Manual Stitching	-	Difference(4)

No	Differences	Explanation
(1)-1	Dust/Water-resistance	The new detectors which are added to the GC85A device have better dust/water-resistance than the predicate device's dust/water-resistance and this change does not contribute any adverse impact to the device's safety and effectiveness.
(1)-2	Max.load capacity	The new detectors which are added to the GC85A device have higher max load capacity than the predicate device's max load capacity and this change does not contribute any adverse impact to the device's safety and effectiveness.
(2)	S-Enhance	S-Enhance is renamed from Tube & Line Enhancement (TLE), which was cleared with K171119, is to enhance visibility of tubes and lines and provide enhanced images separately from original images. This software feature is applied to the GC85A with the scope of application for S-Enhance, which is expanded from tubes and lines on chest images to foreign body (e.g. tubes, lines and needles) and urinary stones on chest, abdomen and L-spine images. This change is considered low risk and does not contribute any adverse impact to the device's safety and effectiveness.
(3)	Remote View	The function of Remote View, which allows remote access to view the current image on the workstation through a web browser, is applied to the GR40CW and this change does not contribute any adverse impact to the device's safety and effectiveness.
(4)	Manual Stitching	Manual Stitching can capture a body part that is larger than the detector's area by capturing multiple images. This function is considered low risk and does not contribute any adverse impact to the device's safety and effectiveness.

B. Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing were conducted according to standard ES 60601-1(2012), and EMC testing was conducted according to IEC 60601-1-2(2007). Wireless function was tested and verified followed by the guidance for Radio frequency Wireless Technology in Medical Devices. All test results were satisfying with the standards.

C. 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.

D. Clinical data

Phantom image evaluations for the new detector and S-Enhance were performed in accordance with FDA guidance for the submission of 510(k)'s for Solid State X-ray Imaging Devices. Anthropomorphic phantom images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device (note X-ray flat-panel detector similar to the predicate detector) but they provide further evidence in addition to the performance data to show that the complete system works as intended. They were evaluated by professional radiologists and found to be equivalent to the predicate devices. There is no significant difference in the average score considering the standard deviation of image quality evaluation between the proposed device and the predicate device and it is confirmed that S-Enhance is able to generate a companion image which provide clear visibility for foreign bodies such as lines, tubes, and needles, and urinary stones in chest, abdomen, and L-spine protocol in addition to the original images. Therefore, these changes do not affect either the safety or the effectiveness, compared to the predicated device.

E. Conclusions

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