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

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

December 21, 2015

Re: K153401
Trade/Device Name: GR40CW
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: November 25, 2015
Received: November 27, 2015

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,

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)*

K153401

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.

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:** November 20, 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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4. **Secondary Contact Person**
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   B. Title: Regulatory Affairs Manager
   C. Phone Number: 978-564-8503
   D. FAX Number: 978-750-6677
   E. E-Mail: ngujar@samsungneurologica.com

5. **Proposed Device**
   A. Trade Name: GR40CW
   B. Device Name: GR40CW
   C. Common Name: Retrofit Kit
   D. Classification Name: Solid State X-ray Imager (Flat panel/Digital imager)
   E. Product Code: MQB
   F. Regulation: 21 CFR 892.1680

6. **Predicate Devices**

	The 1st Predicate Device	The 2nd Predicate Device
Manufacturer	SAMSUNG ELECTRONICS Co., Ltd.	SAMSUNG MOBILE DISPLAY Co., Ltd.
Device Name	GR40CW	LLX240AB01
Common Name	Retrofit Kit	Digital Flat Panel X-Ray Detector
Classification Name	Solid State X-ray Imager (Flat panel/Digital imager)	Solid State X-ray Imager (Flat panel/Digital imager)
Product Code	MQB	MQB
Regulation	21 CFR 892.1680	21 CFR 892.1680
510(k) Number	K152094	K102587
510(k) Decision Date	Oct. 16, 2015	Dec. 01, 2010

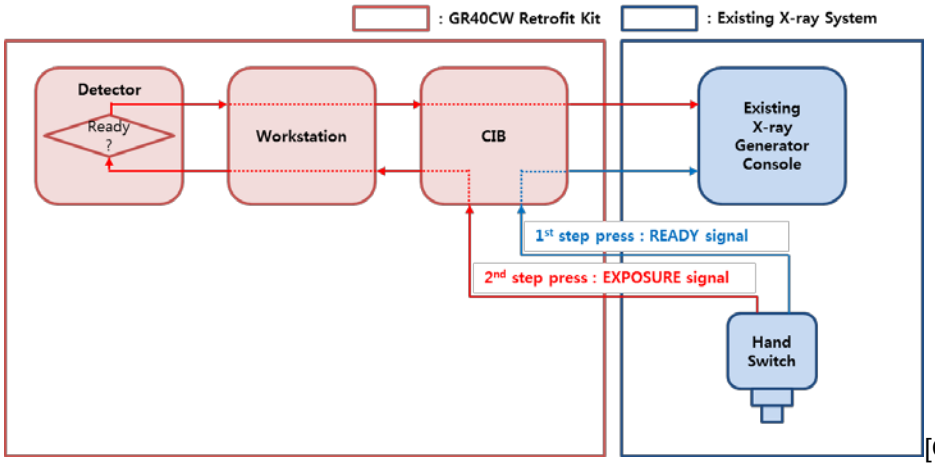
7. **Device Description**

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 and Main cable. 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.

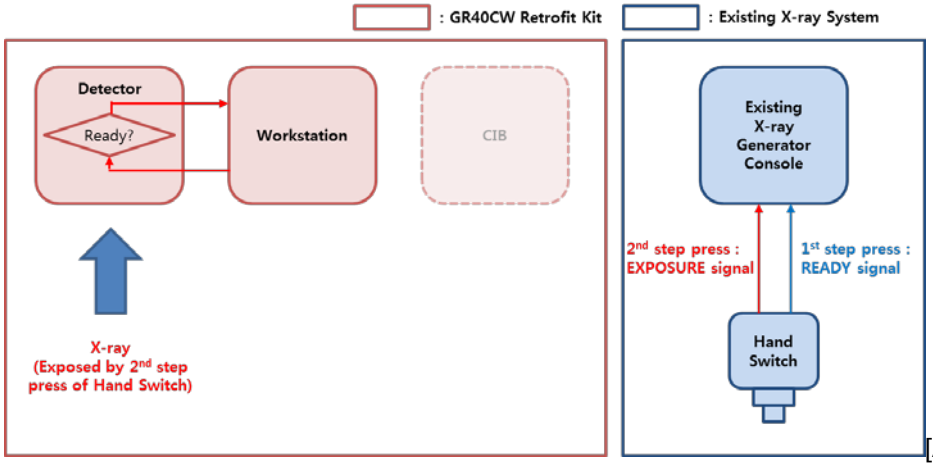
Integration Information

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]

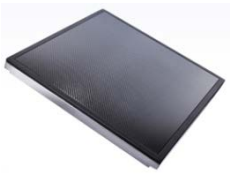
In conclusion, this retrofit kit does not either require a modification / alteration or control in the part of X-ray radiation control of the current X-ray system in anyway.

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 GR40CW has a digital X-ray detector (S4335-WV), which type is Gd_2O_2S as same as the 2nd predicate device (LLX240AB01) cleared with 510(k) K102587, to be added into a list of detectors of the 1st predicate device, GR40CW (K152094). The proposed GR40CW has same software feature, workstation and CIB with the 1st predicate device. There is no significant difference in materials, energy source or technological characteristics compared to the predicate devices. The following technological characteristics are compared and assessed and the results demonstrate the substantial equivalent to the predicate devices.

Specification	1st Predicate Device	2nd Predicate Device	Proposed Device	Discussion
Device Name	GR40CW	LLX240AB01	GR40CW	-
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG MOBILE DISPLAY	SAMSUNG ELECTRONICS	-
510(k) Number	K152094	K102587	N/A	-
Appearance				Same as 1st predicate device
Intended Use	The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic	LLX240AB01 Digital Flat Panel X-Ray Detector is indicated for digital imaging solution designed for providing general	The GR40CW Digital X-ray Imaging System is intended for use in general projection radiographic	Same as 1st predicate device

	applications wherever conventional screen-film systems or CR systems may be used. This device is not intended for mammographic applications.	radiographic diagnosis of human anatomy targeting both adult and children. It is intended to replace film based radiographic diagnostic systems and provide a case diagnosis and treatment planning for physicians and other health care professionals. Not to be used for mammography.	applications wherever conventional screen-film systems or CR systems may be used. This device is not intended for mammographic applications.	

Manufacturer Contents	**GR40CW (K152094)**	**LLX240AB01 (K102587)**	**GR40CW**	**Discussion**
Detector		Note: S4335-WV has not been cleared before.		
Name	S4335-W	LLX240AB01	S4335-WV	-
Detector Type	CsI	Gd_2O_2S	Gd_2O_2S	Same as 2nd predicate device
Detector Area	14”X17” (345mmX425mm)	17”X17” (439mmX439mm)	14”X17” (345mmX425mm)	Same as 1st predicate device
Pixel Pitch (μm)	140	143	140	Same as 1st predicate device
High Contrast Limiting Resolution (lp/mm)	3.5	3.6	3.5	Same as 1st predicate device

Since imaging Workstation and CIB(Control Interface Box) are same as the 1st predicate device has, there is no difference.

In non-clinical data, the proposed device’s detector shows curves and measurements of MTF and DQE that demonstrate a substantially equivalent or improvement to the 2nd predicate device.

10. 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

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.
It conforms to the followings: ISO14971, ISO13485, 21 CFR Subchapter J 1020.30 and 1020.31

12. Clinical data

In clinical data, clinical images were obtained 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 shown equivalent and better than the 2nd predicate device.
The provided clinical data were determined to be not necessary to establish substantial equivalence with the predicate devices.

13. 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.