



Food and Drug Administration
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SAMSUNG ELECTRONICS Co., Ltd.
% Chulsin Kim
Regulatory Affairs Manager
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do, 443-742
REPUBLIC OF KOREA

October 16, 2016

Re: K152094
Trade/Device Name: GR40CW
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: July 24, 2015
Received: July 28, 2015

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the typed name.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K152094

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.

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

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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: October 7, 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

A. Name: Ninad Gujar

B. Title: Regulatory Affairs Manager

C. Phone Number: 978-564-8503

D. FAX Number: 978-750-6677

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 Device

A. Manufacturer: SAMSUNG ELECTRONICS Co., Ltd.

B. Device Name: XGEO 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

G. 510(k) Number: K140235

H. 510(k) Decision Date: May 15, 2014

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.

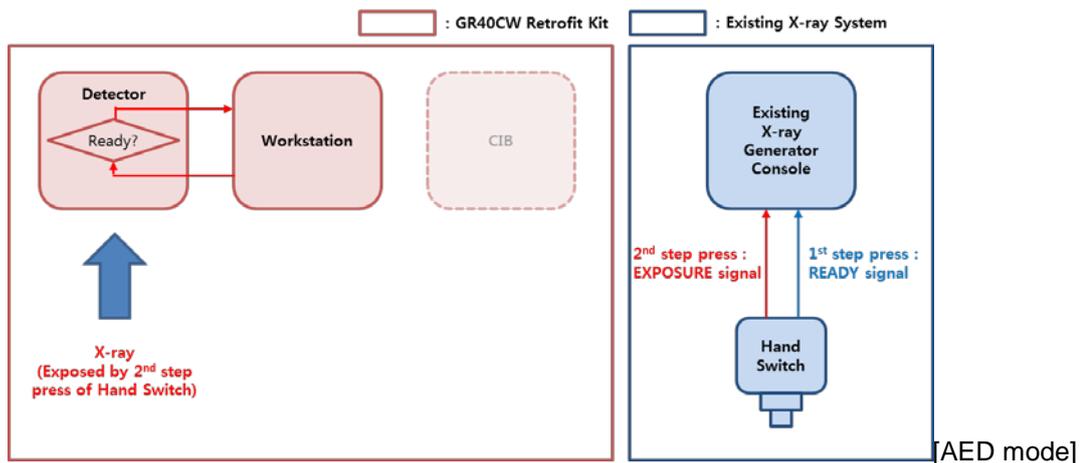
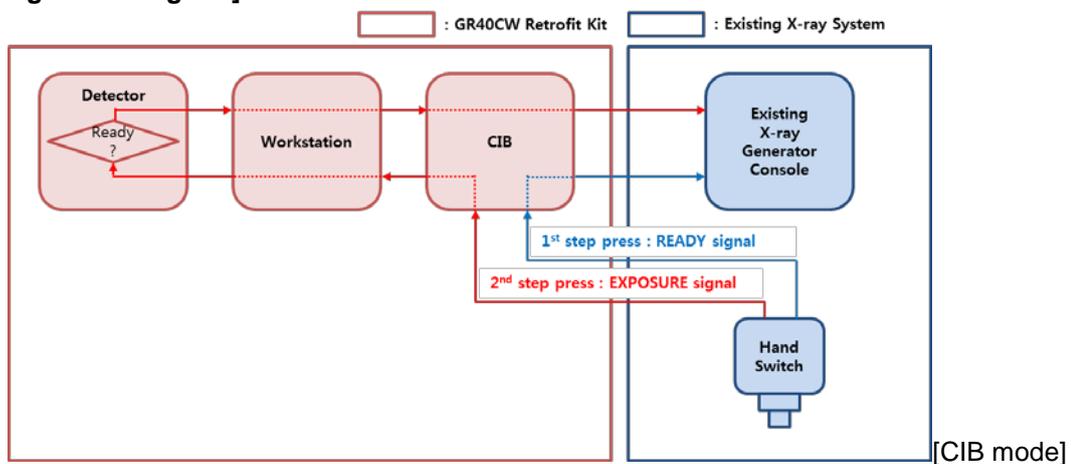
The X-ray passing through a patient's body is sent to the detector and then converted into electrical signals. These signals go through the process of amplification and digital data conversion in the signal process device before being sent to the S-Station (Operation Software) and saved in DICOM file, 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 Detector, 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]



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 two wireless digital X-ray detectors (S4343-W & S3025-W), already cleared by another 510(k) submission, to be added to the list of detector of the predicate device, XGEO GR40CW (K140235), with a new software feature named as S-share by which all our-branded wireless detectors can be connected to the system for better continuous operation, and a new CIB (Control Interface Box) to be added.

There is no significant difference in materials, energy source or technological characteristics compared to the predicate device. Comparisons of the following technological characteristics were assessed and the results demonstrate the substantial equivalence to the predicate device.

Specification	Predicate Device	Proposed Device	Discussion
Device Name	XGEO GR40CW	GR40CW	
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	
510(k) Number	K140235	N/A	
Appearances			Same
Intended Use	The XGEO 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.	Same

Manufacturer Contents	XGEO GR40CW (K140235)	GR40CW			Discussion
Configuration	Detector and Imaging workstation	Detectors and Imaging workstation			Same
(1) Detector *NOTE: S4343-W and S3025-W were already cleared with K150165.					
Name	S4335-W	S4335-W	S4343-W	S3025-W	
Detector Type	Csl	Csl	Csl	Csl	Same
Detector Area	14"X17" (345mmX42 5mm)	14"X17" (345mmX42 5mm)	17"X17" (425mmX42 5mm)	10"X12" (245mmX29 5mm)	Differences (1)
Pixel Pitch (µm)	140	140	140	140	Same
High Contrast Limiting Resolution (LP/mm)	3.5	3.5	3.5	3.5	Same

Manufacturer Contents	XGEO GR40CW (K140235)	GR40CW	Discussion
(2) Imaging Workstation			



CPU	Intel® Core™ i5	Intel® Xeon® E5-1620	Differences (2)
Memory(RAM)	4GB	8GB	Differences (3)
Storage(HDD)	1TB	1TB	Same
Monitor	21.5 inch (1,920 X 1,080)	21 inch (1,920 X 1,080)	Same

Manufacturer Contents	XGEO GR40CW (K140235)	GR40CW	Discussion
(3) CIB(Control Interface Box)			
Max. Signal Input Voltage	300V DC	400V DC/AC	Differences (4)

A. Differences Explanation

No.	Differences	Explanation
(1)	Detector Area	Proposed medical device's S4343-W and S3025-W detectors have larger and smaller area than the predicate device's detector while technical specification is identical among them such as type & pixel pitch, and the area size do not contribute any adverse impacts to the device's safety and performance.
(2)	CPU	Proposed medical device's CPU has faster processing speed than the predicate device's CPU, and the faster processing speed does not contribute any adverse impacts to the device's safety and performance.
(3)	Memory(RAM)	Proposed medical device's memory size is larger than the predicate device's memory size, and the larger memory size does not contribute any adverse impacts to the device's safety and performance.
(4)	Max. Signal Input Voltage	Proposed medical device's maximum-signal input voltage level for preparation and exposure is higher than the predicate device's voltage level. Also, the proposed medical device's CIB supports AC voltage as well as DC voltage. These two improvements do not contribute any adverse impacts to the device's safety and performance.

In non-clinical data, the proposed detector shows curves and measurements of MTF and DQE that improved from the predicate device, and the proposed GR40CW has been shown a substantially equivalent or improved to the 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

Not required since the different detector area, CPU and Memory specification, and a new CIB do not have relation to and affect the clinical images of the detector which was cleared with the predicate device.

13.Conclusions

SAMSUNG ELECTRONICS Co., Ltd.

510(k) Premarket Notification - Traditional



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