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

May 11, 2017

NeuroLogica Corporation, a Subsidiary of Samsung Electronics Co., Ltd
% Dr. Ninad Gujar
Director, Regulatory Affairs and Quality Assurance
14 Electronics Avenue
DANVERS MA 01923

Re: K171085
Trade/Device Name: GMR40
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 24, 2017
Received: April 12, 2017

Dear Dr. Gujar:

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,

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)*
K171085

Device Name
GMR40

Indications for Use *(Describe)*
The GMR40 Digital X-ray Imaging System is intended for use with portable radiographic applications wherever conventional screen-film systems or computed radiography (CR) 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

510(k) SUMMARY

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR § 807.92

Date: March 24, 2017

Submitter:
NeuroLogica Corporation, a subsidiary of Samsung Electronics Co., Ltd
14 Electronics Avenue, Danvers, MA 01923

Contact:
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Proposed Device:

Trade Name:	GMR40
Device Model:	GMR40
Common Name:	Mobile Retrofit Kit
Classification Name:	Stationary x-ray system
Product Code:	MQB
Device Classification:	Class II (per 21 CFR § 892.1680)

Predicate Device:

Trade Name:	GR40CW
Device Model:	GR40CW
Common Name:	Retrofit Kit
Classification Name:	Stationary x-ray system
Product Code:	MQB
Device Classification:	Class II (per 21 CFR § 892.1680)

Device Description:
GMR40 DR Upgrade System (GMR40) integrates a traditional analog portable X-ray system with the speed and image quality benefits of digital capture technology to produce high quality images. The GMR40 can transition a portable system like GE AMX 4 / 4+ into a portable DR solution, improving the workflow of any cassette-based exam.

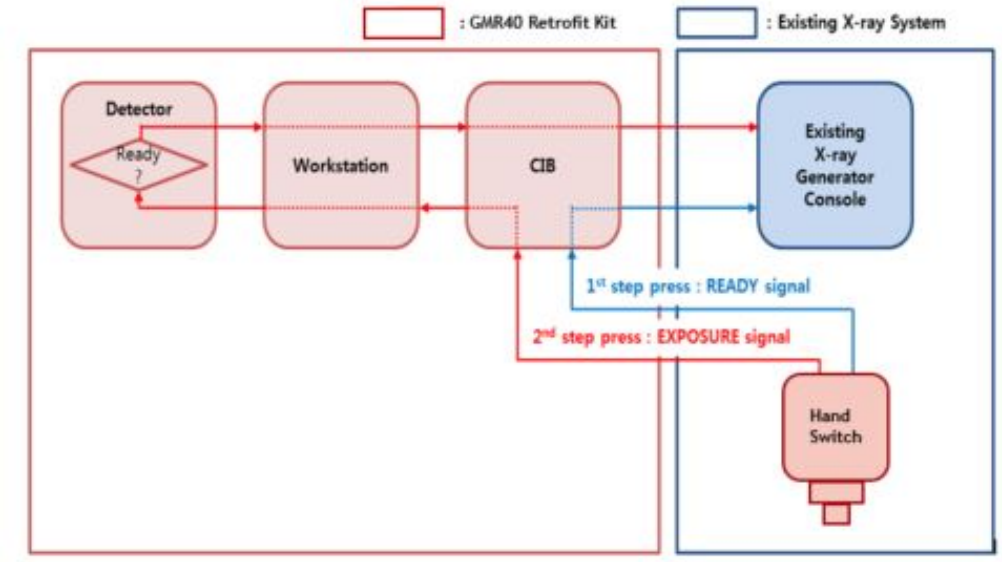
Integration Information:

This is a retrofit system consisting of Detector, Power supply box, Battery pack, Battery charger, Access point, CIB (Control Interface Box), Workstation 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 GMR40 retrofit system can be applied to the existing analogue X-ray system in CIB mode. CIB is 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.

The GMR40 retrofit system has been installed and tested on GE AMX 4 & 4+ models and can be integrated with existing X-ray equipment which has certified generator with minimum 12.5kW capacity using CIB. The detector can be used in bucket with 43cm x 35cm cassette size in wall stand or patient. The EI and DI are guidance values used to emit an acceptable amount of X-rays on the detector.

Integration Diagram:



Indications for Use:
The GMR40 Digital X-ray Imaging System is intended for use with portable radiographic applications wherever conventional screen-film systems or computed radiography (CR) may be used. This device is not intended for mammographic applications.

Comparison of Technological Characteristics with the Predicate Device:
All parameters associated with image quality are the same between the device subject in this application (GMR40) and the predicate device referenced (GR40CW). The proposed GMR40 device has same imaging workstation software, detector, wireless access point and CIB with the GR40CW predicate device. There are no significant differences in materials, energy source or technological characteristics compared to the predicate device other than the ones noted below in the table.

Model # Name	GMR40 (proposed device)	GR40CW (predicate device K153401)	Discussion
Indications for Use	The GMR40 Digital X-ray Imaging System is intended for use with portable radiographic applications wherever conventional screen-film systems or computed radiography (CR) may be used. This device is not intended for mammographic applications.	The GMR40 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.	Different (1)
Detector type	Csl	Csl	Same as predicate device
Detector area	14” x 17” (345mmX425mm)	14” x 17” (345mmX425mm)	Same as predicate device
Pixel Pitch (μm)	140	140	Same as predicate device

Model # Name	GMR40 (proposed device)	GR40CW (predicate device K153401)	Discussion
High Contrast Limiting Resolution (lp/mm)	3.5	3.5	Same as predicate device
CIB	Max. signal input voltage 400V DC/AC	Max. signal input voltage 400V DC/AC	Same as predicate device
Monitor	23 inches (1,920 X 1,080)	21.5 inches (1,920 X 1,080)	Different (2)
Access Point	2.4 GHz and 5 GHz 802.11n radios	2.4 GHz and 5 GHz 802.11n radios	Same as predicate device
Power Management System	AC/DC Hybrid Controller	-	Different (3)
Lead Acid Batteries	12 V , 17 Amp Hr	-	Different (4)
Imaging workstation			
CPU	Intel Core i7-6700T 2.8G 4C	Intel® Xeon® E5-1620	Different (5)
Memory (RAM)	8GB	8GB	Same as predicate device
Storage (HDD)	1TB	1TB	Same as predicate device

Differences:
The differences identified in the above table are described in further detail.

1. Indications for Use

   The indications for use has been modified to make the retrofit unit compatible to portable analog x-ray systems instead of the fixed systems predicate device GR40CW

(K153401) is intended for. The Detector, Power supply box, Battery pack, Battery charger, Access point, Control Interface Box (CIB) from the predicate device GR40CW (K153401) remain the same for the proposed device GMR40.

2. Monitor

The GMR40 monitor has the same resolution as the predicate device GR40CW (K153401) however the screen size is slightly bigger and provides touchscreen functionality.

3. Power Management System

The hybrid controller is a medical grade power management system designed for use with sealed lead acid batteries in mobile / point of care products for hospitals and long term healthcare facilities. The unit uses microprocessor based technology for intelligent charging, reconditioning, state of charge monitoring and DC power control. It is designed, manufactured and certified to the EN 60601 medical equipment standard.

4. Lead Acid Batteries

The retrofit kit is self-powered through its own internal batteries which are valve regulated lead acid batteries. These sealed lead acid batteries are UL recognized and are designed to withstand overcharge, overdischarge and resisting vibration and shock.

5. Workstation CPU

This is an off the shelf equipment that has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. The performance of the S-Station (Operational Software) and the power management system software have been validated as well and do not raise any new safety or effectiveness concerns.

The differences noted above were tested both internally through our verification and validation. These activities tested that the retrofit kit can be operated on battery power or when plugged into a wall outlet for charging besides confirming the operation of the device and wireless connectivity of the detector panel. Usage time, battery functionality, power voltages, PC performance and control interface were verified during the testing. In addition, all modifications were evaluated as part of the system that was tested for product safety (IEC 60601-1) and EMC / EMI (IEC 60601-1-2). The integrated GMR40 retrofit system was installed and tested on GE AMX 4 & 4+ models. The testing ensured that the modifications were successfully integrated and that GMR40 performs as designed.

As these modifications do not raise any new safety or effectiveness concerns, the results demonstrate the GMR40 system is of comparable type and substantially equivalent to the currently marketed GR40CW system (K153401).

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 following the FDA Guidance for Radio frequency Wireless Technology in Medical Devices. All test results were compliant with the standards.

In addition to conformance to the above harmonized standards, GMR40 quality assurance activities include the following:

- Risk analysis and mitigation
- System verification and validation testing
- Testing at unit level

The software contained in the proposed device has been developed based on the FDA Guidance for *Content of Premarket Submissions for Software Contained in Medical Devices* and the in addressing cybersecurity issues considered the FDA guidance document *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*.

The performed verification and validation testing activity confirmed that GMR40 was successfully integrated into radiographic systems where conventional screen-film systems or CR is used and that it performs as designed.

Non-clinical Data:
The digital detector is identical to the predicate device GR40CW (K153401). 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 non-clinical testing data such as MTF and DQE measurements is identical to the predicate device. It conforms to the followings: ISO 14971, ISO 13485, 21 CFR Subchapter J 1020.30 and 1020.31.

Clinical Data:

Image quality of the GMR40 is the same in comparison to the predicate device GR40CW (K153401) since the major image acquisition components such as the detector panel and the imaging software are identical to GR40CW.

Conclusion:

Based upon the above considerations, NeuroLogica Corporation, subsidiary of Samsung Electronics, believes that the GMR40 (proposed device) is as safe, as effective, and performs as well as the legally marketed devices.