April 21, 2022

Samsung Electronics Co. Ltd.
% Jaesang Noh
Senior Professional, Regulatory Affairs
129, Samsung-Ro, Yeongtong-Gu
Suwon-Si, Gyeonggi-Do 16677
REPUBLIC OF SOUTH KOREA

Re: K220175
Trade/Device Name: GM85
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: January 14, 2022
Received: January 21, 2022

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurel Burk
Assistant Director
Diagnostic X-ray Systems Team
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220175

Device Name
GM85

Indications for Use *(Describe)*
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.

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:** April 19, 2022

2. **Submitter**
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   B. Address: 129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16677, Republic of Korea

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4. **Secondary Contact Person**
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   E. E-Mail: ngujar@neurologica.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
   F. Regulation: 21 CFR 892.1720

6. **Predicate Devices**

	Predicate Device
Device Name	GM85
Classification Name	MobileX-ray system.
Product Code	IZL
Regulation	21 CFR 892.1720
510(k)#	K181626
510(K) Decision Date	July 20, 2018

7. Device Description

The GM85 Digital Mobile X-ray Imaging 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 on the S-Station, which is the Operation Software (OS) of Samsung Digital Diagnostic X-ray System, and save in DICOM file, a standard for medical imaging. The captured images are tuned up by an Image Post-processing Engine (IPE) which is exclusively installed in S-Station, and send to the Picture Archiving & Communication System (PACS) sever for reading images.

The GM85 Digital Mobile X-ray imaging System was previously cleared with K181626, and through this premarket notification, we would like to add more configurations in the previously cleared GM85 as an optional collapsible column type with a manual collimator, a tube, four detectors, and exposure switches (two wired and one wireless types) are optionally added, and software including the Image Post-processing Engine (IPE) is changed in order to support new hardware and apply new software features.
The cleared GM85 (K181626) has two types of columns, collapsible and fixed column having an automatic and manual collimator respectively. A manual collimator is optionally added for a collapsible column in proposed device GM85, where a new tube is available. Four detectors are added in the proposed device GM85; two are new and the others have been cleared with K200418.
It was determined that the level of concern for the software contained in the GM85 Digital Mobile 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" and its level is the same as the predicate device.

Note that when using the Mirror View, image transmitted via Miracast is not available for the purpose of diagnosis.

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.

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

The proposed device, GM85, has the same technological characteristics and hardware as its original predicate device, GM85 (K181626), and added an optional collapsible column type with a manual collimator, a tube, four detectors, exposure switches (two wired and one wireless types) and new software features. They do not have significant changes in materials, energy source or technological characteristics compared to the predicate device.

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

A. Comparing with Predicate Device

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

Specification	Proposed Device	Predicate Device	Discussion
Device Name	GM85	GM85	-
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	-
510(k) Number	-	K181626	-
Appearances	 [C-Type*] *Collapsible column type (C-Type)  [F-Type**] **Fixed column type (F-Type)  [Fit-Type***] ***Collapsible column type (Fit-Type)	 [C-Type*] *Collapsible column type (C-Type)  [F-Type**] **Fixed column type (F-Type)	Difference(1)
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 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

Manufacturer Contents		GM85			GM85 (K181626)		Discussion
		C-type	F-type	Fit-type	C-type	F-type	
(1)High Voltage Generator							
Type		High Frequency			High Frequency		-
Max. Power		32kW / 40kW			32kW / 40kW		Same
Output Range	kVp Range	40 to 150kVp			40 to 150kVp		Same
	mA Range	10 - 500mA			10 - 500mA		Same
	Exposure Time	1msec-10sec			1msec-10sec		Same

Manufacturer Contents		GM85			GM85 (K181626)		Discussion
		C-type	F-type	Fit-type	C-type	F-type	
(2)Tube assembly							
Moving Range	Horizontal	793~1355mm			793~1355mm		Same
	Vertical	550~2030 mm	550~2030 or 1850mm	550~2030 mm	550~2030mm	550~2030 or 1850mm	Same
Rotation Range	Column	±315°			±315°		Same
	Tube (Arm axis)	±180°			±180°		Same
	Tube	-30°~90°			-30°~90°		Same

Manufacturer Contents		GM85			GM85 (K181626)		Discussion
		C-type	F-type	Fit-type	C-type	F-type	
	(Tube axis)						
Tube	Model	LUC-13L, XRR-3332X		LUC-11L, XRR-3332X	LUC-13L, XRR-3332X		Difference(2)
	Focal spot	0.6/1.2mm		0.6/1.5mm, 0.6/1.2mm	0.6/1.2mm		Difference(3)
	Target Angle	14°			14°		Same
	Target Material	Rhenium-tungsten faced molybdenum			Rhenium-tungsten faced molybdenum		Same
	Nominal Tube Voltage	150kVp		125kVp	150kVp		Difference(4)
	Max.Anode HU	300kHU		200kHU	300kHU		Same
Collimator		SDR-OGCL40U	SDR-OGCL41U	SDR-OGCL30L	SDR-OGCL40U	SDR-OGCL41U	Difference(5)
		Automatic 212X306 X179mm	Manual 222X271 X140mm	Manual 206X230X 139mm	Automatic 212X306X 179mm	Manual 222X271X 140mm	

Manufacturer Contents	GM85				GM85 (K181626)			Discussion
(3) Detector								
Name	S4335-W S4343-W S3025-W S4335-AW S4343-AW S4335-AWM S4343-AWM S3025-AW S3025-AWM				S4335-W S4343-W S3025-W S4335-AW S4343-AW			Difference(6)
	S4335-AWM	S4343-AWM	S3025-AW	S3025-AWM	S4335-AW	S4343-AW	S3025-W	
Detector Type	CsI				CsI			Same
	Indirect				Indirect			Same
Detector Area	14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10"X12" (251mmX314mm)		14"X17" (345mmX425mm)	17"X17" (425mmX425mm)	10"X12" (245mmX295mm)	Difference(6)-1
Number of pixels	2466X3040	3036X3040	2024X 2536		2466X3040	3036X3040	1750X 2108	Difference(6)-2
Pixel Pitch(um)	140		124		140			Difference(6)-3
High Contrast Limiting Resolution (LP/mm)	3.57		4.03		3.57			Difference(6)-4
Communication	Wired / Wireless		Wireless		Wired / Wireless			Same
Dust/Water-resistance	IP54		IP67		IP54			Difference(6)-5
Max.load capacity (uniform load / local load,, 40 mm in diameter disk at the center)	400 kg/200 kg				400 kg/200 kg		150 kg/100 kg	Difference(6)-6
DQE (Detective Quantum	65% (0lp/	65% (0lp/	75% (0lp/	60% (0lp/	76% (0lp/mm,	76% (0lp/m	78% (0.1lp/	Difference(6)-7

Manufacturer Contents	GM85				GM85 (K181626)			Discussion
(3) Detector								
Efficiency)	mm, Typical)	mm, Typical)	mm, Typical)	mm, Typical)	Typical)	m, Typical)	mm, Typical)	
MTF (Modulation Transfer Function)	88% (0.5lp/mm, Typical)	88% (0.5lp/mm, Typical)	87% (0.5lp/mm, Typical)	90% (0.5lp/mm, Typical)	86% (0.5lp/mm, Typical)	86% (0.5lp/mm, Typical)	86% (0.5lp/mm, Typical)	Difference(6)-8

Manufacturer Contents	GM85			GM85 (K181626)		Discussion
	C-type	F-type	Fit-type	C-type	F-type	
(4) Grid						
Lines/cm	84.6			84.6		Same
Grid mechanism	Stationary			Stationary		Same
Removability	Removable			Removable		Same
(5) Weight Distribution Cap						
Model Name	SDR-OGWD80U			SDR-OGWD80U		Same
Size(mm)	505x553x37.4			505x553x37.4		Same
(6) Exposure Switch						
Name	C2U-45 C2UW-DS-SA01 L01 4C6M L03 4C6M SDR-OGRC30K			C2U-45 C2UW-DS-SA01		Difference (7)
	C2U-45 C2UW-DS-SA01 L01 4C6M L03 4C6M	TS_CES(SAM) C2UW-LP-I SDR-OGRC30K		C2U-45 C2UW-DS-SA01	TS_CES(SAM) C2UW-LP-I	
Types	Wired	Wireless		Wired	Wireless	Same
	2 or 3 Buttom Deadman type	Infra-red/Bluetooth		2 or 3 Buttom Deadman type	Infra-red/Bluetooth	Same
(7) Software Features						
S-Enhance	S-Enhance			S-Enhance		Same
Pediatric Exposure Management(PEM)	PEM			PEM		Same
S-DAP (Dose Area Product)	S-DAP			S-DAP		Same
S-Align	S-Align	N/A		S-Align	N/A	Same
S-Share	S-Share			S-Share		Same
Bone Suppression Image(BSI)	BSI			BSI		Same
Remote View	Remote View			Remote View		Same
Manual Stitching	Manual Stitching			Manual Stitching		Same
SimGrid	Upgraded SimGrid			SimGrid		Difference(8)
Quick Link	Quick Link			-		Difference(9)

Manufacturer Contents	GM85			GM85 (K181626)		Discussion
	C-type	F-type	Fit-type	C-type	F-type	
Mirror View	Mirror View			-		Difference(10)
Clinical Parameter Control	Clinical Parameter Control			-		Difference(11)
Value-up Package	Value-up Package			-		Difference(12)
Remote Software Upgrade	Remote Software Upgrade			-		Difference(13)

No	Differences	Explanation
(1)	Appearances	The collapsible column type which has a manual collimator is added to the proposed device GM85 as an option in comparison with the predicate device's one that has only collapsible column type with an automatic collimator. The collapsible column type has two options about the collimator, automatic and manual in the proposed device GM85 and this change does not contribute any adverse impacts to the device's safety and effectiveness.
(2)	Tube Model	Two tubes are available in the optional collapsible column of the proposed device GM85. One is the same as the predicate device and the other is newly added. This change does not contribute any adverse impact to the device's safety and effectiveness.
(3)	Focal spot	The focal spot size of the new tube used with an optional collapsible column of the proposed device GM85 is bigger than the predicate device's focal spot size and this change does not contribute any adverse impact to the device's safety and effectiveness.
(4)	Nominal tube voltage	The maximum voltage of tubes used with the optional collapsible column of the proposed device GM85 is limited to lower than the predicate device's maximum tube voltage and these changes do not contribute any adverse impact to the device's safety and effectiveness.
(5)	Collimator	The proposed device GM85 has different types of collimator depending on column type. The fixed column type has the same collimator (manual, SDR-OGCL41U) applied to the predicate device and the collapsible column type has two collimators. One is the same (automatic, SDR-OGCL40U) as the predicate device and the other is different (manual, SDR-OGCL30L). This change does not contribute any adverse impacts to the device's safety and effectiveness.
(6)	Detectors	Four detectors are added to the GM85 device. Two detector (S4335-AWM and S4343-AWM) are new and the others (S3025-AW and S3025-AWM) are cleared with K200418. These changes do not contribute any adverse impact to the device's safety and effectiveness.
(6)-1	Detector Area	The new detectors which are added to the GM85 device have the

		same (S4335-AWM and S4343-AWM) or similar (S3025-AW and S3025-AWM) dimension as those of the predicate device and these changes do not contribute any adverse impact to the device's safety and effectiveness.
(6)-2	Number of pixels	The new detectors which are added to the GM85 device have the same (S4335-AWM and S4343-AWM) or higher (S3025-AW and S3025-AWM) pixel number as those of the predicate device and these changes do not impact safety and/or effectiveness.
(6)-3	Pixel Pitch(um)	The new detectors which are added to the GM85 device have the same (S4335-AWM and S4343-AWM) or lower (S3025-AW and S3025-AWM) pixel pitch as those of the predicate device and these changes do not impact safety and/or effectiveness.
(6)-4	High Contrast Limiting Resolution (LP/mm)	The new detectors which are added to the GM85 device have the same (S4335-AWM and S4343-AWM) or higher (S3025-AW and S3025-AWM) resolution as those of the predicate device and these changes do not impact safety and/or effectiveness
(6)-5	Detector Dust/Water-resistance	The new detectors which are added to the GM85 device have the same (S4335-AWM and S4343-AWM) or better (S3025-AW and S3022-AWM) dust/water-resistance as those of the predicate device and these changes do not contribute any adverse impact to the device's safety and effectiveness.
(6)-6	Detector Max.load capacity	The new detectors which are added to the GM85 device have the same (S4335-AWM and S4343-AWM) or higher (S3025-AW and S3022-AWM) max load capacity as those of the predicate device and these changes do not contribute any adverse impact to the device's safety and effectiveness.
(6)-7	DQE (Detective Quantum Efficiency)	The new detectors which are added to the GM85 device have similar (S3025-AW) or a little lower (S4335-AWM, S4343-AWM, and S3025-AWM) DQE as those of the predicate device but these changes do not contribute any adverse impact to the device's safety and diagnostic effectiveness.
(6)-8	MTF (Modulation Transfer Function)	The new detectors which are added to the GM85 device have slightly higher (S4335-AWM, S4343-AWM, S3025-AW and S3025-AWM) MTF as those of the predicate device and these changes do not contribute any adverse impact to the device's safety and diagnostic effectiveness.
(7)	Exposure Switch	Two wired and one wireless exposure switches is added to the proposed device GM85 as an option, which are from different manufacturers in comparison with those of the predicate device, and these changes do not contribute any adverse impact to the device's safety and effectiveness.
(8)	SimGrid	The SimGrid in the predicate device, cleared with K181626, 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 modified to provide a parameter

		for controlling strength which is the extent of the compensation of the contrast loss based on the individual preference is available in the proposed device GM85 and this change does not contribute any adverse impact to the device's safety and effectiveness.
(9)	Quick Link	The function of Quick Link, which allows Quick Link to access to external server such as RIS/PACS server, is applied to the proposed device GM85 and this change does not contribute any impact to the device's safety and effectiveness.
(10)	Mirror View	The function of the Mirror View, which shares the screen with other displays by using Miracast wireless communication, is applied to the proposed device GM85 and this change does not contribute any impact to the device's safety and effectiveness.
(11)	Clinical Parameter Control	The captured images are tuned up by the preset value of an Image Post-processing Engine (IPE) in the predicate device and it is upgraded in the proposed device GM85 to provide the function, called as Clinical Parameter Control, to compare the editing image with the current image simultaneously during presetting the parameters. This change does not contribute any impact to the device's safety and effectiveness.
(12)	Value-up Package	New software features which is an option to provide convenience for use, called as the Value-up Package, is applied to the proposed device GM85 and these changes do not contribute any impact to the device's safety and effectiveness.
(13)	Remote Software Upgrade	The function of the Remote Software Upgrade, which enable the authorized user to download and update the software from the server by the user authentication, is applied the proposed device GM85 and this change does not contribute any impact to the device's safety and effectiveness.

B. 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.

C. Non-clinical data

Non-clinical 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 new detectors that have equivalent image characteristics as the existing ones. Specific description is added to make it clear with the non-clinical data and phantom image evaluation report. And those detectors evaluated by Software

System Test Case for verification and validation.

D. Clinical data

In clinical data, phantom image evaluations of the new detectors, upgraded SimGrid and Image Post-processing Engine (IPE) 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 a professional radiologist and found to be equivalent to the predicate devices. There is no significant difference in the average score of image quality evaluation between the proposed device and the predicate device. Therefore, these changes do not affect either the safety or the effectiveness, compared to the predicate device.

E. Summary of the Standards and Guidance Compliance

1. AAMI ANSI ES60601-1 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2 Edition 4 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic compatibility – Requirements and Tests
3. IEC 60601-1-3 Edition 2.1 Medical Electrical Equipment – Part 1-3: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Radiation protection in Diagnostic X-ray Equipment
4. IEC 60601-2-28 Edition 3 Medical Electrical Equipment – Part 2-28: Particular Requirements for the Basic Safety and Essential Performance of X-ray Tube Assemblies for Medical Diagnosis
5. IEC 60601-2-54 Edition 1.2 Medical Electrical Equipment – Part 2-54: particular Requirements for the Basic Safety and Essential Performance of X-ray Equipment for Radiography and Radioscopy
6. IEC 62220-1-1 Edition 1.0 Medical electrical Equipment - Characteristics of digital X-ray imaging devices Part 1-1: Determination of the detective quantum efficiency Detectors used in radiographic imaging
7. Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff issued on October 2, 2014
8. Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices issued on May 11, 2015
9. Guidance for the Submission for 510(k) for Solid State X-ray Imaging Devices Guidance for Industry and Food and Drug Administration Staff issued on September 1, 2016
10. Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff issued on November 28, 2017

F. Conclusions

The non-clinical and phantom evaluation data demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate devices.