October 1, 2024

SAMSUNG ELECTRONICS Co., Ltd.
℅ Jaesang Noh
Regulatory Affairs, Principal Professional
129, Samsung-ro, Yeongtong-gu
Suwon-si, Gyeonggi-do 16677
SOUTH KOREA

Re: K242651
Trade/Device Name: Gm85
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: August 30, 2024
Received: September 4, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of 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)*
K242651

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:** August 30, 2024

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**
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4. **Secondary Contact Person**
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   B. Title: Vice President, Regulatory Affairs & Quality Control
   C. Phone Number: 978-564-8503
   D. FAX Number: 978-560-0602
   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	Mobile X-ray system.
Product Code	IZL
Regulation	21 CFR 892.1720
510(k)#	K222353
510(K) Decision Date	September 29, 2022

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 K222353, and through this premarket notification, we would like to add more configurations in the previously cleared GM85 as a detector, accessories are newly added and software is updated for user convenience.

The new detector added in the proposed device is designed to achieve a higher IP rating of Dust and Water and reduce weight while maintaining durability, functionality and operation like the detector of the predicate device. The new detector and predicate device's detector are both an x-ray conversion device using an amorphous silicon flat panel and absorb incident x-rays, converts it to a digital signal, and then transmits it to the Samsung Digital X-ray System like that of the predicate device.

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 device

The proposed device, GM85, has the same technological characteristics and hardware as its original predicate device, GM85 (K222353). There are some differences but, they do not have significant changes in energy source or technological characteristics compared to the predicate device.

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

A. Comparing with Predicate Device

Attribute	Proposed Device (GM85)	Predicate Device (GM85, K222353)	Comparison Results
Device Name	GM85	GM85	-
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	-
510(k) Number	-	K222353	-

Attribute	Proposed Device (GM85)			Predicate Device (GM85, K222353)			Comparison Results
Appearances	 [C-Type*] *Collapsible column type with an automatic collimator (C-Type)	 [F-Type**] **Fixed column type with a manual collimator (F-Type)	 [Fit-Type***] ***Collapsible column type a manual collimator (Fit-Type)	 [C-Type*] *Collapsible column type with an automatic collimator (C–Type)	 [F-Type**] **Fixed column type with a manual collimator (F-Type)	 [Fit-Type***] ***Collapsible column type a manual collimator (Fit-Type)	Same
Indications for 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

Attribute	Proposed Device (GM85)	Predicate Device (GM85, K222353)	Comparison Results
(1) Detector			
Name	S4335-W S4343-W S3025-W S4335-AW S4343-AW S4335-AWM S4343-AWM S3025-AW S3025-AWM F4335-AW F4343-AW	S4335-W S4343-W S3025-W S4335-AW S4343-AW S4335-AWM S4343-AWM S3025-AW S3025-AWM F4335-AW	Difference (1)
	F4343-AW	S4343-AW	
Detector Type	CsI	CsI	Same
	Indirect	Indirect	Same
Detector Area	17"X17" (425mmX425mm)	17"X17" (425mmX425mm)	Same
Number of pixels	3036X3040	3036X3040	Same
Pixel Pitch(um)	140	140	Same
High Contrast Limiting Resolution (LP/mm)	3.57	3.57	Same
Communication	Wired / Wireless	Wired / Wireless	Same
Dust/Water-resistance	IP57	IP54	Difference (1)-1
Max.load capacity (uniform load / local load,, 40 mm in diameter disk	400 kg/200 kg	400 kg/200 kg	Same

Attribute	Proposed Device (GM85)	Predicate Device (GM85, K222353)	Comparison Results
(1) Detector			
at the center)			
DQE (Detective Quantum Efficiency)	76% (0lp/mm, Typical)	76% (0lp/mm, Typical)	Same
MTF (Modulation Transfer Function)	86% (0.5lp/mm, Typical)	86% (0.5lp/mm, Typical)	Same
Weight (w/o Battery Set)	Approx. 2.5 kg	Approx. 3.4 kg	Difference (1)-2

Attribute		Proposed Device (GM85)		Predicate Device (GM85, K222353)		Comparison Results
(2) Accessories						
Wireless Exposure Switch	Name	TS_CES(SAM) C2UW-LP-I SDR-OGRC30K CAPE H301W-S1		TS_CES(SAM) C2UW-LP-I SDR-OGRC30K		Difference (2)-1
		TS_CES(SAM) SDR-OGRC30K	C2UW-LP-I CAPE H301W-S1	TS_CES(SAM) SDR-OGRC30K	C2UW-LP-I	
	Types	Infra-red	Bluetooth	Infra-red	Bluetooth	Same
RFID reader	Name	pcProx RDR-80031BKU V2		pcProx		Difference (2)-2
	Type	USB Type		USB Type		Same
	Transmit Frequency	125kHz, 13.56 MHz		125kHz, 13.56 MHz		Same

Attribute	Proposed Device (GM85)	Predicate Device (GM85, K222353)	Comparison Results
(3) Software Features			
S-Share	S-Share	S-Share	Same
S-Enhance	S-Enhance	S-Enhance	Same
SimGrid	SimGrid	SimGrid	Same
PEM	PEM	PEM	Same
QAP	QAP	QAP	Same
Bone Suppression	Bone Suppression	Bone Suppression	Same
Remote View	Remote View	Remote View	Same
Mirror View	Mirror View	Mirror View	Same

Attribute	Proposed Device (GM85)	Predicate Device (GM85, K222353)	Comparison Results
RFID	RFID	RFID	Same
Value-up Package	Value-up Package	-	Difference (3)

No	Comparison Results	Discussion
(1)	Detector	A new detector (F4343-AW) is added to the GM85 device. This change does not contribute any adverse impact to the device's safety and effectiveness.
(1)-1	Dust/Water-resistance	The IP rating of the new detector is higher than that of the predicate device because the process to block any potential water leak paths was added such as adding seals around vulnerable areas. This change does not contribute any adverse impact to the device's safety and diagnostic effectiveness.
(1)-2	Weight (w/o Battery Set)	The new detectors which are added to the GM85 device is lighter than that of the predicate device because a non-glass substrate was used, instead of a glass substrate used in the detector of the predicate device. The non-glass substrate is the same one used for the detector, F4335-AW, cleared with K222353. This change does not contribute any adverse impact to the device's safety and diagnostic effectiveness.
(2)-1	Wireless Exposure Switch	A new Wireless Exposure Switch is added optionally to the GM85 device which is the same specification as those of the predicate device. These changes do not contribute any adverse impact to the device's safety and effectiveness.
(2)-2	RFID reader	A RFID reader is added optionally to the GM85 device which is the same specification as those of the predicate device. These changes do not contribute any adverse impact to the device's safety and effectiveness.
(3)	Value-up Package	Some software features which is an option to provide convenience for use, called as the Value-up Package, is applied to the GM85 device and these changes do 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 according to standard ES 60601-1, IEC 60601-1-2, IEC 60601-1-3, IEC 60601-2-28, IEC 60601-2-54, ISO 14971, 21 CFR1020.30 and 21 CFR1020.31 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 a new detector that has 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 this detector is evaluated by Software System Test Case for verification and validation.
Phantom image evaluation of the new detector was 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 of image quality evaluation between the proposed device and the predicate device. Therefore, this change does not affect either the safety or the effectiveness, compared to the predicate device.

D. Clinical data

This submission does not required clinical data.

E. Summary of the Standards and Guidance Compliance

1. ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
2. IEC 60601-1-2 Edition 4.1 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 2.2 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 2.0 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. Cybersecurity in Medical Device: Quality System Considerations and Content of Premarket Submissions issued on September 27, 2023

8. Content of Premarket Submissions for Device software Functions issued on June 14, 2023
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 data demonstrates that the proposed device is as safe, as effective, and performs as well as the legally marketed devices.