September 29, 2022

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

Re: K222353
Trade/Device Name: GM85
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: July 29, 2022
Received: August 4, 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, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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)*
K222353

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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SAMSUNG ELECTRONICS Co., Ltd.

SAMSUNG

510(k) Premarket Notification - Traditional

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:** July 29, 2022

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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   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)#	K220175
510(K) Decision Date	April 21, 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 K220175, and through this premarket notification, we would like to add more configurations in the previously cleared GM85 as a detector is newly added.
The new detector added in the proposed device is designed to retain the same durability, functionality and operation as the detector of the predicate device and reduce weight by changing a substrate material and appearance. 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. 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.

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 (K220175). The only change is that a configurable detector is added. It does 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 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	Predicate Device	Proposed Device	Discussion
Device Name	GM85	GM85	-
Manufacturer	SAMSUNG ELECTRONICS	SAMSUNG ELECTRONICS	-
510(k) Number	K220175	K222353	-

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

Manufacturer Contents	GM85 (K220175)	GM85 (K222353)	Discussion
(1) 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 S4335-AWM S4343-AWM S3025-AW S3025-AWM F4335-AW	Difference(1)
	S4335-AW	F4335-AW	
Detector Type	CsI	CsI	Same
	Indirect	Indirect	Same
Detector Area	14"X17" (345mmX425mm)	14"X17" (345mmX425mm)	Same
Number of pixels	2466X3040	2466X3040	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	IP54	IP54	Same
Max.load capacity (uniform load / local load,, 40 mm in diameter disk at the center)	400 kg/200 kg	400 kg/200 kg	Same
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	Approx. 2.76 kg	Approx. 2 kg	Difference(1)-1

Manufacturer Contents	GM85 (K220175)	GM85 (K222353)	Discussion
(1) Detector			
(w/o Battery Set)			

No	Differences	Explanation
(1)	Detectors	A new detector (F4335-AW) is added to the GM85 device. This change does not contribute any adverse impact to the device's safety and effectiveness.
(1)-1	Weight	The new detector which is added to the GM85 device is lighter than that of the predicate device because a non-glass substrate, instead of a glass substrate used in the detector of the predicate device, is utilized and the non-metal for the front and rear cover of the new detector is used. These changes do not contribute any adverse impact to the device's safety and diagnostic 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 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.

D. Clinical data

In clinical data, 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.

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.