LG Electronics Inc.
Hanseul Park
RA Specialist
168, Suchul-Daero
Gumi-Si, 39368
Korea, South

February 15, 2024

Re: K240130
Trade/Device Name: Medical Monitor (21HQ613D)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: January 5, 2024
Received: January 17, 2024

Dear Hanseul Park:

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.

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,

Jessica Lamb
Assistant Director
Imaging Software 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)*
K240130

Device Name
Medical Monitor (21HQ613D)

Indications for Use *(Describe)*
This Medical Monitor is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

LG Electronics

510(K) Summary

LG Electronics

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

February 14, 2024

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Applicant: LG Electronics Inc.
  - Address: 168, Suchul-Daero, Gumi-Si, KR 39368
  - Contact Name: Hanseul Park / RA Specialist
  - Telephone No.: +82-10-9490-2109
  - Email Address: hs.park@lge.com

- Name of Manufacturer: LG Electronics Inc.
  - Address: 168, Suchul-Daero, Gumi-Si, KR 39368

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Common name	Medical Monitor
Trade Name	21HQ613D
Classification Name	Medical image management and processing system
Classification Product Code	PGY
Regulation Number	21 CFR 892.2050
Device Class	II
510k Review Panel	Radiology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow:

Predicate Device

- 510(k) Number: K221061
- Applicant: LG Electronics Inc.
- Trade/Device Name: 21HQ613D
- Classification Name: Medical image management and processing system
- Regulation Number: 21 CFR 892.2050
- Classification Product Code: PGY
- Device Class: II
- 510(k) Review Panel: Radiology

5. Description of the Device [21 CFR 807.92(a)(4)]

The Medical monitor is intended to provide high resolution color and grayscale medical imaging for PACS and Radiology system. This Medical Monitor is intended to be used by trained medical practitioners for displaying, reviewing, and analysis of medical images

6. Indications for Use [21 CFR 807.92(a)(5)]

This Medical Monitor is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

Compared with the predicate device, the technological characteristics of the proposed device are substantially equivalent to those of the predicate device. The proposed device is functionally similar to the predicate device. The table below presents comparisons for each device:

[Table. Comparison of Proposed Device to Predicate Device]

	Proposed Device	Predicate Device	SE Note
K Number	K240130	K221061	-
Manufacturer	LG Electronics Inc.	LG Electronics Inc.	-
Model Name	21HQ613D	21HQ613D	-
Classification Name	Medical Image management and processing system	Medical Image management and processing system	Same
Classification Number	21 CFR 892.2050	21 CFR 892.2050	Same
Indications for Use	This Medical Monitor is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.	This Medical Monitor is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.	Same
Display Technology	TFT (Thin Film Translator) LCD (Liquid Crystal Display) Screen	TFT (Thin Film Translator) LCD (Liquid Crystal Display) Screen	Same
Power Consumption	MAX. 120W Off Mode ≤ 0.3W	MAX. 120W Off Mode ≤ 0.3W	Same
Screen size	473.4 x 364.5 mm	473.4 x 364.5 mm	Same
Pixel Pitch	0.165 x 0.165 mm	0.165 x 0.165 mm	Same
Resolution	Max.: 2,048 x 2,560 pixels @60Hz (This is supported in DP IN 2 port only) Recommended: 2,048 x 2,560 pixels @48Hz (This is supported in DP IN 1 port only) 2,048 x 2,560 pixels @60Hz (This is supported in DP IN 2 port only)	Max.: 2,048 x 2,560 pixels @ 50Hz (This is supported in both DP IN 1 and DP IN 2 ports) Recommended: 2,048 x 2,560 pixels @ 50Hz (This is supported in both DP IN 1 and DP IN 2 ports)	Different
Horizontal Frequency	30 kHz to 135kHz	30 kHz to 135kHz	Same

Vertical Frequency	24 Hz to 61 Hz	24 Hz to 61 Hz	Same
Input video signals	DVI IN x 1, DP IN x 2 DP OUT x 1	DVI IN x 1, DP IN x 2 DP OUT x 1	Same
Calibration Tool	LG Calibration Studio Medical / DBI Calibration Feedback System	PerfectLum	Different

The comparison table shows the proposed device (21HQ613D) has shares the same indications for use as the predicate device. Although there are some technological differences, they do not compromise the safety and performance of the proposed device. The major changes include: 1) calibration tools, which have been validated according to IEC 62304, and 2) its module, which also has been verified and validated through physical laboratory testing conducted according to the FDA Guidance, *"Display Devices for Diagnostic Radiology"*.

Based on the physical laboratory test results and software validation reports, all the differences between the proposed and predicate device do not raise any concerns regarding safety and effectiveness of the device.

Therefore, the proposed device is substantially equivalent to the predicate device in terms of its indications for use and technological characteristics.

8. Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

The following data were provided in support of the substantial equivalence determination:

1) Electrical Safety and Electromagnetic Compatibility

The test results demonstrated that the proposed device complies with the following standards:

- *IEC60601-1 Edition 3.2 2020-08*

  Medical electrical equipment - Part 1: General requirements for basic safety and essential

- *IEC60601-1-2 Edition 4.1 2020-09*

  Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

2) Software Validation

21HQ613D contain software that belongs to Basic Documentation Level. The software was designed and developed according to a software development process and was verified and validated.

Its calibration tools, LG Calibration Studio Medical and DBI Calibration Feedback System (CFS), belong to Basic Documentation Level. The software programs were verified and validated according to IEC 62304. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for Device Software Functions (June 14, 2023)

3) Cybersecurity

Cybersecurity documents are provided in accordance with the below FDA guidance:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 27, 2023)
- Postmarket Management of Cybersecurity in Medical Devices (December 28, 2016)

4) Bench Test - Performance Test

- Physical Laboratory Test items suggested in the FDA guidance “Display Devices for Diagnostic Radiology” were tested on 21HQ613D using LG Calibration Studio Medical and DBI Calibration Feedback System.

  Please refer to below table for the summary of its physical laboratory test results.

Measurement	Description	Test result
1. Spatial resolution	Measurements of the transfer of information from the image data to the luminance fields at different spatial frequencies of interest typically done by reporting the modulation transfer function. Non-isotropic resolution properties should be characterized properly by providing two-dimensional measurements or measurements along at least two representative axes.	PASS
2. Pixel defects	Measurements (count, types (e.g., sub-pixel or entire pixel, always-on, always-off), and locations (map)) of pixel defects. This is typically provided as a tolerance limit. Pixel defects can interfere	PASS

	with the visibility of small details in medical images.	
3. Artifacts	Evaluate for image artifacts such as ghosting and/or image sticking from displaying a fixed test pattern for a period of time.	PASS
4. Temporal response	Measurements of the temporal behavior of the display in responding to changes in image values from frame to frame. Since these transitions are typically not symmetric, rise and fall time constants are needed to characterize the system. Slow displays can alter details and contrast of the image when large image stacks are browsed or in video, panning, and zooming modes. For mammography displays, you should measure the rise and fall time constants at several (e.g., every 15 levels) grayscale intervals between 0 and 255.	PASS
5. Luminance	Measurements of the maximum and minimum luminance that the device outputs as used in the application under recommended conditions and the achievable values if the device is set to expand the range to the limit.	PASS
6. Conformance to a grayscale-to-luminance function	Measurements of the mapping between image values and the luminance output following a target model response for 256 or more levels.	PASS
7. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and four corners	Measurements of the luminance response at off-normal viewing related to the target model for the luminance response.	PASS
8. Luminance uniformity or Mura test	Measurements of the uniformity of the luminance across the display screen.	PASS
9. Stability of luminance and chromaticity response with temperature and time of operation (on-time)	Measurements of the change in luminance and chromaticity response with temperature and use time.	PASS
10. Spatial noise	Measurements of the spatial noise level as represented by the noise power spectrum using an appropriate ratio of camera and display pixels. Spatial noise and resolution affect the way images	PASS

	are presented to the viewer and can alter features that are relevant to the interpretation process of the physician or radiologist.	
11. Reflection coefficient	Measurements of the reflection coefficients of the display device. Specular and diffuse reflection coefficients can be used as surrogates for the full bidirectional reflection distribution function.	PASS
12. Veiling glare or small-spot contrast	Measurements of the contrast obtained for small targets.	PASS
13. Color tracking (primary colors and color gamut)	Chromaticity at different luminance levels of primary colors as indicated by the color coordinates in an appropriate units system (e.g., CIE u'v') and the color gamut enveloped by the primary colors.	PASS
14. Gray tracking (gray shades and white point)	Chromaticity at different luminance levels of gray shades, including the white point, as indicated by the color coordinates in an appropriate units system	PASS

All display characteristics of 21HQ613D have met the pre-determined criteria. Therefore, the performance of the proposed 21HQ613D has been verified through the physical laboratory test.

9. Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

10. Conclusion [21 CFR 807.92(b)(3)]

Based on the information provided in this premarket notification and in accordance with the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807, LG Electronics Inc. has determined that there are no significant differences between the proposed device and the predicate device that would negatively impact its use and safety. The proposed device has been proved to be as safe and effective as the predicate device, which was previously cleared in K221061. It shares the same indications for use and similar technological characteristics, with any differences supported by software validation reports and performance test results that demonstrate the proposed device's safety and effectiveness. Therefore, the technological differences between

the proposed device and its predicate device do not raise any new concerns regarding safety or effectiveness, and the proposed device can be considered substantially equivalent to the predicate device.