LG Electronics Inc.
% DoGyun Im
Senior Researcher
GMS Consulting
4th Floor, Digital Cube, 34, Sangamsan-ro
Seoul, Mapo-gu 03909
Korea, South

December 7, 2021

Re: K212295
Trade/Device Name: 21HQ513D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: November 3, 2021
Received: November 4, 2021

Dear DoGyun Im:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated December 3, 2021. Specifically, FDA is updating this SE Letter as an administrative correction. The missing information for the "Dated" field in the original letter should have been November 3, 2021. Additionally, the trade name should have been listed as 21HQ513D.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Dr. Jessica Lamb, Assistant Director, Office of in vitro Diagnostics and Radiological Health at 301-796-6167 or Jessica.Lamb@fda.hhs.gov.

Sincerely,

Jessica Lamb

Jessica Lamb, Ph.D.
Assistant Director
Mammography Ultrasound and Imaging
Software Branch
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

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December 3, 2021

Re: K212295
Trade/Device Name: 21hq513d
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: [NOTE: Use date of most recent supplement]
Received: November 4, 2021

Dear Dogyun Im:

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,

Jessica Lamb
Assistant Director, Mammography Ultrasound and Imaging Software Branch
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212295

Device Name
21HQ513D

Indications for Use *(Describe)*
This Medical Monitor is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

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."

510(k) Summary

[As Required by 21 CFR 807.92]

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

July 20, 2021

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

- Name of Sponsor: LG Electronics Inc.
  - Address: 77, Sanho-daero, Gumi-si, Gyeongsangbuk-do, 39381, Republic of Korea
- Name of Manufacturer: LG Electronics Inc.
  - Address: 77, Sanho-daero, Gumi-si, Gyeongsangbuk-do, 39381, Republic of Korea
- Contact Name: Jinhwan Jun / Chief Research Engineer
  - Telephone No.: +82-31-8066-5641
  - Email Address: jinhwan.jun@lge.com

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

- Trade Name: 21HQ513D
- Common Name: Medical Monitor
- Classification:

Classification Name	Medical image management and processing system
Classification Number	21 CFR 892.2050
Product Code	PGY
Device Class	II
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: K191864
- Applicant: LG Electronics Inc.
- Classification Name: Medical image management and processing system
- Trade Name: 21HK512D

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 for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

7. Intended Use [21 CFR 807.92(a)(5)]

The 21HQ513D is a prescription device, and the display is not intended for mammography.

- The display is indicated for use to display radiological images for review, analysis, and diagnosis.
- The display is indicated for use by trained medical practitioners.
- The display is indicated to provide high-resolution color and grayscale medical imaging for PACS and Radiology systems.

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

The table below presents comparisons between the subject device (21HQ513D) and the legally marketed predicate device (K191864):

[Table 1. Comparison of Proposed Device to Predicate Device]

	Proposed Device	Predicate Device
K Number	Not known	K191864
Manufacturer	LG Electronics Inc.	LG Electronics Inc.
Model Name	21HQ513D	21HK512D
Classification Name	Medical image management and processing system	Medical image management and processing system
Classification Number	21 CFR 892.2050	21 CFR 892.2050
Indications for Use	This Medical Monitor is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.	This Medical Monitor is intended to be used by trained medical practitioners for displaying, reviewing, and analysis of medical images. The display is not intended for mammography.
Power Consumption	MAX. 120W Off Mode ≤ 0.3W	MAX. 85W
LCD Screen	TFT LCD	TFT LCD
Pixel Pitch	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm
Resolution	1,536 x 2,048 pixels	1,536 x 2,048 pixels
Horizontal Frequency	30 kHz to 130 kHz	63 kHz to 96 kHz
Vertical Frequency	56 Hz to 61 Hz	50 Hz to 75 Hz
Input video signals	DisplayPort x 2 DVI-IN x 1	DisplayPort x 1 DVI-IN x 1
Calibration Tool	PerfectLum 4.0	PerfectLum 3.9

The comparison table shows that the subject device (21HQ513D) has the same indications for use the predicate one. Although the devices have some different technological characteristics (power consumption, horizontal & vertical frequency, input video signals), these differences do not make the subject device less safe and reliable, so the subject device fits for diagnostic use as the predicate device does. And there is a difference in the calibration tool. 21HQ513D uses the updated version of the PerfectLum. PerfectLum 4.0 only have differences in UI/UX improvements, supported OS extensions, functional improvements for remote control server. So it does not affect the calibration function of the PerfectLum. And PerfectLum 4.0 was also validated according to the ISO 62304. Therefore, there are no significant differences in the technological characteristics of the subject device. All the differences between the subject and predicate device do not raise different questions of safety and effectiveness. It is substantially equivalent to a predicate device in indications for use and technology characteristics.

9. Non-Clinical Test summary

1) Electrical Safety and Electromagnetic Compatibility

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

- Electrical Basic Safety and Essential Performance requirements in accordance with IEC 60601-1:2005/AMD1:2012
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2 Edition 4.0:2014
- Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability in accordance with IEC 60601-1-6:2010/A1:2013

2) Software Validation

The 21HQ513D contains MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: The content of premarket submissions for software contained in medical devices, on May 11, 2005.

3) Guidance

Display Devices for Diagnostic Radiology – Guidance for Industry and Food and Drug Administration Staff, issued on October 2, 2017

According to the guidance, we test following performance items:

Measurements	Description	SE Note
a. 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. (Using TG18 QC Test Pattern)	Same
b. 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 with the visibility of small details in medical images.	Equivalent
c. Artifacts	Evaluate for image artifacts such as ghosting and/or image sticking from displaying a fixed test pattern for a period of time. (Using 5x5 mosaic pattern, 64Gray / 127 Gray judgment)	Same
d. 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	Equivalent

Measurements	Description	SE Note
	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.	
e. 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.	Same
f. Color tracking	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.	Equivalent
g. 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.	Equivalent

According to the above test results, there are no significant performance differences between 21HQ513D and the predicate device that would adversely affect the use of the product. It has substantially equivalent performance compared to the predicate device.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

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

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification LG Electronics, concludes that the 21HQ513D is substantially equivalent in safety and effectiveness to the predicate devices as described herein.