LG Electronics Inc.
% Daseul An
RA Associate
LG Electronics
222, LG-ro, Jinwi-myeon
PYEONGTAEK-SI, GYEONGGI-DO 17709
KOREA, SOUTH

January 9, 2023

Re: K223789
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: December 16, 2022
Received: December 19, 2022

Dear Daseul An:

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
Imaging Software Team
DHT8B: Division of Radiological 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 K223789
PGY

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.

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510(k) Summary

[As Required by 21 CFR 807.92]

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

December 16, 2022

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

- Name of Sponsor: LG Electronics Inc.
  - Address: 222, LG-ro, Jinwi-myeon, Pyeongtaek-si, Gyeonggi-do, 17709, Republic of Korea
- Name of Manufacturer: LG Electronics Inc.
  - Address: 168, Suchul-daero, Gumi-si, Gyeongsangbuk-do, 39368, Republic of Korea
- Contact Name: Daseul An / Regulatory Affairs Associate
  - Telephone No.: +82-10-8914-0116
  - Email Address: daseul.an@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: K212295
- Applicant: LG Electronics
- Classification Name: Medical image management and processing system
- Trade Name: 21HQ513D

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

The comparison table shows the technical characteristics of the subject device are substantially equivalent to the predicate device. There are no significant differences between the subject device and the primary predicate device (K212295) that would adversely affect the use of the product. The change is to addition of the available calibration tool which is validated according to IEC 62304.

Table 1. Comparison of Proposed Device to Primary Predicate Device K212295

	Proposed Device	Predicate Device	Equivalence
K Number	Not known	K212295	-
Manufacturer	LG Electronics Inc.	LG Electronics Inc.	-
Model Name	21HQ513D	21HQ513D	-
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 for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.	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.	Same
Power Consumption	MAX. 120W Off Mode ≤ 0.3W	MAX. 120W Off Mode ≤ 0.3W	Same
Screen size	676.9 x 459.7 mm	676.9 x 459.7 mm	Same
LCD Screen	TFT LCD	TFT LCD	Same
Pixel Pitch	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm	Same
Resolution	1,536 x 2,048 pixels	1,536 x 2,048 pixels	Same
Horizontal Frequency	30 kHz to 130 kHz	30 kHz to 130 kHz	Same
Vertical Frequency	56 Hz to 61 Hz	56 Hz to 61 Hz	Same
Input video signals	DisplayPort x 2 DVI-IN x 1	DisplayPort x 2 DVI-IN x 1	Same
Calibration Tool	PerfectLum 4.0 / LG Calibration Studio Medical	PerfectLum 4.0	Modified

8. Non-Clinical Test summary

1) Electrical Safety and Electromagnetic Compatibility

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

- IEC 60601-1:2005/AMD2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances – Requirements and tests

2) Software Validation

The 21HQ513D contain MODERATE level of concern software. The software was designed and developed according to a software development process and was verified and validated. There have been firmware updates.

The newly added calibration tool is a moderate level of concern software. The software was verified and validated according to IEC 62304.

- 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) Bench Test – Performance Test Report

The performance items suggested in the FDA guidance "Display Devices for Diagnostic Radiology" were tested on the 21HQ513D.

- Display Devices for Diagnostic Radiology – Guidance for Industry and Food and Drug Administration Staff, issued on September 28, 2022

Measurements	Test Result
a. Spatial resolution	Pass
b. Pixel defects	Pass
c. Artifacts	Pass
d. Temporal response	Pass
e. Luminance	Pass
f. Conformance to a grayscale-to-luminance function	Pass
g. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and four corners	N/A
h. Luminance uniformity or Mura test	N/A
i. Stability of luminance and chromaticity response with temperature and time of operation (on-time)	N/A
j. Spatial noise	N/A
k. Reflection coefficient	N/A
l. Veiling glare or small-spot contrast	N/A
m. Color tracking	Pass
n. Gray tracking	Pass

All display characteristics of the 21HQ513D have met the pre-defined criteria. Therefore, the performance of 21HQ513D was verified through the performance test.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

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

The Medical Monitor 21HQ513D is found to be substantially equivalent in safety and effectiveness to the predicate devices based on the information provided in this premarket notification.