



LG Electronics Inc.
% JongHyun Kim
Chief Consultant
GMS Consulting
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Korea, South

Re: K232985

December 11, 2023

Trade/Device Name: 24hr513c
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: November 22, 2023
Received: November 22, 2023

Dear JongHyun Kim:

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, Ph.D.
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

Indications for Use

510(k) Number (if known)

K232985

Device Name

24HR513C

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.

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K232985

510(k) Summary

[As Required by 21 CFR 807.92]

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

SEPT 22, 2023

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

- **Name of Sponsor:** LG Electronics Inc.
- **Address:** 222, LG-ro, Cheongho-ri, Jinwi-myeon, Pyeongtaek si, Gyeonggi-do, 17709, Republic of Korea
- **Contact Name:** Jinhwan Jun / Chief Research Engineer
- **Telephone No.:** +82-31-8066-5641
- **Email Address:** jinhwan.jun@lge.com

- **Name of Manufacturer:** LG Electronics Inc.
- **Address:** 168, Suchul-daero, Gumi-si, Gyeongsangbuk-do, 39368, Republic of Korea

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

- **Trade Name:** 24HR513C
- **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;

Primary Predicate Device

- **510(k) Number:** K223789
- **Applicant:** LG Electronics
- **Classification Name:** Medical image management and processing system
- **Trade Name:** 21HQ513D

Secondary Predicate Device

- **510(k) Number:** K221136
- **Applicant:** EIZO Corporation
- **Classification Name:** Medical image management and processing system
- **Trade Name:** RadiForce MX243W

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 table below presents comparisons between the subject device (24HR513C) and the legally marketed predicate devices (K223789 and K221136):

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

	Proposed Device		Primary Predicate Device
K Number	K232985		K223789
Manufacturer	LG Electronics Inc.		LG Electronics Inc.
Model Name	24HR513C		21HQ513D
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 indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.
Power Consumption	MAX. 65W Sleep Mode (Standby Mode): ≤ 0.5W Off Mode ≤ 0.3W		MAX. 120W Off Mode ≤ 0.3W
LCD Screen	TFT LCD		TFT LCD
Pixel Pitch	0.27 x 0.27 mm		0.2115 x 0.2115 mm
Resolution	Max Resolution/ Recommended Resolution	1920 x 1200 @ 60Hz ([Screen Rotation]: [Landscape]) 1200 x 1920 @ 60Hz ([Screen Rotation]: [Portrait - 90o], [Portrait +90 o])	1,536 x 2,048 pixels
Horizontal Frequency	30 kHz to 83kHz ([Screen Rotation]: [Landscape]) 30 kHz to 120kHz ([Screen Rotation]: [Portrait -90o], [Portrait +90 o])		30 Hz to 130 Hz
Vertical Frequency	56 Hz to 61 Hz		56 Hz to 61 Hz
Input video signals	DVI IN x 1		DisplayPort x 2

	DP IN x 1 HDMI x 1	DVI-IN x 1
Calibration tools	Calibration software: LG Calibration Studio Medical	Calibration software: PerfectLum / LG Calibration Studio Medical

The comparison table shows that the subject device (24HR513C) has the similar indications for use the primary predicate device. Although the devices have some different technological characteristics (Power Consumption, Pixel Pitch, Resolution, horizontal/vertical frequency and input/output 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. 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.

[Table 2. Comparison of Proposed Device to Secondary Predicate Device]

	Proposed Device		Secondary Predicate Device
K Number	K232985		K221136
Manufacturer	LG Electronics Inc.		EIZO Corporation
Model Name	24HR513C		RadiForce MX243W
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 Product is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.
Power Consumption	MAX. 65W Sleep Mode (Standby Mode): ≤ 0.5W Off Mode ≤ 0.3W		MAX. 56W Off Mode: 0.6W or less
LCD Screen	TFT LCD		TFT LCD
Pixel Pitch	0.27 x 0.27 mm		0.27 x 0.27 mm
Resolution	Max Resolution/ Recommended Resolution	1920 x 1200 @ 60Hz ([Screen Rotation]: [Landscape]) 1200 x 1920 @ 60Hz ([Screen Rotation]: [Portrait - 90o], [Portrait +90 o])	1920 x 1200
Horizontal Frequency	30 kHz to 83kHz ([Screen Rotation]: [Landscape]) 30 kHz to 120kHz ([Screen Rotation]: [Portrait -90o], [Portrait +90 o])		31 - 76 kHz
Vertical Frequency	56 Hz to 61 Hz		59 - 61 Hz
Input video signals	DVI IN x 1 DP IN x 1 HDMI x 1		DVD-D x 1 DisplayPort x 1
Output video signals	DP Out x 1		DisplayPort x 1
Calibration tools	Calibration software:		Calibration software: RadiCS

The comparison table shows that the subject device (24HR513C) has the similar indications for use the Secondary predicate device. Although the devices have some different technological characteristics (Power Consumption, Pixel Pitch, Resolution, horizontal/vertical frequency and input/output 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. 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.

8. 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/AMD2:2020
- Electromagnetic Compatibility Testing in accordance with EN 60601-1-2:2015(IEC 60601-1-2:2014)/ EN 60601-1-2:2015/A1:2021 (IEC 60601-1-2:2014/AMD1:2020)
- 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+A2:2020

2) Software Validation

The software was designed and developed according to IEC 62304 software development process and was verified and validated. According to the guidance, we evaluated the level of Basic level documentation by identifying safety-related characteristics for device documentation level.

- The software information is provided in accordance with FDA guidance: Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff', issued on JUNE 2023.

3) Guidance

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

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)	Equivalent
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	Same

Measurements	Description	SE Note
	displaying a fixed test pattern for a period of time. (Using 5x5 mosaic pattern, 64Gray / 127 Gray judgment)	
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 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.	Equivalent
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. 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
g. 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

According to the above test results, there are no significant performance differences between 24HR513C and the predicate devices that would adversely affect the use of the product. It has substantially equivalent performance compared to the predicate devices.

Clinical Test Summary:

No clinical studies were considered necessary and performed.

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

In accordance 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 24HR513C is substantially equivalent in safety and effectiveness to the predicate devices as described herein.