LG Electronics, Inc.
℅ Jinhwan Jun
Chief Research Engineer
222, LG-ro, Cheongho-ri, Jinwi-myeon
Pyeongtaek-Si, Gyeonggi-do 17709
REPUBLIC OF KOREA

October 8, 2020

Re: K201777
Trade/Device Name: 31HN713D
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: September 7, 2020
Received: September 10, 2020

Dear Jinhwan Jun:

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,

For

Thalia T. Mills, Ph.D.
Director
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)*
K201777

Device Name
31HN713D

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.

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510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)] K201777

June 25, 2020

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: 77, Sanho-daero, Gumi-si, Gyeongsangbuk-do, 39381, Republic of Korea

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

- Trade Name: 31HN713D
- Common Name: Medical Monitor
- Classification:

Classification Name	Picture archiving and communications 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: K141428
- Applicant: BARCO N.V.
- Classification Name: Picture archiving and communications system
- Trade Name: MDMC-12133

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)]

The table below presents comparisons between the subject device (31HN713D) and the legally marketed predicate device (K141428):

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

	Proposed Device	Predicate Device
K Number	Not known	K141428
Manufacturer	LG Electronics Inc.	BARCO N.V.
Model Name	31HN713D	MDMC-12133
Classification Name	Picture archiving and communications system	Picture archiving and communications 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 (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.	The MDMC- 12133 is intended to be used in displaying arid viewing digital images, including standard and multi-frame digital mammography. for review, analysis and diagnosis by trained medical practitioners. It is especially designed for breast tomosynthesis applications.
Display Technology	The 31HN713D has a LB310FTM module for displaying. The LB310FTM is a 31" TFT Liquid Crystal Display module with LED Backlight unit. This module supports 4,200 x 2,800 pixels and can display color driven by 10bit drivers.	Coronis Uniti Barco is a color LCD monitor for viewing radiology, mammography, and breast tomosynthesis images. The color panel employs in-plane switching (IPS) technology allowing wide viewing angles and the matrix size (or resolution) is 4,200 x 2,800 pixels.
Power Consumption	MAX. 150W Sleep Mode ≤ 0.5W Off Mode ≤ 0.3W	190W (nominal) <0.5 W (hibernate)
Screen size	676.9 x 459.7 mm	853.44mm / 33.6″
LCD Screen	TFT LCD	TFT LCD
Pixel Pitch	0.1554 x 0.1554 mm	0.1686 x 0.1686 mm
Resolution	4,200 x 2,800 pixels	4,200 x 2,800 pixels
Horizontal Frequency	30 kHz to 135kHz	25-85 Hz
Vertical Frequency	56 Hz to 61 Hz	25-85 Hz
Viewing angle	View angle free (R/L 178(Typ.), U/D 178(Typ.))	178°
Input video signals	DisplayPort x 2 HDMI x 1	DisplayPort x 2

The comparison table shows that the subject device (31HN713D) has the similar indications for use the predicate device. Although the devices have some different technological characteristics (screen size, pixel pitch, horizontal/vertical frequency and 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. 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/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 31HN713D 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)	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 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. 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. 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.	Equivalent
h. Luminance uniformity or Mura test	Measurements of the uniformity of the luminance across the display screen.	Equivalent
i. 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.	Same
j. 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 are presented to the viewer and can alter features that are relevant to the interpretation process of the physician or radiologist.	Equivalent
k. 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.	Same
l. Veiling glare or small-spot contrast	Measurements of the contrast obtained for small targets.	Equivalent
m. 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
n. Gray tracking	Chromaticity at different luminance levels of gray shades, including the white point, as indicated by the color coordinates in an appropriate units system	Equivalent

According to the above test results, there are no significant performance differences between 31HN713D 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.

9. 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 31HN713D is substantially equivalent in safety and effectiveness to the predicate devices as described herein.