DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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BenQ Corporation
% Mr. Calvin KT Chang
Project Manager
16 Jihu Road, Neihu
Taipei, 114 Taiwan
REPUBLIC OF CHINA

May 25, 2017

Re: K170944
Trade/Device Name: LCD Monitor (MD310C, MD310G, MD210G)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: March 10, 2017
Received: March 30, 2017

Dear Mr. Chang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170944

Device Name

LCD Monitor (MD310C, MD310G, MD210G)

Indications for Use *(Describe)*

BenQ LCD monitor (MD310C, MD310G and MD210G) is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

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

5.1 Type of Submission: Traditional

5.2 Date of Summary: March 10, 2017

5.3 Submitter:

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Contact:	Calvin KT Chang (Calvin.KT.Chang@BenQ.com)

5.4 Identification of the Device:

Proprietary/Trade name:	LCD Monitor
Model Number:	MD310C, MD310G, MD210G
Regulation Description:	Picture archiving and communications system
Review Panel:	Radiology
Regulation Number:	892.2050
Device Class:	II
Product Code:	PGY

5.5 Identification of the Predicate Devices:

Predicate Device Name:	3MP Color LCD Monitor, RadiForce RX350
Manufacturer:	EIZO Corporation
Regulation number:	892.2050
Device Class:	II
Product Code:	PGY
510(k) Number:	K153354

Predicate Device Name:	Nio 3MP LED (MDNG-3220)
Manufacturer:	Barco N.V.
Regulation number:	892.2050
Device Class:	II
Product Code:	PGY
510(k) Number:	K150821

Predicate Device Name:	20.1 inch (51 cm) Monochrome LCD Monitor ME205 (ML20205)
Manufacturer:	JVC KENWOOD CORPORATION
Regulation number:	892.2050
Device Class:	II
Product Code:	PGY
510(k) Number:	K143076

5.6 Intended Use/ Indications for Use of the Device

BenQ LCD monitor (MD310C, MD310G and MD210G) is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

5.7 Device Description

BenQ LCD monitor (MD310C, MD310G and MD210G) is for viewing medical images other than those of mammography. MD310C is a 21.3" color LCD monitor with the resolution 1,536 x 2,048 pixels (3MP) and MD310G is a 21.3" Monochrome LCD monitor with the same resolution. MD210G is a 20.1" Monochrome LCD monitor with the resolution 1,200 x 1,600 pixels (2MP).

5.8 Non-clinical Testing

A series of safety and performance tests were conducted on the subject device, LCD Monitor (MD310C, MD310G, MD210G).

- Reliability test
- Software Validation
- Electromagnetic compatibility and electrical safety
- Function test
- Usability test

All test results demonstrate that LCD Monitor (MD310C, MD310G, MD210G) meets the requirements of its pre-defined acceptance criteria, and is substantially equivalent to the predicate device.

5.9 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.10 Substantial Equivalence Determination

The LCD Monitor (MD310C, MD310G, MD210G) has the same intended use, principle of operation and technological characteristics with the 3MP Color LCD Monitor, RadiForce RX350 (K153354), Nio 3MP LED (MDNG-3220) (K150821) and 20.1 inch (51 cm) Monochrome LCD Monitor ME205 (ML20205) (K143076). A series of tests were performed and demonstrated substantial equivalence between the subject and the predicate device. Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

Item	Subject device	Predicate device	Substantial equivalence determination
Proprietary name	LCD monitor	3MP Color LCD Monitor	NA

Model	MD310C	RadiForce RX350	NA
510(k) No.	–	K153354	NA
Intended use	BenQ LCD monitor (MD310C, MD310G and MD210G) is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	This product is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	The subject device has the same intended use as the predicate device.
LCD panel			
Technology	TFT color LCD panel (IPS)	Color (IPS)	Same
Backlight	LED	LED	Same
Panel size (diagonal)	21.3" (54.1 cm)	21.3" (54.1 cm)	Same
Display size (H x V)	433.1 x 324.8 mm	433.2 mm x 324.9 mm	Slightly different but does not adversely impact safety and effectiveness of subject device
Mega pixels	3 megapixel	3 megapixel	Same
Native resolutions (H x V)	2048 x 1536	2048 x 1536	Same
Pixel pitch (H x V)	0.2115 x 0.2115 mm	0.2115 mm x 0.2115 mm	Same

Viewing angle (H, V)	176°/176°	178°/ 178°	Different but does not adversely impact safety and effectiveness of subject device
Response time	40 ms (Typ.)	25 ms (Typ.)	Different but does not adversely impact safety and effectiveness of subject device
Brightness	800 cd/m² (Typ.)	1,000 cd/m^2 (Typ.)	Different but does not adversely impact safety and effectiveness of subject device
Contrast ratio	1400:1 (Typ.)	1500 : 1 (Typ.)	Different but does not adversely impact safety and effectiveness of subject device
Aspect ratio	4 : 3	4 : 3	Same
Display colors	1.07 billion colors (maximum)	1.07 billion colors (maximum)	Same
Luminance non-uniformity compensation	Digital Uniformity Equalizer	Digital Uniformity Equalizer	Same
Connectivity			
Input terminals	DVI-D (Dual Link) DisplayPort	DVI-D (dual link) DisplayPort	Same
USB ports/standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	Same

Scanning frequency (H, V)	V: 50~76Hz, H: 30KHz~80KHz	31-127 kHz / 29-61.5 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	Different but does not adversely impact safety and effectiveness of subject device
Power supply			
Power input	AC 100-240V, 50~60 Hz	AC 100-240V, 50 / 60 Hz	Same
Power consumption	95 W (Maximum)	89 W / Less than 1 W	Different but does not adversely impact safety and effectiveness of subject device
Power management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.2a	Different but does not adversely impact safety and effectiveness of subject device
Physical			
Dimensions w/o stand (W x H x D)	Portrait: 369 x 490.4 x 94.4 mm Landscape: 490.4 x 369 x 94.4 mm	354 x 462 x 78 mm	Different but does not adversely impact safety and effectiveness of subject device
Mounting	100 x 100 mm VESA compliant	100 x 100 mm VESA compliant	Same
Miscellaneous Features/Specifications			
QC software	N/A	RadiCS	BenQ LCD Monitor is calibrated in

			factory before shipment
Sensors	Backlight Sensor, Eco(Presence) Sensor, Front Sensor, Ambient Light Sensor	Backlight Sensor, Presence Sensor, Integrated Front Sensor, Ambient Light Sensor	Same

Item	**Subject device**	**Predicate device**	**Substantial equivalence determination**
Proprietary name	LCD monitor	Nio 3MP LED	NA
Model	MD310G	MDNG-3220	NA
510(k) No.	—	K150821	NA
Intended use	BenQ LCD monitor (MD310C, MD310G and MD210G) is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	The Nio 3MP LED (MDNG-3220) Medical Flat Panel Display System is intended to be used as a tool in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.	The subject device has the same intended use as the predicate device.
LCD panel			
Technology	TFT monochrome LCD panel (IPS)	TFT AM LCD Dual Domain IPS	Same
Backlight	LED	LED	Same
Panel size (diagonal)	21.3" (54.1 cm)	20.8” (52.0 cm)	Different but does not adversely

			impact safety and effectiveness of subject device
Display size (H x V)	433.1 x 324.8 mm	424 mm x 318 mm	Different but does not adversely impact safety and effectiveness of subject device
Mega pixels	3 megapixel	3 megapixel	Same
Native resolutions (H x V)	2048 x 1536	2048 x 1536	Same
Pixel pitch (H x V)	0.2115 x 0.2115 mm	0.207 mm x 0.207 mm	Different but does not adversely impact safety and effectiveness of subject device
Viewing angle (H, V)	176°/176°	176°/176°	Same
Response time	40 ms (Typ.)	30 ms (typical)	Different but does not adversely impact safety and effectiveness of subject device
Brightness	1700 cd/m² (Typ.)	1200 cd/m² typical	Different but does not adversely impact safety and effectiveness of subject device
Contrast ratio (typical)	1400:1	1200:1	Different but does not adversely impact safety and

			effectiveness of subject device
Aspect ratio (H:V)	4 :3	4:3	Same
Color imaging	No	No	Same
Gray imaging	Yes	Yes	Same
Connectivity			
Input terminals	DVI-D (Dual Link) DisplayPort	DVI-D Dual Link DisplayPort	Same
USB ports/standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	Same
Scanning frequency (H, V)	V: 50~76Hz, H: 30KHz~80KHz	15-129 kHz; 25-98 Hz	Different but does not adversely impact safety and effectiveness of subject device
Power supply			
Power input	AC 100-240V, 50~60 Hz	AC 100-240V,	Same
Power consumption	80 W (Maximum)	50 W (nominal)	Different but does not adversely impact safety and effectiveness of subject device
Physical			
Dimensions w/o stand (W x H x D)	Portrait: 369 x 490.4 x 94.4 mm Landscape: 490.4 x 369 x 94.4 mm	378 x 491 x 84 mm	Different but does not adversely impact safety and

			effectiveness of subject device
Mounting	100 x 100 mm VESA compliant	100 x 100 mm VESA compliant	Same

Item	**Subject device**	**Predicate device**	**Substantial equivalence determination**
Proprietary name	LCD monitor	20.1 inch (51 cm) Monochrome LCD Monitor ME205	NA
Model	MD210G	ML20205	NA
510(k) No.	—	K143076	NA
Intended use	BenQ LCD monitor (MD310C, MD310G and MD210G) is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	20.1 inch (51 cm) Monochrome 2M pixel LCD Monitor ME205 (ML20205) is intended to be used in displaying and viewing medical images for diagnosis by trained Medical practitioners. It is not meant to be used in digital mammography.	The subject device has the same intended use as the predicate device.
LCD panel			
Technology	TFT Monochrome LCD Panel	Monochrome TFT	Same
Backlight	LED	LED	Same
Panel size (diagonal)	20.1" (51.1 cm)	20.1"	Same
Display size	408 x 306 mm	408 x 306 mm	Same

(H x V)			
Mega pixels	2 megapixel	2 megapixel	Same
Native resolutions (H x V)	1600 x 1200	1600 x 1200	Same
Pixel pitch (H x V)	0.255 x 0.255 mm	0.255 x 0.255 mm	Same
Viewing angle (H, V)	170°/170°	170°/170°	Same
Brightness	1000 cd/m² (Typ.)	1000 cd/m^2 typ.	Same
Contrast ratio	1400:1 (Typ.)	1000:1 (Typ.)	Different but does not adversely impact safety and effectiveness of subject device
Connectivity			
Input terminals	VGA DVI-D DisplayPort	DVI-I 29-pin connector DisplayPort connector	Different but does not adversely impact safety and effectiveness of subject device
USB ports/standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	Same
Scanning frequency (H, V)	Digital: 31.47 – 80 kHz, 60 Hz, Analog: 31.47 – 80 kHz, 55 – 76 Hz	Horizontal: 30 – 75 kHz, Vertical: 55 – 60 Hz	Different but does not adversely impact safety and effectiveness of subject device
Power supply			

Power input	AC 100-240V, 50~60 Hz	AC 100-240V, 50~60 Hz	Same
Power consumption	55 W (Maximum)	38W Power management feature	Different but does not adversely impact safety and effectiveness of subject device
Physical			
Dimensions w/o stand (W x H x D)	Portrait: 369 x 490.4 x 94.4 mm Landscape: 490.4 x 369 x 94.4 mm	Portrait: 353 x 512 – 573 x 220 mm Landscape: 453 x 462 – 523 x 220 mm	Different but does not adversely impact safety and effectiveness of subject device
Mounting	100 x 100 mm VESA compliant	100 x 100 mm VESA compliant	Same

5.11 Similarity and Difference

The LCD Monitor, model MD310C, MD310G and MD210G has been compared with "*3MP Color LCD Monitor, RadiForce RX350*," "*Nio 3MP LED (MDNG-3220)"* and "*20.1 inch (51 cm) Monochrome LCD Monitor ME205 (ML20205")* respectively. The subject device has the same intended use, principle of operation and technological characteristics as these predicate devices. Although there are several specification that are different between two devices, the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the subject device and the predicate device did not raise any problems of substantial equivalence. The subject device is substantially equivalent to the predicate devices in intended use, safety and performance claims.

5.12 Conclusion

After analyzing non-clinical laboratory studies and safety testing data, it can be concluded that LCD Monitor (MD310C, MD310G, MD210G) is substantially equivalent to the predicate devices.