Shenzhen Beacon Display Technology Co., Ltd.
% Fu Ailing
Document Engineer
12F, Block B1, Nanshan Zhiyuan, No.1001 Xueyuan Road
Shenzhen, Guangdong 518055
CHINA

September 3, 2020

Re: K201211
Trade/Device Name: 3MP Color LCD Monitors C32S+, C32SP+, 3MP Monochrome LCD Monitors G32S+, G32SP+
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: July 28, 2020
Received: August 6, 2020

Dear Fu Ailing:

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)*

K201211

Device Name

3MP Color LCD Monitors C32S+, C32SP+; 3MP Monochrome LCD Monitors G32S+, G32SP+

Indications for Use *(Describe)*

The 3MP Color LCD Monitors C32S+, C32SP+ are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The displays are not intended for mammography.

The 3MP Monochrome LCD Monitors G32S+, G32SP+ are intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The devices are not specified for digital mammography systems.

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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K201211

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR807.92 (a) (1)]

April 15, 2020

2. Submitter's Information [21 CFR807.92 (a) (1)]

Name of Sponsor: Shenzhen Beacon Display Technology Co., Ltd.
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3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name/Model: 3MP Color LCD Monitors C32S+, C32SP+;
3MP Monochrome LCD Monitors G32S+, G32SP+
Common Name: 3MP LCD Monitors C32S+, C32SP+, G32S+, G32SP+
Classification Name: Picture archiving and communications system
Regulation Number: 21 CFR 892.2050
Product code: PGY
Classification Panel: Radiology
Device Class: II

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicate within this submission is as follows:

EIZO Corporation, RadiForce RX360, RX360-AR has been cleared by FDA through 510(k) No. K182591 (Decision Date - October 18, 2018).

EIZO NANAO Corporation, 3MP Monochrome LCD Monitor, RadiForce GX340 has been cleared by FDA through 510(k) No. K113784 (Decision Date - May 4, 2012).

5. Description of the Device [21 CFR 807.92(a) (4)]

3MP Color LCD monitors C32S+, C32SP+; 3MP Monochrome LCD monitors G32S+, G32SP+ are specifically designed to provide the high definition image outputs for general Radiography.

The products have been strictly calibrated so they meet DICOM Part 3.14 and other standards. They use the latest generation of LED backlight panels, supporting resolution 2048 x 1536. The built-in brightness stabilization control circuits make sure the brightness of these monitors are stable in their life and the calibrations are continuous, so the products meet the demands of high precision medical imaging. For the C32SP+ and G32SP+ surface protection panels with anti-reflection coating, there are characteristics such as anti-reflection, easy cleaning and anti-scratch screen.

Model variations are distinguished by characters. C means the Color monitor, G means the Monochrome monitor, and P means the monitor with an additional glass screen. For example, C32S+ is a color LCD monitor; G32SP+ is a monochrome LCD monitor with the additional glass screen.

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

The 3MP Color LCD Monitors C32S+, C32SP+ are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The displays are not intended for mammography.

The 3MP Monochrome LCD Monitors G32S+, G32SP+ are intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The devices are not specified for digital mammography systems.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

C32S+, C32SP+ Color LCD Monitors

Monitor characteristics:	
Screen technology	21.3”, TFT, color, LCD screen, anti-glare, hard coating
Active area(H x V)	324.86 x 433.15 mm
Pixel pitch	0.2115 mm (H) x 0.2115 mm (V)
Resolution	1536 x 2048
Contrast ratio	1500:1 (typical), 1200:1 (minimal)
Viewing angle (CR > 10)	Horizontal: 178° (typical)
	Vertical: 178° (typical)
Screen brightness	1000 cd/m^2 (typical)
Refresh rate	60 Hz
Backlighting	LEDs
Lifetime of backlight	50000 hours
Response time (T_{on} + T_{off})	25 ms (typical)
Power supply:	
Line voltage	12 V
Current consumption	6.67 A
Power consumption	80 W (maximum)
Standby	< 5 W
Adaptor	**1:GSM90A12** Input: 100~240V, 1.3-0.6A, 50/60Hz, Output: +12VDC, 6.67A **2:GSM120A12** Input: 100~240V, 1.4-0.7A, 50/60Hz, Output: +12VDC, 8.5A
Control and connection:	
Front	1 operation LED, 6 functional keys
Back	• Ground*1 • Power switch*1 • DVI-D*1 • DP*1 • USB Upstream Port*1 • USB Downstream Port*2
Mechanical characteristics :	
Housing components	Plastic
Ventilation openings	Natural heat radiation

Protection level	IP 20 IP 65 (Applicable to the front of C32SP+)
Climatic conditions :	
Working temperature	0℃ - 40℃
Working humidity	15% - 85% Relative humidity, no condensation
Working atmospheric	700 hPa - 1060 hPa
Transport and storage	-20℃ - 60℃
Transport and storage	10% - 90% Relative humidity, no condensation
Transport and storage	700 hPa - 1060 hPa
Safety regulations :	
Safety standards	IEC60601-1, EN60601-1 ANSI/AAMI ES60601-1: 2005 + A2(R2012) + A1 CAN/CSA-C22.2 NO. 60601-1
Conformity	CCC, CE, TUV, FCC
Dimension:	
Dimensions (W x H x D) in	369 x 511.5 ~ 596.15 x 220 mm
With packing (W x H x D)	608 x 561 x 327 mm
Weight :	
Net weight	9.5 ± 0.5 kg
Gross weight	11.0 ± 0.5 kg

G32S+, G32SP+ Monochrome LCD monitors

Monitor characteristics:	
Screen technology	21.3”, TFT, grayscale, LCD screen, anti-glare, hard
Active area(H x V)	324.86 x 433.15 mm
Pixel pitch	0.2115 mm (H) x 0.2115 mm (V)
Resolution	1536 x 2048
Contrast ratio	1500:1 (typical), 1200:1 (minimal)
Viewing angle (CR > 10)	Horizontal: 170° (typical)
	Vertical: 170° (typical)
Screen brightness	2000 cd/m^2 (typical)
Refresh rate	60 Hz
Backlighting	LEDs
Lifetime of backlight	50000 hours
Response time (T_{on} + T_{off})	28 ms (typical)

Power supply:	
Line voltage	12 V
Current consumption	6.67 A
Power consumption	50 W (maximum)
Standby	< 5 W
Adaptor	**1:GSM90A12** Input: 100~240V, 1.3-0.6A, 50/60Hz Output: +12VDC, 6.67A **2:GSM120A12** Input: 100~240V, 1.4-0.7A, 50/60Hz Output: +12VDC, 8.5A
Control and connection:	
Front	1 operation LED, 6 functional keys
Back	• Ground*1 • Power switch*1 • DVI-D*1 • DP*1 • USB Upstream Port*1 • USB Downstream Port*2
Mechanical characteristics：	
Housing components	Plastic
Ventilation openings	Natural heat radiation
Protection level	IP 20
Climatic conditions：	
Working temperature	0℃ - 40℃
Working humidity	15% - 85% Relative humidity, no condensation
Working atmospheric	700 hPa - 1060 hPa
Transport and storage	-20℃ - 60℃
Transport and storage	10% - 90% Relative humidity, no condensation
Transport and storage	700 hPa - 1060 hPa
Safety regulations：	
Safety standards	IEC60601-1, EN60601-1
Conformity	CCC, CE, TUV, FCC
Dimension:	
Dimensions (W x H x D) in	369 x 511.15 ~ 596.15 x 220 mm
With packing (W x H x D)	608 x 561 x 327 mm
Weight：	
Net weight	9.0 ± 0.5 kg
Gross weight	11.0 ± 0.5 kg

8. Substantial Equivalence [21 CFR 807.92(b) (1) and 807.92]

8.1 Intended uses:

Table 1 Intended Use Comparison of C32S+, C32SP+

ID	Comparison Item	Proposed Device 3MP Color LCD Monitors C32S+, C32SP+	Predicate Device 3MP Color LCD Monitor RadiForce RX360, RX360-AR
1	Intended Use	The 3MP Color LCD Monitors C32S+, C32SP+ are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The displays are not intended for mammography.	The 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.

Table 2 Intended Use Comparison of G32S+, G32SP+

ID	Comparison Item	Proposed Device 3MP Monochrome LCD Monitors G32S+, G32SP+	Predicate Device 3MP Monochrome LCD Monitor RadiForce GX340
2	Intended Use	The 3MP Monochrome LCD Monitors G32S+, G32SP+ are intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The devices are not specified for digital mammography systems.	The RadiForce GX340 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device is not specified for digital mammography system.

8.2 Comparison table

Table 3 General Comparison of C32S+, C32SP+

ID	Comparison Item	Proposed Device 3MP Color LCD Monitors C32S+, C32SP+	Predicate Device 3MP Color LCD Monitor RadiForce RX360, RX360-AR	Explanation of Differences
	Display Performance/Specifications			
3.1	**Display technology**	Color (IPS)	Color (IPS)	-
3.2	**Screen size**	54.1cm/21.3” Aspect ratio:3:4	54.1cm/21.3” Aspect ratio:3:4	-
3.3	**Viewing angle (H/V)**	$178^0/178^0$	$178^0/178^0$	-
3.4	**Native resolution**	1536 x 2048	1536 x 2048	-
3.5	**Viewable image size (H x V)**	324.86 x 433.15 mm	324.9 x 433.2 mm	-
3.6	**Pixel pitch**	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm	-
3.7	**Response time (typical)**	25 ms (on / off)	12 ms (on / off)	Different screen
3.8	**Brightness (typical)**	1000 cd/m^2	1100 cd/m^2	Different screen
3.9	**Recommended brightness for**	500 cd/m^2	500 cd/m^2	-

3.10	**Contrast ratio (typical)**	1500:1	1500:1	-
3.11	**Backlight type**	LED	LED	-
3.12	**Display colors**	10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,384 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,384 tones	10-bit colors (DisplayPort) : 1.07 billion (maximum) colors 8-bit colors: 16.77 million from a palette of 543 billion colors	Tone between the predicate device and our proposed devices are different. But they pass the exams in AAPM-TG18 4.3 “Luminance Response”. Therefore, they are equivalent to the predicate device.
	Video Signals			
4.1	**Input video signals**	DVI-D (dual link) x 1, DisplayPort x 1	DVI-D (dual link) x 1, DisplayPort x 2	Different design scheme
4.2	**Digital Scanning Frequency (H, V)**	31 - 97 kHz/59 - 61 Hz	31 - 127 kHz/29 - 61.5 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	Different design scheme
4.3	**Video bandwidth**	DVI: 216 MHz DisplayPort: 216 MHz	DVI: 215MHz DisplayPort: 215MHz	Different design scheme
	Power Related Specifications			
5.1	**Power Requirements**	DC 12 V / 6.67 A	AC 100 - 240 V:50 / 60 Hz	Difference between built-in power supply and built-out power supply
5.2	**Maximum power consumption**	80 W	74 W	Different design scheme

5.3	**Power save mode**	Less than 5 W	1 W or less	Different design scheme
5.4	**Power Management**	DVI DMPM, DisplayPort 1.2	DVI DMPM, DisplayPort 1.1a	Different design scheme
	Miscellaneous Features/Specifications			
6.1	**Quality-control Software**	Beacon Monitor Manage	RadiCS	Different design scheme
6.2	**Sensors**	Backlight sensor Integrated front sensor Ambient light sensor	Backlight sensor Integrated front sensor Presence sensor Ambient light sensor	Different design scheme
6.3	**Luminance calibration tools**	Integrated optical sensor External optical sensor Calibration software: Beacon Monitor Manage	Integrated optical sensor External optical sensor Calibration software: RadiCS	Different design scheme
6.4	**USB Ports**	**Upstream** USB 2.0: Type-B x 1	**Upstream** USB 2.0: Type-B x 2	Different design scheme
6.5	**Brightness stabilization**	Yes	Yes	-
6.6	**Digital uniformity equalizer**	Yes	Yes	-
6.7	**Net weight**	9.5	8	Different weight due to different components and parts
6.8	**Hole Spacing (VESA Standard)**	100 x 100mm	100 x 100mm	-
6.9	**Dimensions w/o stand (W x H x D)**	369 x 220 x 511.5 ~ 596.15	341.3 x 200 x 481.5 - 571.5	Different housing design due to the different panel size

Table 4 General Comparison of G32S+/G32SP+

ID	Comparison Item	Proposed Device 3MP Monochrome LCD Monitors G32S+, G32SP+	Predicate Device 3MP Monochrome LCD Monitor RadiForce GX340	Explanation of Differences
	Display Performance/Specifications			
3.1	**Display technology**	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
3.2	**Screen size**	54 cm / 21.3” (541 mm diagonal)	54 cm / 21.3” (541 mm diagonal)	-
3.3	**Viewing angle (H/V)**	$170^0/170^0$	$176^0/176^0$	Different screen
3.4	**Native resolution**	1536 x 2048 (3:4 aspect ratio)	1536 x 2048 (3:4 aspect ratio)	-
3.5	**Viewable image size (H x V)**	324.86 x 433.15 mm	324.8 x 433.1 mm	-
3.6	**Pixel pitch**	0.2115 mm (H) x 0.2115 mm	0.2115 x 0.2115 mm	-
3.7	**Response time (typical)**	28 ms (On/Off)	40 ms (On/Off)	Different screen
3.8	**Brightness (typical)**	2000 cd/m^2	1200 cd/m^2	Different screen
3.9	**Recommended brightness for**	500 cd/m^2	500 cd/m^2	-
3.10	**Contrast ratio (typical)**	1500:1	1400:1	Different screen

3.11	**Backlight type**	LED	LED	-
3.12	**Grayscale Tones**	10-bit (DisplayPort): 1,024 from a palette of 16,384 tones 8-bit (DVI): 256 from a palette of 16,384 tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	Tone between the predicate device and our proposed devices are different. But they pass the exams in AAPM-TG18 4.3 “Luminance Response”. Therefore, they are equivalent to the predicate device.
	Video Signals			
4.1	**Input video signals**	DVI-D (dual link) x 1 DisplayPort x 1	DVI-D (dual link) x 1 DisplayPort x 1	-
4.2	**Digital Scanning Frequency (H, V)**	31 - 97 kHz, 60 - 70 kHz	31 - 127 kHz, 29.5 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	Different design scheme
4.3	**Dot Clock**	216 MHz	215 MHz	Different design scheme
	Power Related Specifications			
5.1	**Power Requirements**	DC 12 V / 6.67 A	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	Difference between built-in power supply and built-out power supply
5.2	**Maximum power consumption**	50 W	90 W	Different design scheme
5.3	**Power save mode**	Less than 5 W	Less than 1.6 W	Different design scheme

5.4	**Power Management**	DVI DMPM, DisplayPort 1.2	DVI DMPM, DisplayPort 1.1a	Different design scheme
	Miscellaneous Features/Specifications			
6.1	**Quality-control procedures**	Beacon Monitor Manage	RadiCS	Different design scheme
6.2	**Sensors**	Backlight Sensor Integrated Front Sensor Ambient Light Sensor	Backlight Sensor Integrated Front Sensor Presence Sensor Ambient Light Sensor	Different design scheme
6.3	**Luminance calibration tools**	Integrated optical sensor External optical sensor Calibration software: Beacon Monitor Manage	Integrated optical sensor External optical sensor Calibration software: RadiCS	Different design scheme
6.4	**USB Ports**	1 upstream 2 downstream / Rev. 2.0	1 upstream 2 downstream / Rev. 2.0	-
6.5	**Brightness stabilization**	Yes	Yes	-
6.6	**Digital uniformity equalizer**	Yes	Yes	-
6.7	**Net weight**	9.0 kg	10.2 kg	Different weight due to different components and parts
6.8	**Hole Spacing (VESA Standard)**	VESA standard 100 x 100 mm	VESA standard 100 x 100 mm	-
6.9	**Dimensions w/o stand (W x H x D)**	369 x 511.15 ~ 596.15 x 220	376 x 520~599 x 245.5	Different housing design due to the different panel size

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the C32S+, C32SP+, G32S+, G32SP+.

8.3 Performance Testing Comparation

The bench tests were performed on the proposed devices C32S+, C32SP+, G32S+, G32SP+ as below.

1) Verify the conformance to DICOM GSDF in accordance with *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline).
2) Measure the luminance non-uniformity characteristics of the display screen in accordance with TG18 guideline.
3) Measure the luminance stability with the temperature 0 ℃ , 25 ℃ and 40 ℃ on Luminance response by AAPM-TG18.
4) Measure the luminance at the angles of 30^0 and 45^0 in diagonal, horizontal and vertical directions at center and four corners by AAPM-TG18.
5) Measure the temporal response using the typical data provided by the panel manufacturer.
6) Visually check the presence or absence of miscellaneous artifacts on the display screen in accordance with TG18 guideline.
7) Measure the spatial noise by noise power spectrum.
8) Measure the spatial resolution expressed as modulation transfer function (MTF)
9) Maximum number allowed for each type of pixel defects/faults
10) Meausure the maximum, minimum, achievable, and recommended luminance.
11) Measure the color tracking (primary colors and color gamut).

The test results showed that C32S+, C32SP+, G32S+, G32SP+ are with display characteristics equivalent to those of the predicate devices, RadiForce RX360, RX360-AR and 3MP Monochrome LCD Monitor, RadiForce GX340 except some items, each of which was determined that it would not affect observer's performance. No animal or clinical testing is needed for C32S+, C32SP+, G32S+, G32SP+.

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, Shenzhen Beacon Display Technology Co., Ltd. concludes that:

- The intended uses of C32S+, C32SP+, G32S+, G32SP+ are totally same as those of the predicate devices.
- The technological characteristics differences between C32S+, C32SP+, G32S+, G32SP+ and the predicate devices do not affect the safety and effectiveness, so no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of C32S+, C32SP+, G32S+, G32SP+ are equivalent to those of the predicate devices.