



Shenzhen Beacon Display Technology Co., Ltd.
% Fu Ailing
Document Engineer
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Shenzhen, Guangdong 518055
CHINA

July 2, 2020

Re: K201599

Trade/Device Name: 2MP Color/Monochrome LCD Monitors C22S+, C22SP+/G22S+
G22SP+, G23S+, G23SP+

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: Class II

Product Code: PGY

Dated: May 29, 2020

Received: June 12, 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

006_Indications for Use Statement

Indications for Use

510(k) Number (if known)

K201599

Device Name

2MP Color/Monochrome LCD Monitors C22S+, C22SP+/G22S+, G22SP+, G23S+, G23SP+

Indications for Use (Describe)

The 2MP Color/Monochrome LCD Monitors C22S+, C22SP+/G22S+, G22SP+, G23S+, G23SP+ are intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. The monitors do 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.

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007_510 (k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

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

K201599

May 29, 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: 2MP Color/Monochrome LCD Monitors C22S+, C22SP+/G22S+,
G22SP+, G23S+, G23SP+

Common Name: 2MP LCD Monitors C22S+, C22SP+, G22S+, G22SP+, G23S+,
G23SP+

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 predicates within this submission are as follows:

EIZO Corporation, 2MP Color LCD Monitor, RadiForce RX250 and RX250-AR has been cleared by FDA through 510(k) No. K160247 (Decision Date - February 23, 2016).

EIZO NANA Corporation, 2MP Monochrome LCD Monitor, RadiForce GX240 has been cleared by FDA through 510(k) No. K120407 (Decision Date - April 19, 2012).

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

C22S+, C22SP+/G22S+, G22SP+, G23S+, G23SP+ are 21.3-inch TFT LCD color/grayscale monitors. They 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 panel, supporting resolution 1200 x 1600. The built-in brightness stabilization control circuits make sure the brightness of these monitors is stable in their life and the calibration is continuous, so the products meet the demand of high precision medical imaging. For C22SP+, G22SP+, G23SP+ 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 acryl glass. 2 means 2MP; 2 or 3 means a screen change. For example, C22S+ is a color LCD monitor; G22SP+ is a monochrome LCD monitor with the additional acryl glass on the front of the screen, and G23SP+ is a monochrome LCD monitor with the additional acryl glass on the front of the screen which is different with that of G22SP+.

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

The 2MP Color/Monochrome LCD Monitors C22S+, C22SP+/G22S+, G22SP+, G23S+, G23SP+ are intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. The monitors do not support the display of mammography images for diagnosis.

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

C22S+/C22SP+ Color LCD monitor

Panel	21.3", TFT, color, LCD screen, anti-glare, hard coating
Brightness (Typ.)	1000 cd/m ²
CR (Typ.)	1800:1
Viewing angle	R/L 178°, U/D 178° Typ. (CR > 10)
Pixel Pitch	(H) 0.270 × (V) 0.270 mm
Native resolution	1,200 x 1,600
Display area	324 mm(H) x 432 mm (V)
Aspect ratio	3:4
Screen size	21.3" real diagonal
Power	DC 12 V/6.0 A
Power consumption	Max. 60 W
Input signals	DVI-D, Display Port, VGA
Plug and play	VESA DDC 2B
Dimension	369 mm (W) x 511.15 ~ 596.15 mm (H) x 220 mm (D) (with stand) 608 x 561 x 327 mm (with packing)
Weight	8.0 ± 0.5 kg (Net) 11.0 ± 0.5 kg (Gross)
Operating temperature and humidity	Temperature: 0°C ~ 40°C Humidity: 15% ~ 85%
Storage temperature and humidity	Temperature: -20°C ~ 60°C Humidity: 10% ~ 90%

G22S+/G22SP+ Monochrome LCD monitor

Panel	21.3", TFT, monochrome, LCD screen, anti-glare,
Brightness (Typ.)	2000 cd/m ²
CR (Typ.)	1800:1
Viewing angle	R/L 178°, U/D 178° Typ. (CR > 10)
Pixel Pitch	(H) 0.270 × (V) 0.270 mm
Native resolution	1,200 x 1,600
Display area	324 mm(H) x 432 mm (V)
Aspect ratio	3:4
Screen size	21.3" real diagonal

Power	DC 12 V/6.0 A
Power consumption	Max. 50 W
Input signals	DVI-D, Display Port, VGA
Plug and play	VESA DDC 2B
Dimension	369 x 511.5 ~ 596.15 x 220 mm (with stand) 608 x 561 x 327 mm (with packing)
Weight	8.0 ± 0.5 kg (Net) 11.0 ± 0.5 kg (Gross)
Operating temperature and humidity	Temperature: 0°C ~ 40°C Humidity: 15% ~ 85%
Storage temperature and humidity	Temperature: -20°C ~ 60°C Humidity: 10% ~ 90%

G23S+/G23SP+ Monochrome LCD monitor

Panel	21.3", TFT, monochrome, LCD screen, anti-glare,
Brightness (Typ.)	1900 cd/m ²
CR (Typ.)	1800:1
Viewing angle	R/L 178°, U/D 178° Typ. (CR > 10)
Pixel Pitch	(H) 0.270 × (V) 0.270 mm
Native resolution	1,200 x 1,600
Display area	324 mm(H) x 432 mm (V)
Aspect ratio	3:4
Screen size	21.3" real diagonal
Power	DC 12 V/6.0 A
Power consumption	Max. 50 W
Input signals	DVI-D, Display Port, VGA
Plug and play	VESA DDC 2B
Dimension	369 mm (W) x 511.5 ~ 596.15 mm (H) x 220 mm (D) (with stand) 608 mm (W) x 561 mm (H) x 327 mm (D) (with packing)
Weight	8.0 ± 0.5 kg (Net) 11.0 ± 0.5 kg (Gross)
Operating temperature and humidity	Temperature: 0°C ~ 40°C Humidity: 15% ~ 85%
Storage temperature and humidity	Temperature: -20°C ~ 60°C Humidity: 10% ~ 90%

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

8.1 Intended use:

Table 1 Intended Use Comparison of C22S+/C22SP+

ID	Comparison Item	Proposed Device 2MP Color LCD Monitors (C22S+, C22SP+)	Predicate Device 2MP Color LCD Monitor (RX250, RX250-AR)
1	Intended Use	The 2MP LCD Monitors C22S+, C22SP+ are intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. The monitors do 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.

Table 2 Intended Use Comparison of G22S+, G22SP+, G23S+, G23SP+

ID	Comparison Item	Proposed Device 2MP Monochrome LCD Monitors (G22S+, G22SP+, G23S+, G23SP+)	Predicate Device 2MP Monochrome LCD Monitor (RadiForce GX240)
1	Intended Use	The 2MP LCD Monitors G22S+, G22SP+, G23S+, G23SP+ are intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. The monitors do not support the display of mammography images for diagnosis.	The RadiForce GX240 is intended to be used in displaying and viewing digital images by trained medical practitioners. The RadiForce GX240 does not support the display of mammography images for diagnosis.

8.2 Comparison table

Table 3 General Comparison of C22S+/C22SP+

ID	Comparison Item	Proposed Device 2MP Color LCD Monitors (C22S+, C22SP+)	Predicate Device 2MP Color LCD Monitor (RX250, RX250-AR)	Explanation of Difference
2	Display Performance/Specifications			
2.1	Screen Technology	IPS TFT Color LCD Panel	IPS TFT Color LCD Panel	-
2.2	Viewing angle (H, V)	H: 178°, V: 178°	H: 176°, V: 176°	Different screen
2.3	Resolution	2MP (1,200 x 1,600)	2MP (1,200 x 1,600)	-
2.4	Aspect ratio	3 : 4	3 : 4	-
2.5	Active screen size	324.0 mm x 432.0 mm	324.0 mm x 432.0 mm	-
2.6	Pixel pitch	0.270 mm x 0.270 mm	0.270 mm x 0.270 mm	-
2.7	Typical luminance	1000 cd/m ²	800 cd/m ²	Different screen
2.8	DICOM calibrated luminance	500 cd/m ²	400 cd/m ²	Different screen
2.9	Contrast ratio	1800 : 1	1400 : 1	Different screen
2.10	Backlighting	LED	LED	-
2.11	Display Colors	From a palette of 1.07 billion colors: - 10-bit input (DisplayPort): 1.07 billion colors (maximum) - 8-bit input: 16.77 million colors	From a palette of 68 billion colors: - 10-bit input (DisplayPort): 1.07 billion colors (maximum) - 8-bit input: 16.77 million colors	Different screen
2.12	Luminance non-uniformity compensation	-	Digital Uniformity Equalizer	Different design scheme

3		Video Signals		
3.1	Input video signals	DVI-D x 1, DisplayPort x 1, VGA x 1	DVI-D x 1, DisplayPort x 1	Different design scheme
3.2	Ouput video signals	-	-	-
3.3	Scanning Frequency (H, V)	31 - 82 kHz / 59 – 61 Hz Frame synchronous mode: 59 - 61 Hz	31 - 100 kHz / 59 – 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 - 61 Hz	-
4		Power Related Specifications		
4.1	Power Requirements	DC 12 V/6.0 A	AC 100 - 240 V: 50 / 60Hz	Difference between Built-in power supply and Built-out power supply
4.2	Power Consumption / Save Mode	60 W/Less than 5 W	79 W / Less than 1.6 W	Different design scheme
4.3	Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
5		Miscellaneous Features/Specifications		
5.1	QC software	Beacon Monitor Manage	RadiCS	Different design scheme
5.2	Sensors	C22S+: Backlight Sensor, Ambient Light Sensor C22SP+: Backlight Sensor, Ambient Light Sensor Integrated Front Sensor	Backlight Sensor, Presence Sensor	Different design scheme

5.3	USB Ports/Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
5.4	Dimensions w/o stand (W x H x D)	365 x 478 x 75 mm	361 x 465 x 78 mm	Different housing design due to the different panel size

Table 4 General Comparison of G22S+/G22SP+

ID	Comparison Item	Proposed Device 2MP Monochrome LCD Monitors (G22S+, G22SP+)	Predicate Device 2MP Monochrome LCD Monitor (RadiForce GX240)	Explanation of Difference
2	Display Performance/Specifications			
2.1	Screen Technology	Monochrome TFT LCD Panel (IPS)	Monochrome TFT LCD Panel (IPS)	-
2.2	Viewing angle (H, V)	H: 178°, V: 178°	H: 176°, V: 176°	Different screen
2.3	Resolution	2MP (1,200 x 1,600)	2MP (1,200 x 1,600)	-
2.4	Aspect ratio	3 : 4	3 : 4	-
2.5	Active screen size	324.0 mm x 432.0 mm	324.0 mm x 432.0 mm	-
2.6	Pixel pitch	0.270 mm x 0.270 mm	0.270 mm x 0.270 mm	-
2.7	Typical luminance	2000 cd/m ²	1200 cd/m ²	Different screen
2.8	DICOM calibrated luminance	500 cd/m ²	500 cd/m ²	-
2.9	Contrast ratio	1800:1	1400 : 1	Different screen
2.10	Backlighting	LED	LED	-

2.11	Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 1,024 tones 8-bit: 256 from a palette of 1,024 tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	Different screen
2.12	Luminance non-uniformity compensation	-	Digital Uniformity Equalizer	Different design scheme
3	Video Signals			
3.1	Input video signals	DVI-D x 1, DisplayPort x 1, VGA x 1	DVI-D x 1, DisplayPort x 1	Different design scheme
3.2	Ouput video signals	-	DisplayPort x 1 (daisy chain)	Different design scheme
3.3	Scanning Frequency (H, V)	31 - 82 kHz / 59 – 61 Hz Frame synchronous mode: 59 - 61 Hz	31 - 100 kHz / 59 – 61 Hz Frame synchronous mode: 59 - 61 Hz	-
4	Power Related Specifications			
4.1	Power Requirements	DC 12 V/6.0 A	AC 100 -120 V, 200 - 240 V: 50 / 60 Hz	Difference between Built-in power supply and Built-out power supply
4.2	Power Consumption / Save Mode	50 W/Less than 5 W	76 W / Less than 1.6 W	Different design scheme
4.3	Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
5	Miscellaneous Features/Specifications			
5.1	QC software	Beacon Monitor Manage	RadiCS	Different design scheme

5.2	Sensors	G22S+: Backlight Sensor, Ambient Light Sensor G22SP+: Backlight Sensor, Ambient Light Sensor Integrated Front Sensor	Backlight Sensor, Presence Sensor, Integrated Front Sensor Ambient Light Sensor	Different design scheme
5.3	USB Ports/Standard	1 upstream, 2 downstream	1 upstream, 2 downstream	-
5.4	Dimensions w/o stand (W x H x D)	365 x 478 x 75 mm	376 x 505 x 98 mm	Different housing design due to the different panel size

Table 5 General Comparison of G23S+/G23SP+

ID	Comparison Item	Proposed Device 2MP Monochrome LCD Monitors (G23S+, G23SP+)	Predicate Device 2MP Monochrome LCD Monitor (RadiForce GX240)	Explanation of Difference
2	Display Performance/Specifications			
2.1	Screen Technology	Monochrome TFT LCD Panel (IPS)	Monochrome TFT LCD Panel (IPS)	-
2.2	Viewing angle (H, V)	H: 178°, V: 178°	H: 176°, V: 176°	Different screen
2.3	Resolution	2MP (1,200 x 1,600)	2MP (1,200 x 1,600)	-
2.4	Aspect ratio	3 : 4	3 : 4	-
2.5	Active screen size	324.0 mm x 432.0 mm	324.0 mm x 432.0 mm	-
2.6	Pixel pitch	0.270 mm x 0.270 mm	0.270 mm x 0.270 mm	-
2.7	Typical luminance	1900 cd/m ²	1200 cd/m ²	Different screen

2.8	DICOM calibrated luminance	500 cd/m ²	500 cd/m ²	-
2.9	Contrast ratio	1800:1	1400 : 1	Different screen
2.10	Backlighting	LED	LED	-
2.11	Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 1,024 tones 8-bit: 256 from a palette of 1,024 tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	Different screen
2.12	Luminance non-uniformity compensation	-	Digital Uniformity Equalizer	Different design scheme
3	Video Signals			
3.1	Input video signals	DVI-D x 1, DisplayPort x 1, VGA x 1	DVI-D x 1, DisplayPort x 1	Different design scheme
3.2	Ouput video signals	-	DisplayPort x 1 (daisy chain)	Different design scheme
3.3	Scanning Frequency (H, V)	31 - 82 kHz / 59 – 61 Hz Frame synchronous mode: 59 - 61 Hz	31 - 100 kHz / 59 – 61 Hz Frame synchronous mode: 59 - 61 Hz	-
4	Power Related Specifications			
4.1	Power Requirements	DC 12 V/6.0 A	AC 100 -120 V, 200 - 240 V: 50 / 60 Hz	Difference between Built-in power supply and Built-out power supply
4.2	Power Consumption / Save Mode	50 W/Less than 5 W	76 W / Less than 1.6 W	Different design scheme
4.3	Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-

5	Miscellaneous Features/Specifications			
5.1	QC software	Beacon Monitor Manage	RadiCS	Different design scheme
5.2	Sensors	G23S+: Backlight Sensor, Ambient Light Sensor G23SP+: Backlight Sensor, Ambient Light Sensor Integrated Front Sensor	Backlight Sensor, Presence Sensor, Integrated Front Sensor Ambient Light Sensor	Different design scheme
5.3	USB Ports/Standard	1 upstream, 2 downstream	1 upstream, 2 downstream	-
5.4	Dimensions w/o stand (W x H x D)	365 x 478 x 75 mm	376 x 505 x 98 mm	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 C22S+, C22SP+, G22S+, G22SP+, G23S+, G23SP+.

8.3 Performance Testing

The bench tests were performed on C22S+, C22SP+, G22S+, G22SP+, G23S+, G23SP+ as below.

- Verify the conformance to DICOM GSDF in accordance with *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline).
- Measure the luminance non-uniformity characteristics of the display screen in accordance with TG18 guideline.
- Measure the chromaticity non-uniformity characteristics of the display screen in accordance with TG18 guideline.
- Measure the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance.
- Visually check the presence or absence of miscellaneous artifacts on the display

screen in accordance with TG18 guideline.

- Measure the spatial resolution expressed as modulation transfer function (MTF)
- Maximum number allowed for each type of pixel defects/faults

The test results showed that C22S+, C22SP+, G22S+, G22SP+, G23S+, G23SP+ are with display characteristics equivalent to those of the predicate device, RadiForce RX250 and RX250-AR, and RadiForce GX240 except some items, each of which was determined that it would not affect observer's performance.

No animal or clinical testing is needed for C22S+, C22SP+, G22S+, G22SP+, G23S+, G23SP+.

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 C22S+, C22SP+, G22S+, G22SP+, G23S+, G23SP+ are totally same as those of the predicate devices.
- The technological characteristics differences between C22S+, C22SP+, G22S+, G22SP+, G23S+, G23SP+ and RadiForce RX250 and RX250-AR, RadiForce GX240 do not affect the safety and effectiveness, so no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of C22S+, C22SP+, G22S+, G22SP+, G23S+, G23SP+ are equivalent to those of the predicate devices.