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

October 27, 2017

Re: K172815
Trade/Device Name: 2MP LCD Monitor (G22S+, G22SP+, C22S+, C22SP+)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: August 29, 2017
Received: September 18, 2017

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. 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.

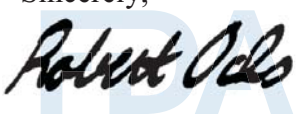
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 (DICE) 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 (DICE) 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172815

Device Name

2MP LCD Monitor (G22S+, G22SP+, C22S+, C22SP+)

Indications for Use *(Describe)*

The 2MP LCD Monitor (G22S+, G22SP+, C22S+, C22SP+) 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.

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510(k) Summary

[As required by 21 CFR 807.92]

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

August 29, 2017

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 LCD Monitor (G22S+, G22SP+, C22S+, C22SP+)
Common Name: 2MP LCD Monitor
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 NANAO Corporation, 2MP Monochrome LCD Monitor, RadiForce GX240 has been cleared by FDA through 510(k) No. K120407 (Decision Date - April 19, 2012).

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).

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

Beacon LCD monitor (G22S+, G22SP+, C22S+, C22SP+) is for viewing medical images other than those of mamography. Its using the latest generation of LED back light panel, with the resolution 1600 x 1200 (landscape), 1200 x 1600 (portrait), built-in brightness stabilization circuit, the monitor can guarantee the stable brightness and persistent calibration throughout its life. The anti-glare screen can prevent display from reflection under highlight conditions, making the image and display clearer. The monitor supports DVI-D, DP and VGA.

Model variations are distinguished by characters. G means the Monochrome monitor, C means the Color monitor, and P means the monitor with an additional glass screen. For example, G22S+ is a monochrome LCD monitor; C22SP+ is a color LCD monitor with the additional glass screen.

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

The 2MP LCD Monitor (G22S+, G22SP+, C22S+, C22SP+) 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.

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

G22S+/G22SP+ Monochrome LCD monitor

Panel	21.3”, TFT, monochrome, LCD screen, anti-glare, hard coating
Brightness (Typ.)	500 cd/m^2
CR (Typ.)	1400:1
Viewing angle	R/L 176°, U/D 176° 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. 40 W
Input signals	DVI-D, Display Port, VGA
Plug and play	VESA DDC 2B
Dimension	369 mm (W) x 506 ~ 626 mm (H) x 235 mm (D) (with stand) 369 mm (W) x 483 mm (H) x 65 mm (D) (without stand)
Weight	6.0 kg (without Stand) 9.2 kg (with Stand)
Operating temperature and humidity	Temperature: 5°C ~ 35°C Humidity: 15% ~ 85%
Storage temperature and humidity	Temperature: -20°C ~ 60°C Humidity:10% ~ 90%

C22S+/C22SP+ Color LCD monitor

Panel	21.3”, TFT, color, LCD screen, anti-glare, hard coating
Brightness (Typ.)	500 cd/m^2
CR (Typ.)	1400:1
Viewing angle	R/L 176°, U/D 176° 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 506 ~ 626 mm (H) x 235 mm (D) (with stand) 369 mm (W) x 483 mm (H) x 65 mm (D) (without stand)
Weight	6.0 kg (without Stand) 9.2 kg (with Stand)
Operating temperature and humidity	Temperature: 5°C ~ 35°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 uses:

Table 1 Intended Use Comparison of G22S+/G22SP+

ID	Comparison Item	Proposed Device 2MP Monochrome LCD Monitor (G22S+, G22SP+)	Predicate Device 2MP Monochrome LCD Monitor (RadiForce GX240)
1	**Intended Use**	The 2MP LCD Monitor (G22S+, G22SP+) 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 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.

Table 2 Intended Use Comparison of C22S+/C22SP+

ID	Comparison Item	Proposed Device 2MP Color LCD Monitor (C22S+, C22SP+)	Predicate Device 2MP Color LCD Monitor (RX250, RX250-AR)
1	**Intended Use**	The 2MP LCD Monitor (C22S+, C22SP+) 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.

8.2 Comparison table

Table 3 General Comparison of G22S+/G22SP+

ID	Comparison Item	Proposed Device 2MP Monochrome LCD Monitor (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: 176°, V: 176°	H: 176°, V: 176°	-
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	1400:1	1400 : 1	-
2.10	Backlighting	LED	LED	-
2.11	Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones	-
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 - 100 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	40 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)	369 x 483 x 65 mm	376 x 505 x 98 mm	Different housing design due to the different panel size

Table 4 General Comparison of C22S+/C22SP+

ID	Comparison Item	Proposed Device 2MP Color LCD Monitor (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: 176°, V: 176°	H: 176°, V: 176°	-
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	900 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	1400 : 1	1400 : 1	-
2.10	Backlighting	LED	LED	-
2.11	Display Colors	From a palette of 68 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	-
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 - 100 kHz / 59 – 61 Hz (VGA Text: 69 - 71 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)	369 x 483 x 65 mm	361 x 465 x 78 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 G22S+, G22SP+, C22S+, C22SP+.

8.3 Performance Testing

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

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

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