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

October 19, 2020

Re: K202374
Trade/Device Name: 4MP/8MP Color LCD Monitors C44W+/C82W+, C83W+, C85W+
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: August 15, 2020
Received: August 19, 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)*

K202374

Device Name

4MP/8MP Color LCD Monitors C44W+/C82W+, C83W+, C85W+

Indications for Use *(Describe)*

These products are intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. They 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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K202374

510(k) Summary

[As required by 21 CFR 807.92]

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

July 1, 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: 4MP/8MP Color LCD Monitors C44W+/C82W+, C83W+, C85W+
Common Name: LCD Monitors C44W+, C82W+, C83W+, C85W+
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 Nanao Corporation, RadiForce RX440 has been cleared by FDA through 510(k) No.

K130070 (Decision Date - February 08, 2013).

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

C44W+ is a 30-inch TFT color LCD monitor. It is specifically designed to display high quality, high definition images required for Ultrasound and General Radiography. With built-in multi-display modes, it facilitates convenient viewing by doctors of various images, data, and layout of information. The product is designed to be able to meet DICOM 3.14 calibration standards. With features such as brightness stability control, 14 bit image processing technology, and interfaces with external calibration software, it ensures optimal viewing conditions over the life of the display. The specially designed base supports height and tilt adjustments for ergonomic comfort.

C82W+ is a 31.5-inch TFT color LCD monitor. It is specifically designed to display high quality, high definition images required for diagnostic, interventional radiology and other medical applications. With built-in multi-display modes, it facilitates convenient viewing by doctors of various images, data, and layout of information. The product is designed to be able to meet DICOM 3.14 calibration standards. With features such as brightness stability control, 14 bit image processing technology, and interfaces with external calibration software, it ensures optimal viewing conditions over the life of the display. The specially designed base supports height and tilt adjustments for ergonomic comfort.

C83W+ and C85W+ are 27-inch TFT color LCD monitors. They are specifically designed to provide the high definition images output 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 3840 x 2160. With built-in brightness stabilization control circuit, make sure the brightness of this monitors are stable in their life, and the products meet the demand of high precision medical imaging.

For C44W+, C82W+, C83W+, C85W+, the only difference is the screen. C83W+ and C85W+ have the same screen, but their customers are different, which results in the two models.

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

These products are intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. They do not support the display of mammography images for diagnosis.

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

C44W+ Color LCD monitor

Panel	30”, TFT, color, LCD screen, AG type, 3H hard coating
Brightness (Typ.)	700 cd/m^2
CR (Typ.)	1000:1
Viewing angle	R/L 178°, U/D 178° Typ. (CR > 10)
Pixel Pitch	(H) 0. 2505 × (V) 0.2505 mm
Native resolution	2,560 x 1,600
Display area	641.28 mm (H) x 400.8 mm (V)
Aspect ratio	16:10
Screen size	30” real diagonal
Power	DC 24 V/9 A
Power consumption	80 W (max.)
	< 5 W (standby)
Refresh rate	60 Hz
Backlighting	LED
Response time（Gray to gray）	6 ms (typ.)
Color support	1.073G
Input signals	DVI-D, Display Port, VGA
Dimension (W x H x D)	699.3 x 513~633 x 251.4 mm (without packing) 864 x 600 x 334 mm (with packing)
Weight	13 ± 0.5 kg (wet) 15 ± 0.5 kg (gross)
Operating temperature and humidity	Temperature: 0°C ~ 40°C Humidity: 20% ~ 80%
Storage temperature and humidity	Temperature: -20°C ~ 60°C Humidity:10% ~ 90%

C82W+ Color LCD monitor

Panel	31.5”, TFT, color, LCD screen, AG type
Brightness (Typ.)	1000 cd/m^2
CR (Typ.)	1300:1
Viewing angle	R/L 178°, U/D 178° Typ. (CR > 10)
Pixel Pitch	(H) 0. 182 × (V) 0.182 mm
Native resolution	3,840 x 2,160
Display area	697.31 mm (H) x 392.23 mm (V)
Aspect ratio	16:9
Screen size	31.5” real diagonal
Power	DC 24 V/9.0 A
Power consumption	160 W (max.)
	< 5 W (standby)
Refresh rate	60 Hz
Backlighting	LED
Response time (Gray to Gray)	14 ms (typ.)
Color support	1.07B
Input signals	DVI-D, Display Port, VGA
Dimension (W x H x D)	753 x 503~583 x 251 mm (without packing) 850 x 580 x 320 mm (with packing)
Weight	18.5 kg ± 0.5 kg (wet) 23.5 ± 0.5 kg (gross)
Operating temperature and humidity	Temperature: 0°C ~ 40°C Humidity: 20% ~ 80%
Storage temperature and humidity	Temperature: -20°C ~ 60°C Humidity:10% ~ 90%

C83W+/C85W+ Color LCD monitor

Panel	27”, TFT, color, LCD screen, AG type, 3H hard coating
Brightness (Typ.)	800 cd/m^2
CR (Typ.)	1000:1
Viewing angle	R/L 178°, U/D 178° Typ. (CR > 10)
Pixel Pitch	(H) 0. 1553 × (V) 0.1553 mm

Native resolution	3,840 x 2,160
Display area	596.16 mm (H) x 335.34 mm (V)
Aspect ratio	16:9
Screen size	27” real diagonal
Power	DC 24 V/5.0 A
Power consumption	100 W (max.)
	< 5 W (standby)
Refresh rate	60 Hz
Backlighting	LED
Response time (T_R + T_F)	16 ms (typ.)
Color support	1.07B
Input signals	DVI-D, Display Port, VGA
Dimension (W x H x D)	651 x 463~583 x 251.4 mm (without packing) 764 x 556 x 344 mm (with packing)
Weight	10 ± 0.5 kg (wet) 13 ± 0.5 kg (gross)
Operating temperature and humidity	Temperature: 0°C ~ 40°C Humidity: 20% ~ 80%
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 C44W+, C82W+, C83W+, C85W+

ID	Comparison Item	Proposed Devices C44W+, C82W+, C83W+, C85W+	Predicate Device RadiForce RX440
1	**Intended Use**	These products are intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. They do not support the display of mammography images for diagnosis.	The product is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. They do not support the display of mammography images for diagnosis.

8.2 Comparison table

Table 2 General Comparison of C44W+, C82W+, C83W+, C85W+

ID	Comparison Item	Proposed Devices				Predicate Device	Explanation of Differences
		C44W+	C82W+	C83W+	C85W+	RadiForce RX440	
2	Display Performance/Specifications						
2.1	Screen technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
2.2	Viewing angle (H, V)	H: 178^0, V:178^0 @CR>10	H: 178^0, V:178^0 @CR>10	H: 178^0, V:178^0 @CR>10	H: 178^0, V:178^0 @CR>10	H: 176^0, V:176^0 @CR=10	Different screen provided by the different manufacturer
2.3	Active screen size	641.28 mm x 400.8 mm	697.31 mm x 392.23 mm	596.16 mm x 335.34 mm	596.16 mm x 335.34 mm	641.28 mm x 400.8 mm	Different screen provided by the different manufacturer
2.4	Resolution	4MP (2,560 x 1,600)	8MP (3, 840 x 2,160)	8MP (3, 840 x 2,160)	8MP (3, 840 x 2,160)	4MP (2,560 x 1,600)	Different screen provided by the different manufacturer

2.5	**Aspect ratio**	16:10	16:9	16:9	16:9	16:10	Different screen provided by the different manufacturer
2.6	**Pixel pitch**	0.2505 mm x 0.2505 mm	0.182 mm x 0.182 mm	0.1553 mm x 0.1553 mm	0.1553 mm x 0.1553 mm	0.2505 mm x 0.2505 mm	Different screen provided by the different manufacturer
2.7	**Maximum luminance**	700 cd/m^2	1000 cd/m^2	800 cd/m^2	800 cd/m^2	750 cd/m^2	Different screen provided by the different manufacturer
2.8	**DICOM calibrated luminance**	500 cd/m^2	500 cd/m^2	500 cd/m^2	500 cd/m^2	400 cd/m^2	Different screen provided by the different manufacturer
2.9	**Contrast ratio**	1000:1	1300:1	1000:1	1000:1	1100:1	Different screen provided by the different manufacturer
2.10	**Backlighting**	LED	LED	LED	LED	LED	-

2.11	**Display Colors**	10-bit, 1,073,741,824 color	1.07 Billion colors	1.07 Billion colors, 10Bit (8Bit + A-FRC)	1.07 Billion colors, 10Bit (8Bit + A-FRC)	10-bit colors 1.07 Billion (maximum) colors 8-bit colors: 16.77 million from a palette of 68 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.
2.12	**Luminance non-uniformity compensation**	-	-	-	-	Digital Uniformity Equalizer	Different design scheme
3	**Video Signal Input**						
3.1	**Input video signals**	DVI-D (dual link) x 2, DisplayPort x 2 VGA x 1	DVI-D (dual link) x 2, DisplayPort x 2 VGA x 2	DVI-D (dual link) x 2, DisplayPort x 2 VGA x 1	DVI-D (dual link) x 2, DisplayPort x 2 VGA x 1	DVI-D (dual link) x 1, DVI-D (single link) x 1, DisplayPort x 1	Different design scheme

3.2	**Scanning Frequency (H, V)**	31 - 140 kHz, 29 - 61 Hz Frame synchronous mode: 59 -61 Hz, 29.5 - 30.5 Hz	31 - 140 kHz, 29 - 61 Hz Frame synchronous mode: 59 -61 Hz, 29.5 - 30.5 Hz	31 - 140 kHz, 29 - 61 Hz Frame synchronous mode: 59 -61 Hz, 29.5 - 30.5 Hz	31 - 140 kHz, 29 - 61 Hz Frame synchronous mode: 59 -61 Hz, 29.5 - 30.5 Hz	31 - 159 kHz, 29 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 -61 Hz, 29.5 - 30.5 Hz	-
3.3	**Dot Clock**	268 MHz	533 MHz	533 MHz	533 MHz	280 MHz	Different design scheme
4	**Power Related Specifications**						
4.1	**Power Requirements**	DC 24 V / 9 A	DC 24 V / 9 A	DC 24 V / 5 A	DC 24 V / 5 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**	80 W / Less than 5 W	160 W / Less than 5 W	100 W / Less than 5 W	100 W / Less than 5 W	167 W / Less than 0.7 W	Compared with the predicate device, the proposed devices consume less power normally, and more power in the power saving mode.

4.3	**Power Management**	DVI DMPM, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2	DVI DMPM, DisplayPort 1.1a	Different design scheme
5	**Miscellaneous Features/Specifications**						
5.1	**QC software**	Beacon Monitor Manage	Beacon Monitor Manage	Beacon Monitor Manage	Beacon Monitor Manage	RadiCS	Different design scheme
5.2	**Sensors**	Backlight Sensor, Integrated Front Sensor, Ambient Light Sensor	Backlight Sensor, Integrated Front Sensor, Ambient Light Sensor	Backlight Sensor	Backlight Sensor	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor	Different design scheme
5.3	**USB Ports/Standard**	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-	-	1 upstream, 2 downstream / Rev. 2.0	Same for C44W+ and C82W+; different design scheme for C83W+ and C85W+
5.4	**Dimensions w/o stand (W x H X D**	699.3 x 459.8 x 67.7 mm	752.7 x 449.2 x 73.05 mm	650.7 x 389.5 x 67.8 mm	650.7 x 389.5 x 67.8 mm	720 x 498 x 119 mm	Different housing design due to the different panel size

It is clear that the technological characteristic differences discussed above do not affect the safety and the effectiveness of the C44W+, C82W+, C83W+, C85W+.

8.3 Performance Testing

The bench tests were performed on C44W+, C82W+, C83W+, C85W+ as below.

- Measure the spatial resolution expressed as modulation transfer function (MTF).
- 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.
- Visually check the presence or absence of miscellaneous artifacts on the display screen in accordance with TG18 guideline.
- Meausure the maximum, minimum, achievable, and recommended luminance.
- Measure the temporal response using the typical data provided by the panel manufacturer.
- Maximum number allowed for each type of pixel defects/faults
- Measure the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance as specified in *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket* Notification (510(k)) Submissions.
- Measure the color tracking (primary colors and color gamut).

The test results showed that C44W+, C82W+, C83W+, C85W+ are with display characteristics equivalent to those of the predicate device, RadiForce RX440 except some items, each of which was determined that it would not affect observer's performance.

No animal or clinical testing is needed for C44W+, C82W+, C83W+, C85W+.

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 C44W+, C82W+, C83W+, C85W+ is totally same as that of the predicate device.
- The technological characteristic differences between C44W+, C82W+, C83W+, C85W+ and the predicate device do not affect the safety and effectiveness, so no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of C44W+, C82W+, C83W+, C85W+ are equivalent to those of the predicate device.