August 18, 2023

Shenzhen Beacon Display Technology Co., Ltd.
℅ Li Yafei
Official Correspondent
15F, Building 6, Hengda Shishang Huigu (East), Fulong Road,
Dalang Subdistrict, Longhua
Shenzhen, Guangdong 518109
CHINA

Re: K231026
Trade/Device Name: 12MP Color LCD Monitor C1216W, C12*** ("*" = 0 to 9, A to Z or blank, and the difference among models means the product is named according to different appearance colors and customer models)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: July 19, 2023
Received: July 19, 2023

Dear Li Yafei:

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

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231026

Device Name
12MP Color LCD Monitor (C1216W, C12*** ("*" = 0 to 9, A to Z or blank, and the difference among models means the product is named according to different appearance colors and customer models))

Indications for Use *(Describe)*
These products are indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

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 17, 2023

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

Name of Sponsor:	Shenzhen Beacon Display Technology Co., Ltd.
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Contact Name:	Li Yafei
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Email Address:	liyf@beacon-display.cn

3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

- Trade Name/Model: 12MP Color LCD Monitor (C1216W, C12*** ("*" = 0 to 9, A to Z or blank, and the difference among models means the product is named according to different appearance colors and customer models))
- Common Name: 12MP Color LCD Monitor
- Classification Name: Medical Image Management and Processing 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, 12MP Color LCD Monitor, RadiForce RX1270, RX1270-AR has been cleared by FDA through 510(k) No. K200485 (Decision Date - March 23, 2020).

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

The C1216W and C12*** are 12MP color LCD monitors, which are specifically designed to provide the high definition image output for general radiography. They are using the latest generation of LED back light panel, with high resolution 4200 x 2800, built-in brightness stabilization circuit, front sensor and ambient light sensor, stable brightness and persistent calibration can be guaranteed throughout its life. The anti-glare screen can prevent display from reflection under highlight conditions, make the image and display clearer.

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

These products are indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

7. Indications for Use

These products are indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

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

Panel characteristics：	
Screen technology	31”, TFT, color, LCD screen, AG type
Active area（H x V）	652.68 x 435.12 mm
Pixel pitch	0.1554 mm (H) x 0.1554 mm (V)
Resolution	4200 x 2800 Pixels
Contrast ratio	1050:1 (minimum), 1500:1 (typical)
Viewing angle（CR > 10）	Horizontal: 178° (typical)

	Vertical: 178° (typical)
Screen brightness	1200cd/m^2 (typical)
Refresh rate	60 Hz
Backlighting	LED
Lifetime of backlight	50000 hours（minimum）
Response time (Gray to Gray)	14ms (typical)
Color support	1.07G
Power supply：	
Power connection	Power cord connector with protective conductor, IEC60320-C14
Input voltage	AC 100-240V 50/60Hz
Current consumption	2.4-1.0 A
Power consumption	≤200W
Standby	< 0.5 W
Control and connection：	
Front	1 operation LED, 6 functional keys
Back	• Power switch * 1 • AC socket * 1 • HDMI * 2 • Display Port * 3 • Service Connector * 1 • USB * 7
Mechanical characteristics：	
Housing components	Plastic, Metal
Ventilation openings	Natural heat dissipation
Degree of protection	IP20
Climatic conditions：	
Operational temperature	0°C ~40°C
Operational humidity	15%~ 85% Relative humidity, no condensation

Transport and storage temperature	-20°C ~ +60°C
Transport and storage humidity	10% ~ 90% Relative humidity, no condensation
Operational pressure	700 hPa~1060 hPa
Safety regulations:	
Safety standards	IEC 60601-1 EN 60601-1 ANSI/AAMI ES60601-1 CAN/CSA-C22.2 NO. 60601-1:14
Conformity	CCC,CE,FCC,TUV,CB,CECP
Dimension:	
With packing (W x H x D)	840 x 643 x321 mm
Weight:	
Net weight	18.3± 1 kg
Gross weight	22.8 ± 1 kg

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

9.1 Intended uses:

Table 1 Intended Use Comparison

ID	Comparison Item	**Proposed Device** **12MP Color LCD Monitor** (C1216W ,C12***)	**Predicate Device** **12MP Color LCD Monitor** (RX1270, RX1270-AR)
1	**Intended Use**	These products are indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.	The 12MP Color LCD Monitor (RX1270, RX1270-AR)" is intended to be used in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

9.2 Comparison table

Table 2 General Comparison

Attributes	**Proposed Device 12MP Color LCD Monitor (**C1216W ,C12***)	**Predicate Device 12MP Color LCD Monitor (**RX1270, RX1270-AR**)**	**Explanation of Difference**
Display Technology			
	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
Screen size			
	78.4cm / 31"	78.4cm / 30.9"	Different screen provided by the different manufacturer
Resolution			
	4200 x 2800 (3:2 aspect ratio)	4200 x 2800 (3:2 aspect ratio)	-
Pixel pitch			
	0.1554 x 0.1554 mm	0.1554 x 0.1554 mm	-
Backlight type			
	LED	LED	-
Maximum luminance			
	1200 cd/m^2	1200 cd/m^2	Different screen provided by the different manufacturer
DICOM calibrated luminance			

	450 cd/m^2	500 cd/m^2	Different screen provided by the different manufacturer
Contrast Ratio (typical)			
	1500:1	1500:1	-
Response Time (typical)			
	14 ms (Gray to Gray)	12 ms (black-white-black)	Different design scheme.
Frame rate and refresh rate			
Digital Scanning Frequency (H / V)	HDMI: 31.5 - 133.32 kHz / 30 - 60 Hz DisplayPort: 31.5 - 172.8 kHz / 60 Hz	HDMI: 31 - 160 kHz / 59 - 61 Hz (VGA Text: 69 - 71 Hz) DisplayPort: 31 - 175 kHz / 29 -61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	Different design scheme.
Analog Scanning Frequency (H / V)	-	HDMI: 31 - 160 kHz / 59 - 61 Hz (VGA Text: 69 - 71 Hz) DisplayPort: 31 - 175 kHz / 29 -61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	Different design scheme.
Display Interface			
Input video signals	HDMI x 2, DisplayPort x 2	DisplayPort x 2, HDMI	Different design scheme.
Output video signals	DisplayPort x 1	-	Different design scheme.
Video bandwidth			

	HDMI: 594MHz DisplayPort: 753.25MHz	HDMI: 260MHz DisplayPort: 765MHz	Different design scheme.
Ambient light sensing			
Ambient light sensor	Yes	Yes	Different design scheme.
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.
Quality-control procedures			
	Beacon Monitor Manage	Software: RadiCS	Different design scheme.

It is clear that the technological characteristic differences discussed above do not affect the safety and the effectiveness of the C1216W and C12***.

9.3 Performance Testing

According to the instructions in" *Guidance for Industry and Food and Drug Administration Staff Display Devices for Diagnostic Radiology*", the bench tests were performed on C1216W and C12*** 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 luminance stability and chromaticity response with the temperature 0℃, 25℃ and 40℃ on Luminance response by AAPM-TG18.
- Measure the chromaticity non-uniformity characteristics of the display screen in accordance with TG18 guideline.

- 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.
- Measure the temporal response using the typical data provided by the panel manufacturer.
- Measurement of Luminance
- Visually check the presence or absence of miscellaneous artifacts on the display screen in accordance with TG18 guideline.
- Measure the spatial noise by noise power spectrum.
- Measure the reflection coefficient with specular reflection and diffuse reflection by TG18.
- Measure the veiling glare of small-spot contrast performing veiling glare test by TG-18.
- Measure the spatial resolution expressed as modulation transfer function (MTF)
- Maximum number allowed for each type of pixel defects/faults
- Measurement of Color tracking and Gray tracking
- Measure pixel fill factor like pixel structure and aperture ratio etc.

The test results showed that C1216W and C12*** are with display characteristics equivalent to those of the predicate device, RadiForce RX1270 except some items, each of which was determined that it would not affect observer's performance.

No animal or clinical testing is needed for C1216W and C12***.

10. 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 C1216W and C12*** is totally same as that of the predicate device.
- The technological characteristic differences between C1216W (C12***) and RadiForce RX1270 do not affect the safety and effectiveness, no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of C1216W and C12*** are equivalent to those of the predicate device.