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

December 13, 2018

Re: K182291
Trade/Device Name: 6MP Color LCD Monitor (C61W+)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: Class II
Product Code: PGY
Dated: September 25, 2018
Received: October 1, 2018

Dear Fu Ailing:

This letter corrects our substantially equivalent letter of November 20, 2018.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. 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)*

Device Name

6MP Color LCD Monitor (C61W+)

Indications for Use *(Describe)*

The 6MP Color LCD Monitor (C61W+) is intended to be used in displaying and viewing digital images for review and analysis 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
K182291

[As required by 21 CFR 807.92]

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

July 26, 2018

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

Name of Sponsor: Shenzhen Beacon Display Technology Co., Ltd.

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Email Address: fuailing@beacon-display.cn

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

Trade Name/Model: 6MP Color LCD Monitor (C61W+)

Common Name: 6MP Color LCD Monitor

Classification Name: System, Image Processing, Radiological

Regulation Number: 21 CFR 892.2050

Product code: LLZ

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, 6MP Color LCD Monitor, RadiForce RX650 has been cleared by FDA through 510(k) No. K134002 (Decision Date - January 31, 2014).

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

C61W+ is a 30-inch TFT color LCD monitor. It is specifically designed to display high quality, high definition images required for general radiography.

With built-in multi-display modes, the monitor 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, the monitor ensures optimal viewing conditions over the life of the display. The specially designed base supports height and tilt adjustments for ergonomic comfort.

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

The 6MP Color LCD Monitor (C61W+) is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

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

Monitor characteristics:	
Screen technology	30”, TFT, color, LCD screen, anti-glare, hard coating
Active area（H x V）	654.4 x 408.6 mm
Pixel pitch	0.197 mm (H) x 0.197mm (V)
Resolution	3,280 x 2,048 Pixels
Contrast ratio	950:1 (Typ.), 750:1 (Min.)
Viewing angle（CR > 10）	Horizontal: 170° (Typ.）
	Vertical: 170° (Typ.）
Brightness	800 cd/m^2（Typ.）
Refresh rate	50 Hz
Backlight	LED
Lifetime of backlight	50,000 hours

Response time（T_r + T_f）	30 ms (Typ.)
Color support	1.07 billion
Power supply:	
Power connection	Adapter (FSP, FSP220-KAAM1, Input: 100-240 V, 47-63 Hz; 2.5-1.2 A; Output: 24 V; 9.17 A, Max. 220 W). The approved adapter is considered as part of LCD Monitor.
Line voltage	24 V
Current consumption	9.0 A
Power consumption	160 W (Max.）
Standby	< 5 W
Inputs/outputs:	
DVI input	Dual link DVI-D socket
VGA input	For updating software
USB	For connecting external PC
DP input	Display Port socket
Control and connection:	
Front	1 operation LED, 6 functional keys
Back	• 3 USB port • 2 DVI connector • 2 DP connector • 1 VGA connector • 1 Ground • 1 DC socket • 1 Power switch
Mechanical characteristics:	
Housing components	Plastic
Ventilation openings	Natural heat radiation

Connector panel	On rear panel, under cover
Weight	15.5 kg +/- 0.5 kg
Dimensions (W x H x D) in mm	718.5 x 549.1 ~ 629.1 x 251.4 mm (with stand)
Climatic conditions:	
Working temperature	0°C ... 40°C
Working humidity	20% ... 80% Relative humidity, no condensation
Transport and storage temperature	-20°C ... 60°C
Transport and storage humidity	10% ... 90% Relative humidity, no condensation
Air pressure	700 - 1060 hPa
Safety regulations:	
Safety standards	IEC60601-1, EN60601-1 ANSI/AAMI ES60601-1: 2005 + A2(R2012) + A1 CAN/CSA-C22.2 NO. 60601-1:14
Protection class	Class III (adapter)
Degree of protection	IP20
Conformity	CE according to MDD 93/42/EEC (Class I)
Electromagnetic compatibility:	
Noise immunity/interference emissions	IEC 60601-1-2, EN 60601-1-2
Dimension:	
With packing (W x H x D)	814 x 606 x 327 mm
Weight:	
Gross weight	18 kg

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

8.1 Intended uses:

Table 1 Intended Use Comparison

ID	Comparison Item	Proposed Device 6MP Color LCD Monitor (C61W+)	Predicate Device 6MP Color LCD Monitor (RX650)
1	**Intended Use**	The 6MP Color LCD Monitor (C61W+) is intended to be used in displaying and viewing digital images for review and analysis 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 and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

8.2 Comparison table

Table 2 General Comparison

ID	Comparison Item	Proposed Device 6MP Color LCD Monitor (C61W+)	Predicate Device 6MP Color LCD Monitor (RX650)	Explanation of Difference
2	**Display Performance/Specifications**			
2.1	Screen technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
2.2	Viewing angle (H, V)	H:170^0, V:170^0	H:176^0, V:176^0	Different screen provided by the different manufacturer
2.3	Active screen size	654.4 x 408.6 mm	645.5 mm x 403.0 mm	Different screen provided by the different manufacturer

2.4	Resolution	6MP (3,280 x 2,048)	6MP (3,280 x 2,048)	-
2.5	Aspect ratio	16:10	16:10	-
2.6	Pixel pitch	0.197 mm x 0.197 mm	0.197 mm x 0.197 mm	-
2.7	Typical luminance	800 cd/m^2	800 cd/m^2	-
2.8	DICOM calibrated luminance	500 cd/m^2	400 cd/m^2	Different screen provided by the different manufacturer
2.9	Contrast ratio	950:1	1000:1	Different screen provided by the different manufacturer
2.10	Backlighting	LED	LED	-
2.11	Display Colors	From a palette of 68 billion colors: - 10-bit (DisplayPort): 1.07 billion colors (maximum)	From a palette of 68 billion colors: - 10-bit (DisplayPort): 1.07 billion colors (maximum) - 8-bit colors: 16.77 million colors	-
2.12	Luminance non-uniformity compensation	Digital Uniformity Equalizer	Digital Uniformity Equalizer	-
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 (two inputs are required)	Different design scheme
3.2	Scanning Frequency (H, V)	31.5 - 120 kHz/29 - 61 Hz (VGA Text: 59 - 75 Hz) Frame synchronous mode: 29.5- 30.5Hz, 50 - 60 Hz	31 - 129 kHz/29 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	-

4	**Power Related Specifications**			
4.1	Power Requirements	DC 24 V, 9.0 A	AC 100 - 120 V, 200 - 240 V: 50/60 Hz	The difference between Built-in power supply and Built-out power supply
4.2	Power Consumption /Save Mode	160 W/less than 5 W	225 W/ Less than 6 W	Different design scheme
4.3	Power Management	DC Socket, Power switch	DVI DMPM, DisplayPort 1.1a	Different design scheme
5	**Miscellaneous Features/Specifications**			
5.1	QC software	Beacon Monitor Manage	RadiCS	Different design scheme
5.2	Sensors	Backlight Sensor, Integrated Front Sensor, Ambient Light Sensor	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor	-
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)	698 x 470 x 78 mm	692 x 466 x 109 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 C61W+.

8.3 Performance Testing

The bench tests were performed on C61W+ 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 in accordance with *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k) Submissions*.
- Visually check the presence or absence of miscellaneous artifacts on the display screen in accordance with TG18 guideline.
- Maximum number allowed for each type of pixel defects/faults.

The test results showed that C61W+ is with display characteristics equivalent to those of the predicate device, RadiForce RX650 except some items, each of which was determined that it would not affect observer's performance.

No animal or clinical testing is needed for C61W+.

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 C61W+ is totally same as that of the predicate device.
- The technological characteristics differences between C61W+ and RadiForce RX650 do not affect the safety and effectiveness, no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of C61W+ are equivalent to those of the predicate device.