DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Shenzhen Beacon Display Technology Co., Ltd. October 6, 2016
% Miss Fu Ailing
Document Engineer
12F, Block B1, Nanshan Zhiyuan, No.1001 Xueyuan Road
Shenzhen, Guangdong 518055
CHINA

Re: K162527
Trade/Device Name: 8MP Color LCD Monitor (C81W+)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: August 1, 2016
Received: September 9, 2016

Dear Miss Ailing:

This letter corrects our substantially equivalent letter of September 30, 2016.

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 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″ (21CFR 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 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,

for 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name

8MP Color LCD Monitor (C81W+)

Indications for Use *(Describe)*

The 8MP Color LCD Monitor (C81W+) is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.

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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008_510 (k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

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

July 6, 2016

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: 8MP Color LCD Monitor (C81W+)
Common Name: 8MP Color LCD Monitor
Classification Name: Display, Diagnostic Radiology
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, 8MP Color LCD Monitor, RadiForce RX850, RX850-AR has been cleared by FDA through 510(k) No. K152713 (Decision Date - November 20, 2015).

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

The C81W+ is an 8MP color LCD monitor for viewing medical images including breast tomosynthesis, digital mammography, ultrasound and general radiography. Its using the latest generation of LED back light panel, with high resolution 4096X2160, 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)]

The 8MP Color LCD Monitor (C81W+) is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.

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

Panel	31”, TFT, color, LCD screen, anti-glare, hard coating
Brightness (Max.)	850 cd/m^2
CR (Typ.)	1450:1
Viewing angle	R/L 178°, U/D 178° Typ. (CR > 10)
Pixel Pitch	(H) 0.1704 × (V) 0.1704 mm
Native resolution	4,096 x 2,160
Display area	697.9mm(H)x368.0mm (V)
Compatible video signals	4096 x 2160@60Hz; DP/DVI
Horizontal resolution	4096
Aspect ratio	17:9
Screen size	31.1” real diagonal
Power	DC 24V/9A

Power consumption	Max. 180 W
Input signals	DVI-D, Display Port
Digital input	TMDS（dual link）* 2
Plug and play	VESA DDC 2B
Dimension	755 mm (W) x 600.6 mm (H) x 251.4mm (D) (with stand) 755 mm (W) x 433.8 mm (H) x 99.1 mm (D) (without stand)
Weight	13 kg (without Stand) 17.5 kg (with Stand)
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

ID	Comparison Item	Proposed Device 8MP Color LCD Monitor (C81W+)	Predicate Device 8MP Color LCD Monitor (RX850, RX850-AR)
1	**Intended Use**	The 8MP Color LCD Monitor (C81W+) is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.	" 8MP Color LCD Monitor (RX850, RX850-AR)" is intended to be used in displaying and viewing digital images, including standard and multi-frame digital mammography, for review, analysis and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis application.

8.2 Comparison table

Table 2 General Comparison

ID	Comparison Item	Proposed Device 8MP Color LCD Monitor (C81W+)	Predicate Device 8MP Color LCD Monitor (RX850, RX850-AR)	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: 178°, V: 178°	H: 178°, V: 178°	–
2.3	Resolution	8MP (4,096 x 2,160)	8MP (4,096 x 2,160) (4MP: 2,048 x 2,160 x2)	–
2.4	Aspect ratio	17:9 (8.5 : 9 x 2)	17:9 (8.5 : 9 x 2)	–
2.5	Active screen size	697.9 mm x 368.0 mm	697.9 mm x 368.0 mm	–
2.6	Pixel pitch	0.1704 mm x 0.1704 mm	0.1704 mm x 0.1704 mm	–
2.7	Maximum luminance	850 cd/m^2	850 cd/m^2	–
2.8	DICOM calibrated luminance	500 cd/m^2	500 cd/m^2	–
2.9	Contrast ratio	1450:1	1450:1	–
2.10	Response Time (typ.)	20 ms (On/Off)	20 ms (On/Off)	–
2.11	Backlighting	LED	LED	–
2.12	Grayscale Tones	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	–
2.13	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	DVI-D (dual link) x 2, DisplayPort x 2 (two inputs are required)	–
3.2	Scanning Frequency (H, V)	31 - 140 kHz / 59 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	31 - 140 kHz / 59 - 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	DC24V/9.0A	AC 100 - 120V, 200 - 240 V: 50 / 60 Hz	The difference between Built-in power supply and Built-out power supply.
4.2	Power Consumption / Save Mode	180 W / Less than 5 W	227 W / Less than 6 W	Different design scheme.
4.3	Power Management	DVI DMPM, DisplayPort 1.2	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	Sensor	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)	755 x 433.8 x 99.1 mm	747 x 430 x 130 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 C81W+.

8.3 Performance Testing

According to the instructions in *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions*, the bench tests were performed on C81W+ 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 angle dependency of luminance response in horizontal, vertical and diagonal directions.
- 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.
- Measure the display reflections including specular, diffuse and haze components.
- Measure the small-spot contrast ratio.
- Measure the spatial resolution expressed as modulation transfer function (MTF).
- Measure the noise expressed as noise power spectrum (NPS).
- Measure the pixel aperture ratio.
- Visually check the presence or absence of miscellaneous artifacts on the display screen in accordance with TG18 guideline.
- Measure the temporal response.
- The performance data on luminance stability
- Maximum number allowed for each type of pixel defects/faults

The test results showed that C81W+ is with display characteristics equivalent to those of the predicate device, RadiForce RX850 except some items, each of which was determined that it would not affect observer's performance.

No animal or clinical testing is needed for C81W+.

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 C81W+ is totally same as that of the predicate device.
- The technological characteristics differences between C81W+ and RadiForce RX850 do not affect the safety and effectiveness, no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of C81W+ are equivalent to those of the predicate device.