December 19, 2025

Shenzhen Beacon Display Technology Co., Ltd.
Yafei Li
Safety Engineer
15F, Building 6, Hengda Shishang Huigu (East)
Fulong Road, Dalang Subdistrict, Longhua
Shenzhen, Guangdong 518109
China

Re: K252780
Trade/Device Name: LCD Monitor (CL1902A, CL2103F)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: November 18, 2025
Received: November 18, 2025

Dear Yafei Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb, Ph.D.
Assistant Director
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252780

Please provide the device trade name(s).

LCD Monitor (CL1902A , CL2103F)

Please provide your Indications for Use below.

CL1902A and CL2103F are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1. Submitter's Information

Name of Sponsor:	Shenzhen Beacon Display Technology Co., Ltd.
Address:	15F, Building 6, Hengda Shishang Huigu(East), Fulong Road, Dalang Subdistrict, Longhua, Shenzhen, 518109 China
Contact Name:	Li Yafei
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Fax No.:	+86-024-88087629
Email Address:	liyf@beacon-display.cn
Date of Prepared:	July 24,2025

2. Trade Name, Common Name, Classification

- Trade Name/Model: LCD Monitor (CL1902A, CL2103F)
- Common Name: Display, diagnostic radiology
- Classification Name: Medical image management and processing system
- Regulation Number: 21 CFR 892.2050
- Product code: PGY
- Classification Panel: Radiology
- Device Class: II

3. Identification of Predicate Device(s)

The identified predicate within this submission is as follows:
EIZO Corporation, RadiForce MX217, K230684;
EIZO Corporation, RadiForce MX194, K180961.

4. Description of the Device

1.3MP LCD Monitor CL1902A is a 19-inch TFT LCD monitor, which is specifically designed to provide the high definition image output for general radiography.
This product has been strictly calibrated so that it can meet DICOM Part 3.14 and other standards. It

uses the latest generation of LED backlight panel, supporting resolution 1280 x 1024. The built-in brightness stabilization control circuit makes sure the brightness of this monitor is stable, so this product meets the demand of high precision medical imaging. The anti-glare screen can prevent display from reflection under highlight conditions, make the image and display clearer.

2MP LCD Monitor CL2103F is a 21.3-inch TFT LCD monitor, which is specifically designed to provide the high definition image output for general radiography.

This product has been strictly calibrated so that it can meet DICOM Part 3.14 and other standards. It uses the latest generation of LED backlight panel, supporting resolution 1600 x 1200. The built-in brightness stabilization control circuit makes sure the brightness of this monitor is stable, so this product meets the demand of high precision medical imaging. The anti-glare screen can prevent display from reflection under highlight conditions, make the image and display clearer.

Component / Feature	**CL1902A**	**CL2103F**
Main Board Interfaces	DVI + VGA + BNC	DVI + VGA
Power Board	Built-in	Built-in
OSD Control Board	Physical buttons	Capacitive touch

5. Indications for use

CL1902A and CL2103F are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

6. Substantial Equivalence

6.1 Comparison table

Table 1 General Comparison of CL1902A

Comparison Item	**Proposed Device**	**Predicate Device**	**Explanation of Differences**
	CL1902A	**RadiForce MX194**	
Display technology			
	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (VA)	Different Panel

Screen size			
	48.26cm/19.0” Aspect ratio: 5:4	48.1cm / 19.0" Aspect ratio: 5: 4	Different Panel
Backlight type			
	LED	LED	-
Frame rate and refresh rate			
Digital Scanning Frequency (H, V)	31 - 75 kHz / 59 - 61 Hz	31 - 64 kHz / 59 - 61 Hz	-
Analog Scanning Frequency (H / V)	15.5 – 75 kHz / 25 - 60 Hz	24.8 - 80 kHz / 50 - 75 Hz	Different design scheme
Pixel pitch			
	0.294 x 0.294 mm	0.294 x 0.294 mm	-
Display Interface			
Input video signals	DVI-D x 1, D-Sub mini 15 pin x 1 BNC x 3	DVI-D x 1, DisplayPort x 1, D-Sub mini 15 pin x 1	Different design scheme
Output video signals	N/A	N/A	-
Video bandwidth			
	DVI : 162MHz Analog : 162MHz	DVI : 108MHz DisplayPort : 108MHz Analog : 135MHz	Different design scheme
Ambient light sensing			
Ambient light sensor	N/A	Yes	Different design scheme
Luminance calibration tools:			
	Integrated backlight sensor	Integrated optical sensor External optical sensor Calibration software: RadiCS	Different design scheme
USB Ports			
	N/A	/	Different design scheme
Power Related Specifications			
Power Requirements	AC100-240V ±10%, 50/60Hz±3Hz, 1.1A-0.6A	AC 100 - 240 V: 50 / 60 Hz	Different design scheme
Maximum power consumption	<50W	<28W	Different design scheme

Power save mode	<3W	<0.6W	Different design scheme
Power Management	VESA DPMS and EPA power saving management	VESA DPMS and EPA power saving management	-
Indications for Use	This product is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. This product is not intended for mammography.	This product is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. This product is not intended for mammography.	-

Table 2 General Comparison of CL2103F

Comparison Item	**Proposed Device**	**Predicate Device**	**Explanation of Differences**
	CL2103F	**RadiForce MX217**	
Display technology			
	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
Screen size			
	54.0cm / 21.3" Aspect ratio: 4: 3	54.0cm / 21.3" Aspect ratio: 3: 4	Different Panel
Backlight type			
	LED	LED	-
Frame rate and refresh rate			
Digital Scanning Frequency (H, V)	31 - 75 kHz / 59 - 61 Hz	31 - 100 kHz / 59 - 61 Hz	Different design scheme
Analog Scanning Frequency (H / V)	31 - 75 kHz / 59 - 61 Hz	N/A	Different design scheme
Pixel pitch			
	0.27 x 0.27mm	0.27 x 0.27mm	-
Display Interface			
Input video signals	DVI-D x 1, D-SUB MINI 15PIN x 1	DVI-D x 1, DisplayPort x 1	Different design scheme
Output video signals	N/A	DisplayPort x 1 (daisy chain)	Different design scheme

Video bandwidth			
	DVI: 25-162MHz VGA: 25-162MHz	DVI : 25-164.5MHz DisplayPort : 25-164.5MHz	Different design scheme
Ambient light sensing			
Ambient light sensor	Yes	Yes	Different design scheme
Luminance calibration tools:			
	Integrated backlight sensor	Integrated optical sensor External optical sensor Calibration software: RadiCS	Different design scheme
USB Ports			
	N/A	/	Different design scheme
Power Related Specifications			
Power Requirements	AC100-240V ±10%, 50/60Hz±3Hz, 1.1A-0.6A	AC 100 - 240 V: 50 / 60 Hz	Different design scheme
Maximum power consumption	<50W	<54W	Different design scheme
Power save mode	<3W	<0.6W	Different design scheme
Power Management	VESA DPMS and EPA power saving management	VESA DPMS and EPA power saving management	-
Indications for Use	This product is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. This product is not intended for mammography.	This product is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. This product is not intended for mammography.	-

The technological characteristics differences discussed above do not affect the safety and the effectiveness of CL1902A and CL2103F.

6.2 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 CL1902A and CL2103F as below.

- Measurement of spatial resolution
- The maximum number allowed for each type of pixel defects/faults
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in TG18 guideline
- Measure the temporal response using the typical data provided by the panel manufacturer
- Meausure the maximum, minimum, achievable, and recommended luminance
- Verification of the conformance to DICOM GSDF as specified in Assessment of Display Performance for Medical Imaging Systems by AAPM Task Group 18 (TG18 guideline)
- Measurement of Color tracking (primary colors and color gamut)

The test results showed that CL1902A and CL2103F are with display characteristics equivalent to those of the predicate devices.
No animal or clinical testing is needed for CL1902A and CL2103F.

7. Conclusion

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 uses of the proposed devices (CL1902A and CL2103F) are equivalent to those of the predicate devices.
- The differences in technological characteristics between the proposed devices (CL1902A and CL2103F) and the predicate devices do not impact safety or effectiveness and do not introduce new risks.
- Bench testing demonstrates that the display characteristics of the proposed devices (CL1902A and CL2103F) are equivalent to those of the predicate devices.
- The data support the devices are substantially equivalent to the predicates.