



October 29, 2025

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

Re: K253242

Trade/Device Name: LCD Monitor (C1216W, C822W, C821W)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: September 28, 2025
Received: September 29, 2025

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 (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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style and is positioned over a large, light blue, semi-transparent watermark of the letters "FDA".

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

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.

K253242

?

Please provide the device trade name(s).

?

LCD Monitor (C1216W, C822W, C821W)

Please provide your Indications for Use below.

?

-- C822W

This Medical Monitor is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

-- C1216W

This Medical Monitor is 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.

-- C821W

This Medical Monitor is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

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)

?

K253242

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
Telephone No.: +86-024-88087610
Fax No.: +86-024-88087629
Email Address: liyf@beacon-display.cn
Date of Prepared: September 3, 2025

2. Trade Name, Common Name, Classification

- Trade Name/Model: LCD Monitor C1216W, C822W, C821W
- Common Name: LCD Monitor C1216W, C822W, C821W
- 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 devices within this submission are as follows.

Predicate Device for C1216W

- 510(k) Number: K231026
- Applicant: Shenzhen Beacon Display Technology Co., Ltd.
- Trade Name: C1216W

Predicate Device for C822W

- 510(k) Number: K172815

- Applicant: Shenzhen Beacon Display Technology Co., Ltd.
- Trade Name: C22S+

Predicate Device for C821W

- 510(k) Number: K200864
- Applicant: Shenzhen Beacon Display Technology Co., Ltd.
- Trade Name: C53S+

4. Description of the Device

C1216W is 31 inch TFT color LCD monitor, C822W and C821W are 31.5 inch TFT color LCD monitor, they are intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners.

These products have been strictly calibrated so that they can meet DICOM Part 3.14 and other standards. They use the latest generation of LED backlight panel. The built-in brightness stabilization control circuit makes sure the brightness of these monitors 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.

5. Indications for use

-- C822W

This Medical Monitor is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

-- C1216W

This Medical Monitor is 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.

-- C821W

This Medical Monitor is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

6. Substantial Equivalence

6.1 Comparison table

Table 1 General Comparison of C1216W

Comparison Item	Proposed Device	Predicate Device	Explanation of Differences
	C1216W	C1216W	
Display technology			
	TFT Color LCD Panel	TFT Color LCD Panel	-
Screen size			
	652.68 x 435.12 mm/ 31"	652.68 x 435.12 mm/ 31"	-
Resolution			
	4200 x 2800 Pixels	4200 x 2800 Pixels	-
Backlight type			
	LED	LED	-
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/ 59.96-60Hz	HDMI: 31.5 - 133.32 kHz/ 30 - 60 Hz DisplayPort: 31.5 - 172.8 kHz/ 59.96-60Hz	-
Analog Scanning Frequency (H / V)	N/A	N/A	-
Pixel pitch			
	0.1554 x 0.1554 mm	0.1554 x 0.1554 mm	-
Display Interface			
Input video signals	HDMI IN x 1, DP IN x 2 DP OUT x 1	HDMI IN x 1, DP IN x 2 DP OUT x 1	-
Output video signals	N/A	N/A	-
Video bandwidth			
	HDMI: 533.25MHz DisplayPort: 753.25MHz	HDMI: 533.25MHz DisplayPort: 753.25MHz	-
Ambient light sensing			

Ambient light sensor	Yes	Yes	-
USB Ports			
	USB x 7	USB x 7	-
Calibration Tool			
	ProView QA/ Calibration Feedback System	Beacon Monitor Manage	-
Power Consumption			
	MAX. ≤200W Standby < 0.5 W	MAX. ≤200W Standby < 0.5 W	-
Indications for Use			
Indications for Use	This Medical Monitor is 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.	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.	-

Table 2 General Comparison of C821W

Comparison Item	Proposed Device	Predicate Device	Explanation of Differences
	C821W	C53S+	
Display technology			
	TFT Color LCD Panel	TFT Color LCD Panel	Different Panel
Screen size			
	697.31 x 392.23 mm/ 31.5"	337.92 x 422.4 mm/ 21.3"	Different Panel
Resolution			
	3840 x 2160 Pixels	2048 x 2560 Pixels	Different Panel
Backlight type			
	LED	LED	-
Frame rate and refresh rate			
Digital Scanning Frequency (H, V)	31.5 kHz to 133.3 kHz/ 30 Hz to 75 Hz	104.852KHz/ 50Hz	Similar

Analog Scanning Frequency (H / V)	N/A	N/A	-
Pixel pitch			
	0.182 x 0.182 mm	0.165x 0.165 mm	Different Panel
Display Interface			
Input video signals	DVI IN x 1, DP IN x 2 DP OUT x 1	DVI-D x 1 DP x 1	Similar
Output video signals	N/A	N/A	-
Video bandwidth			
	DVI: 277.2M Hz DP:533.3M Hz	DVI:285.2M Hz DP:285.2M Hz	Similar
Ambient light sensing			
Ambient light sensor	Yes	Yes	-
USB Ports			
	USB x 5	USB x 3	Similar
Calibration Tool			
	ProView QA/ Calibration Feedback System	Beacon Monitor Manage	-
Power Consumption			
	MAX.130W Standby< 0.5 W	MAX. 80W Standby< 5W	Similar
Indications for Use			
Indications for Use	This Medical Monitor is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	This Medical Monitor is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It's intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	-

Table 3 General Comparison of C822W

Comparison Item	Proposed Device	Predicate Device	Explanation of Differences
	C822W	C22S+	
Display technology			
	TFT Color LCD Panel	TFT Color LCD Panel	Different Panel
Screen size			
	697.31 x 392.23 mm/ 31.5"	324 x 432 mm 21.3"	Different Panel
Resolution			
	3840 x 2160 Pixels	1200 x 1600 pixels	Different Panel
Backlight type			
	LED	LED	-
Frame rate and refresh rate			
Digital Scanning Frequency (H, V)	31.5 kHz to 133.3 kHz/ 30 Hz to 75 Hz	31kHz to 100 kHz / 59Hz to 61Hz	Similar
Analog Scanning Frequency (H / V)	N/A	N/A	-
Pixel pitch			
	0.182 x 0.182 mm	0.270 x 0.270 mm	Different Panel
Display Interface			
Input video signals	DVI x 2 Display Port x 2	DVI x 1 Display Port x 1 VGA x 1	Similar
Output video signals	N/A	N/A	-
Video bandwidth			
	DVI: 277.2MHz DP:533.3MHz	162.000 MHz	Similar
Ambient light sensing			
Ambient light sensor	Yes	Yes	-
USB Ports			
	USB x 3	USB x 3	-
Calibration Tool			
	ProView QA/ Calibration Feedback System	Beacon Monitor Manage	-

Power Consumption			
	MAX.80W Standby<5 W	MAX.60W Standby<5 W	Similar
Indications for Use			
Indications for Use	This Medical Monitor is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	This Medical Monitor is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.	-

The technological characteristics differences discussed above do not affect the safety and the effectiveness of C1216W, C822W and C821W.

- The modifications between the proposed C1216W and K231026 C1216W are as follows:
- The OSD now includes an additional selectable color temperature, changing from the original two color temperatures (clear/blue) to three color temperatures (clear/blue/6500K), with the same functionality and design principles as the original C1216W.
- The calibration tool has been renamed from "Beacon Monitor Manage" to "ProView QA."
- A new calibration tool, the "Calibration Feedback System," has been added.

The modifications between the C821W and C53S+ are as follows:

- The C821W features an 8-megapixel LCD panel (resolution of 3840 x 2160), while the C53S+ uses a 5-megapixel LCD panel (resolution of 2560 x 2048).
- The power adapter has been updated, with functionality and design principles similar to the C53S+ or other Gigaforce diagnostic monitors.
- The C821W adopts a new internal electronics processing board, with functionality and design principles similar to the C53S+ monitor.
- The C821W uses new firmware, with functionality and design principles similar to the C53S+ diagnostic monitor.
- The C821W features a new enclosure, display stand, and internal mechanical structure, with functionality and design principles similar to the C53S+ or any other Gigaforce diagnostic monitors.
- The packaging has been modified, with functionality and design principles similar to the C53S+ or

any other Gigaforce diagnostic monitors.

- The calibration tool has been renamed from "Beacon Monitor Manage" to "ProView QA."
- A new calibration tool, the "Calibration Feedback System," has been added.

The modifications between the C822W and C22S+ are as follows:

- The C822W features an 8-megapixel LCD panel (resolution of 3840 x 2160), while the C22S+ uses a 2-megapixel LCD panel (resolution of 1600 x 1200).
- The C822W adopts a new power adapter, with functionality and design principles similar to the C22S+ or other Gigaforce diagnostic monitors.
- The C822W uses a new internal electronics processing board, with functionality and design principles similar to the C22S+ monitor.
- The C822W uses new firmware, with functionality and design principles similar to the C22S+ diagnostic monitor.
- The C822W features a new enclosure, display stand, and internal mechanical structure, with functionality and design principles similar to the C22S+ or any other Gigaforce diagnostic monitors.
- The C822W adopts new packaging, with functionality and design principles similar to the C22S+ or any other Gigaforce diagnostic monitors.
- The calibration tool has been renamed from "Beacon Monitor Manage" to "ProView QA."
- A new calibration tool, the "Calibration Feedback System," has been added.

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 C1216W, C822W and C821W.

--C1216W, C821W

- 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°C, 25°C and 40°C 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° and 45° 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 TG18.
- 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.

-- C822W

- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- 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
- Measure 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 C1216W, C822W and C821W are with display characteristics equivalent to those of the predicate devices and did not reveal new issues of safety and performance.

Additionally, C1216W, C822W and C821W are compliant to EMC and Safety standards, the environmental tests and software tests passed.

No animal or clinical testing is needed for C1216W, C822W and C821W.

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 (C1216W, C822W and C821W) are equivalent to those of the predicate devices.
- The differences in technological characteristics between the proposed devices (C1216W, C822W and C821W) 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 (C1216W, C822W and C821W) are equivalent to those of the predicate devices.