



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

March 29, 2024

Re: K240310

Trade/Device Name: LCD Monitors C310S, G310S, C316S, G316S, C616W
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: February 2, 2024
Received: February 2, 2024

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.

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,

 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

Indications for Use

Submission Number (if known)

K240310

Device Name

LCD Monitors C310S, G310S, C316S, G316S, C616W

Indications for Use (Describe)

C310S, C316S and C616W are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The displays are not intended for mammography.

G310S and G316S are intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The devices are not specified for digital mammography systems.

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

510(k) Summary

[As required by 21 CFR 807.92]

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

Feb 29, 2024

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

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

- Trade Name/Model: 3MP Color LCD Monitors C310S, C316S;
3MP Monochrome LCD Monitors G310S, G316S;
6MP Color LCD Monitor C616W.
- Common Name: LCD Monitors C310S, G310S, C316S, G316S, C616W
- 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 predicate within this submission is as follows:

Shenzhen Beacon Display Technology Co., Ltd., 3MP Color LCD Monitors C32S+, 3MP Monochrome LCD Monitors G32S+ has been cleared by FDA through 510(k) No. K201211 (Decision Date - 09/03/2020).

Shenzhen Beacon Display Technology Co., Ltd., 6MP Color LCD Monitor (C61W+) has been cleared by FDA through 510(k) No. K182291 (Decision Date - 11/20/2018).

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

3MP LCD Monitors C310S, G310S, C316S, G316S are 21.3-inch TFT LCD monitors, which are specifically designed to provide the high definition image output for general radiography.

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, supporting resolution 1536 x 2048. The built-in brightness stabilization control circuit makes sure the brightness of these monitors is stable, so these products meet 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.

6MP Color LCD Monitor C616W is a 30-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 they can meet DICOM Part 3.14 and other standards. They use the latest generation of LED backlight panel, supporting resolution 3280 x 2080. 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.

C310S and C316S have the same color LCD panel and similar functionality. For C310S and C316S, the difference is the main board and design principle.

G310S and G316S have the same monochrome LCD panel and similar functionality. For G310S and G316S, the difference is the main board and design principle.

C310S and G310S have the same main board and design principle.

C316S and G316S have the same main board and design principle.

6. Indications for use

C310S, C316S and C616W are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The displays are not intended for mammography.

G310S and G316S are intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The devices are not specified for digital mammography systems.

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

C310S Color LCD monitor

Panel characteristics:	
Screen technology	21.3", TFT, color, LCD screen, AG type
Active area(H x V)	324.86(H) x 433.15(V) mm
Pixel pitch	0.2115 (per one triad) x 0.2115 mm
Resolution	1536(x3) x 2048
Contrast ratio	1600:1 (Minimum), 2000:1 (Typical)
Viewing angle(CR > 10)	Horizontal: 178° (Typical)
	Vertical: 178° (Typical)
Screen brightness	1100cd/m ² (Typical)
Refresh rate	60 Hz
Backlighting	LED
Lifetime of backlight	50000 hours(Minimum)
Response time (T _R +T _F)	11 + 14 ms (typical)
Color support	1.07G
Power supply:	
Line voltage	DC 24 V
Current consumption	5.0 A

Power consumption	< 100 W
Standby	≤ 0.5 W
Control and connection :	
Front	1 operation LED, 6 functional keys
Back	• Power switch*1 • DVI-D*1 • DP*1 • USB Upstream Port*2 • USB Downstream Port*4

Mechanical characteristics :	
Housing components	Plastic
Ventilation openings	Natural heat radiation
Degree of protection	IP20
Climatic conditions :	
Working temperature	0°C - 40°C
Working 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
Air pressure	700hPa - 1060hPa
Safety regulations :	
Safety standards	IEC 60601-1, IEC 60601-1-2 EN 60601-1, EN 60601-1-2 ANSI/AAMI ES60601-1:2005+ A2:2010(R2012) +A1:2012+ A2:2021 CAN/CSA-C22.2 NO. 60601-1:14+ A2:2022
Conformity	CCC,CE,FCC,cTUVus,China energy
Dimension:	

With packing (W x H x D)	483 x 321 x 627 mm
Weight:	
Net weight	Approximate 8.2 ± 0.5 kg

C316S Color LCD monitor

Panel characteristics:	
Screen technology	21.3", TFT, color, LCD screen, AG type
Active area(H x V)	324.86(H) x 433.15(V) mm
Pixel pitch	0.2115 (per one triad) x 0.2115 mm
Resolution	1536(x3) x 2048
Contrast ratio	1600:1 (Minimum), 2000:1 (Typical)
Viewing angle(CR > 10)	Horizontal: 178° (Typical)
	Vertical: 178° (Typical)
Screen brightness	1100cd/m ² (Typical)
Refresh rate	60 Hz
Backlighting	LED
Lifetime of backlight	50000 hours(Minimum)
Response time (T _R +T _F)	11 + 14 ms (typical)
Color support	1.07G
Power supply:	
Power connection	Adapter
Output	+24VDC, 5.0A
Power consumption:	
Normal Mode	100W (Maximum)
Standby Mode	0.5 W (Maximum)
Control and connection:	

Front	1 operation LED, 6 functional keys
Back	• Power switch*1 • DC Input*1 • DVI-D*1 • DP*2 • DP-OUT*1 • USB-A*1 • USB Upstream Port*2 • USB Downstream Port*4

Mechanical characteristics :	
Housing components	Plastic
Ventilation openings	Natural heat radiation
Degree of protection	IP20
Climatic conditions :	
Working temperature	0°C - 40°C
Working 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
Air pressure	700hPa - 1060hPa
Safety regulations :	
Safety standards	IEC 60601-1, IEC 60601-1-2 EN 60601-1, EN 60601-1-2 ANSI/AAMI ES60601-1:2005+ A2:2010(R2012) +A1:2012+ A2:2021 CAN/CSA-C22.2 NO. 60601-1:14+ A2:2022
Conformity	CCC,CE,FCC,cTUVus,Energy Conservation Certification
Dimension:	
With packing(W x H x D)	483 x 321 x 627 mm
Weight:	

Net weight	Approximate 8.6 ± 0.5 kg
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G310S Monochrome LCD Monitor

Panel characteristics :	
Screen technology	21.3", TFT, grayscale, LCD screen, anti-glare, hard coating
Active area(H x V)	324.86 x 433.15 mm
Pixel pitch	0.2115 mm (H) x 0.2115 mm (V)
Resolution	1536 x 2048
Contrast ratio	2500:1 (typical), 2000:1 (minimal)
Viewing angle(CR > 10)	Horizontal: 178° (Typical)
	Vertical: 178° (Typical)
Screen brightness	2500 cd/m ² (typical)
Refresh rate	60 Hz
Backlighting	LEDs
Lifetime of backlight	50,000 hours
Response time (T _R +T _F)	12 + 13 ms (typical)
Power supply:	
Power connection	Adapter
Input	100~240V, 1.4 ~ 0.7A, 50/60Hz
Output	+24VDC, 5.0A
Power consumption:	
Normal Mode	60W (Maximum)
Standby Mode	0.5 W (Maximum)
Control and connection :	
Front	1 operation LED, 6 functional keys

Back	• Power switch*1 • DVI-D*1 • DP*1 • USB Upstream Port*2 • USB Downstream Port*4
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Mechanical characteristics :	
Housing components	Plastic
Ventilation openings	Natural heat radiation
Degree of protection	IP20
Climatic conditions :	
Working temperature	0°C - 40°C
Working 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
Air pressure	700hPa - 1060hPa
Safety regulations :	
Safety standards	IEC 60601-1, IEC 60601-1-2 EN 60601-1, EN 60601-1-2 ANSI/AAMI ES60601-1:2005+ A2:2010(R2012) +A1:2012+ A2:2021 CAN/CSA-C22.2 NO. 60601-1:14+ A2:2022
Conformity	CCC,CE,FCC,cTUVus,China energy
Dimension:	
With packing (W x H x D)	483 x 321 x 627 mm
Weight:	
Net weight	Approximate 8.2 ± 0.5 kg

G316S Monochrome LCD Monitor

Panel characteristics :	
Screen technology	21.3", TFT, grayscale, LCD screen, anti-glare, hard coating
Active area(H x V)	324.86 x 433.15 mm
Pixel pitch	0.2115 mm (H) x 0.2115 mm (V)
Resolution	1536 x 2048
Contrast ratio	2500:1 (typical), 2000:1 (minimal)
Viewing angle(CR > 10)	Horizontal: 178° (Typical)
	Vertical: 178° (Typical)
Screen brightness	2500 cd/m ² (typical)
Refresh rate	60 Hz
Backlighting	LEDs
Lifetime of backlight	50,000 hours
Response time(T _R +T _F)	12 + 13 ms (typical)
Power supply:	
Power connection	Adapter
Output	+24VDC, 5.0A
Power consumption:	
Normal Mode	60W (Maximum)
Standby Mode	0.5 W (Maximum)
Control and connection :	
Front	1 operation LED, 6 functional keys
Back	• Power switch*1 • DC Input*1 • DVI-D*1 • DP*2 • DP-OUT*1 • USB-A*1 • USB Upstream Port*2 • USB Downstream Port*4

Mechanical characteristics :	
Housing components	Plastic
Ventilation openings	Natural heat radiation
Degree of protection	IP20
Climatic conditions :	
Working temperature	0°C - 40°C
Working 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
Air pressure	700hPa - 1060hPa
Safety regulations :	
Safety standards	IEC 60601-1, IEC 60601-1-2 EN 60601-1, EN 60601-1-2 ANSI/AAMI ES60601-1:2005+ A2:2010(R2012) +A1:2012+ A2:2021 CAN/CSA-C22.2 NO. 60601-1:14+ A2:2022
Conformity	CCC,CE,FCC,cTUVus,Energy Conservation Certification
Dimension:	
With packing(W x H x D)	483 x 321 x 627 mm
Weight:	
Net weight	Approximate 8.6 ± 0.5 kg

C616W Color LCD monitor

Panel characteristics:	
Screen technology	30", TFT, color, LCD screen, AG type, 3H hard coating
Active area (H x V)	645.504 x 409.344 mm
Pixel pitch	0.197 mm (H) x 0.197 mm (V)
Resolution	3280 x 2080 Pixels
Contrast ratio	1400:1 (minimum), 2000:1 (typical)
Viewing angle (CR > 10)	Horizontal: 178° (typical)
	Vertical: 178° (typical)
Screen brightness	1300 cd/m ² (typical)
Refresh rate	60 Hz
Backlighting	LED
Lifetime of backlight	50000 hours (minimum)
Response time (TR + TF)	13+15 ms (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	≤160W
Standby	< 0.5 W
Control and connection:	
Front	1 operation LED, 6 functional keys
Back	• Power switch * 1 • AC socket * 1 • DVI * 1 • Display Port * 3 • 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, IEC 60601-1-2 EN 60601-1, EN 60601-1-2 ANSI/AAMI ES60601-1:2005+ A2:2010(R2012) +A1:2012+ A2:2021 CAN/CSA-C22.2 NO. 60601-1:14+ A2:2022
Conformity	CCC,CE,FCC,TUV,CB,CECP
Dimension:	
With packing (W x H x D)	840 x 643 x321 mm
Weight:	
net weight	18.7 ± 0.5 kg

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

8.1 Comparison table

Table 1 General Comparison of C310S, C316S

ID	Comparison Item	Proposed Device		Predicate Device	Explanation of Differences
		C310S	C316S	C32S+	
	1.Display Performance/Specifications				
1.1	Display technology	Color (IPS)	Color (IPS)	Color (IPS)	-
1.2	Screen size	54.1cm/21.3” Aspect ratio:3:4	54.1cm/21.3” Aspect ratio:3:4	54.1cm/21.3” Aspect ratio:3:4	-
1.3	Viewing angle (H/V)	178°/178°	178°/178°	178°/178°	-
1.4	Native resolution	1536 x 2048	1536 x 2048	1536 x 2048	-
1.5	Viewable image size (H x V)	324.86 x 433.15 mm	324.86 x 433.15 mm	324.86 x 433.15 mm	-
1.6	Pixel pitch	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm	-
1.7	Response time (typical)	25 ms (on / off)	25 ms (on / off)	25 ms (on / off)	-
1.8	Brightness (typical)	1100cd/m²	1100cd/m²	1000 cd/m²	Different Panel
1.9	Recommended brightness	450 cd/m²	450 cd/m²	500 cd/m²	Different design scheme
1.10	Contrast ratio (typical)	2000:1	2000:1	1500:1	Different Panel

1.11	Backlight type	LED	LED	LED	-
1.12	Display colors	10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,384 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,384 tones	10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,384 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,384 tones	10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,384 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,384 tones	-
2.Video Signals					
2.1	Input video signals	DVI-D (dual link) x 1, DisplayPort x 1	DVI-D (dual link) x 1, DisplayPort x 2	DVI-D (dual link) x 1, DisplayPort x 1	Different design scheme
2.2	Digital Scanning Frequency (H, V)	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	31 - 97 kHz/59 - 61 Hz	Different design scheme
2.3	Video bandwidth	DVI: 214.25 MHz DisplayPort: 214.25 MHz	DVI: 216 MHz DisplayPort: 216 MHz	DVI: 216 MHz DisplayPort: 216 MHz	Different design scheme
3.Power Related Specifications					
3.1	Power Requirements	DC 24V/ 5.0A	DC 24V/ 5.0A	DC 12 V / 6.67 A	Different design scheme
3.2	Maximum power consumption	100 W	100 W	80 W	Different design scheme
3.3	Power save mode	Less than or equal to 0.5 W	Less than or equal to 0.5 W	Less than 5 W	Different design scheme

3.4	Power Management	VESA DPMS and EPA power saving management, DisplayPort 1.2	VESA DPMS and EPA power saving management, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2	-
	4. Miscellaneous Features/Specifications				
4.1	Quality-control Software	Beacon Monitor Manage	Beacon Monitor Manage	Beacon Monitor Manage	-
4.2	Sensors	Backlight sensor Integrated front sensor Ambient sensor	Backlight sensor Integrated front sensor Ambient sensor Presence sensor Gravity sensor	Backlight sensor Integrated front sensor Ambient light sensor	Different design scheme
4.3	USB Ports	2 USB Upstream Port 4 USB Downstream Port	1 USB-A 2 USB Upstream Port 4 USB Downstream Port	USB Upstream Port*1 USB Downstream Port*2	Different design scheme
4.4	Brightness stabilization	Yes	Yes	Yes	-
4.5	Net weight	8.2 ± 0.5 kg	8.6 ± 0.5 kg	9.5	Different weight due to different components and parts
4.6	Dimensions w/o stand (W x H x D)	342.5 x 520.26 ~ 620.26 x 224	342.5 x 520.26 ~ 620.26 x 224	369 x 220 x 511.5 ~ 596.15	Different housing design due to the different panel size
	5. Indications for Use				

5.1	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 3MP Color LCD Monitors C32S+ are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The displays are not intended for mammography.	-
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Table 2 General Comparison of G310S, G316S

ID	Comparison Item	Proposed Device		Predicate Device	Explanation of Differences
		G310S	G316S	G32S+	
	1.Display Performance/Specifications				
1.1	Display technology	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
1.2	Screen size	54.1 cm / 21.3” (541 mm diagonal)	54.1 cm / 21.3” (541 mm diagonal)	54 cm / 21.3” (541 mm diagonal)	-
1.3	Viewing angle (H/V)	178°/178°	178°/178°	170°/170°	Different Panel
1.4	Native resolution	1536 x 2048 (3:4 aspect ratio)	1536 x 2048 (3:4 aspect ratio)	1536 x 2048 (3:4 aspect ratio)	-
1.5	Viewable image size (H x V)	324.86 x 433.15 mm	324.86 x 433.15 mm	324.86 x 433.15 mm	-

1.6	Pixel pitch	0.2115 mm (H) x 0.2115 mm (V)	0.2115 mm (H) x 0.2115 mm (V)	0.2115 mm (H) x 0.2115 mm (V)	-
1.7	Response time (typical)	25 ms (On/Off)	25 ms (On/Off)	28 ms (On/Off)	Different Panel
1.8	Brightness (typical)	2500 cd/m ²	2500 cd/m ²	2000 cd/m ²	Different Panel
1.9	Recommended brightness	450 cd/m ²	450 cd/m ²	500 cd/m ²	Different design scheme
1.10	Contrast ratio (typical)	2500:1	2500:1	1500:1	Different Panel
1.11	Backlight type	LED	LED	LED	-
1.12	Grayscale Tones	10-bit (DisplayPort): 1,024 from a palette of 16,384 tones 8-bit (DVI): 256 from a palette of 16,384 tones	10-bit (DisplayPort): 1,024 from a palette of 16,384 tones 8-bit (DVI): 256 from a palette of 16,384 tones	10-bit (DisplayPort): 1,024 from a palette of 16,384 tones 8-bit (DVI): 256 from a palette of 16,384 tones	-
2.Video Signals					
2.1	Input video signals	DVI-D (dual link) x 1 DisplayPort x 1	DVI-D (dual link) x 1 DisplayPort x 1	DVI-D (dual link) x 1 DisplayPort x 1	-
2.2	Digital Scanning Frequency (H, V)	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	31 - 97 kHz, 60 - 70 Hz	Different design scheme
2.3	Dot Clock	DVI: 214.25 MHz DisplayPort: 214.25 MHz	DVI: 216 MHz DisplayPort: 216 MHz	216 MHz	Different design scheme
3.Power Related Specifications					

3.1	Power Requirements	DC 24V/ 5.0A	DC 24V/ 5.0A	DC 12 V / 6.67 A	Different design scheme
3.2	Maximum power consumption	60 W	60 W	50 W	Different design scheme
3.3	Power save mode	Less than or equal to 0.5 W	Less than or equal to 0.5 W	Less than 5 W	Different design scheme
3.4	Power Management	VESA DPMS and EPA power saving management, DisplayPort 1.2	VESA DPMS and EPA power saving management, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2	-
4. Miscellaneous Features/Specifications					
4.1	Quality-control procedures	Beacon Monitor Manage	Beacon Monitor Manage	Beacon Monitor Manage	-
4.2	Sensors	Backlight sensor Integrated front sensor Ambient sensor	Backlight sensor Integrated front sensor Ambient sensor Presence sensor Gravity sensor	Backlight Sensor Integrated Front Sensor Ambient Light Sensor	Different design scheme
4.3	USB Ports	2 USB Upstream Port 4 USB Downstream Port/ Rev. 2.0	1 USB-A 2 USB Upstream Port 4 USB Downstream Port/ Rev. 2.0	1 upstream 2 downstream / Rev. 2.0	Different design scheme
4.4	Brightness stabilization	Yes	Yes	Yes	-
4.5	Net weight	8.2 ± 0.5	8.6 ± 0.5	9.0 kg	Different weight due to different components and parts
4.6	Dimensions w/o stand (W x H x D)	342.5 x 520.26 ~ 620.26 x 224	342.5 x 520.26 ~ 620.26 x 224	369 x 511.15 ~ 596.15 x 220	Different housing design due to the different panel size

5. Indications for Use					
5.1	Indications for Use	This product is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. This product is not specified for digital mammography systems.	This product is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. This product is not specified for digital mammography systems.	The 3MP Monochrome LCD Monitors G32S+ are intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The devices are not specified for digital mammography systems.	-

Table 3 General Comparison of C616W

ID	Comparison Item	Proposed Device	Predicate Device	Explanation of Differences
		C616W	C61W+	
	1.Display Performance/Specifications			
1.1	Display technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
1.2	Screen size	30” (Aspect Ratio 16:10)	30” (Aspect Ratio 16:10)	-
1.3	Viewing angle (H/V)	H: 178°; V: 178°	H:170°, V:170°	Different Panel
1.4	Native resolution	3280 × 2080	3280 x 2048	Different Panel
1.5	Viewable image size (H x V)	645.504 x 409.344 mm	654.4 x 408.6 mm	-
1.6	Pixel pitch	0.197 mm (H) x 0.197 mm (V)	0.197 mm (H) x 0.197 mm (V)	-

1.7	Response time (typical)	28ms	30ms	Different Panel
1.8	Brightness (typical)	1300cd/m ²	800 cd/m ²	Different design scheme
1.9	Recommended brightness	450 cd/m ²	500 cd/m ²	-
1.10	Contrast ratio (typical)	2000:1	950:1	-
1.11	Backlight type	LED	LED	-
1.12	Display colors	10bit	From a palette of 68 billion colors: - 10-bit (DisplayPort): 1.07 billion colors (maximum)	Tone between the predicate device and our proposed devices are different. But they pass the exams in AAPM-TG18 4.3 “Luminance Response” . Therefore, they are equivalent to the predicate device.
2.Video Signals				
2.1	Input video signals	DVI-D (dual link) x 1, DisplayPort x 2	DVI-D (dual link) x 2, DisplayPort x 2 VGA x 1	Different design scheme

2.2	Digital Scanning Frequency (H, V)	1P DVI : Horizontal: 63.3KHz Vertical: 30.0Hz 1P DP Horizontal: 128.3KHz Vertical: 60Hz 2P DVI: Horizontal: 128.3KHz Vertical: 60.0Hz 2P DP Horizontal: 128.3KHz Vertical: 60.0Hz	31.5 - 120 kHz/29 - 61Hz (VGA Text: 59 - 75Hz) Frame synchronous mode: 29.5- 30.5Hz, 50 - 60 Hz	Different design scheme
2.3	Video bandwidth	DVI: 217.75/ 441.5 231.00 MHz DisplayPort: 441.5/ 231.00 MHz	-	Different design scheme
3.Power Related Specifications				
3.1	Power Requirements	100-240VAC 50/60Hz	DC 24 V, 9.0 A	Difference between built-in power supply and built-out power supply
3.2	Maximum power consumption	160W	160W	-
3.3	Power save mode	Less than 0.5 W	Less than 0.5 W	-
3.4	Power Management	VESA DPMS and EPA power saving management, DisplayPort 1.2	DC Socket, Power switch	Different design scheme
4.Miscellaneous Features/Specifications				
4.1	Quality-control Software	Beacon Monitor Manage	Beacon Monitor Manage	-

4.2	Sensors	Integrated front sensor Ambient sensor Presence sensor	Backlight Sensor, Integrated Front Sensor, Ambient Light Senso	Different design scheme
4.3	USB Ports	1 USB-1 2 USB Upstream Port 4 USB Downstream Port/ Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	Different design scheme
4.4	Brightness stabilization	Yes	Yes	-
4.5	Net weight	18.7 kg	15.5 kg	Different weight due to different components and parts
4.6	Dimensions w/o stand (W x H x D)	With base: 687.14 x 531.11 ~ 631.11 x 264.00 mm	698 x 470 x 78 mm	Different housing design due to the different panel size
5. Indications for Use				
5.1	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.	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.	-

The technological characteristics differences discussed above do not affect the safety and the effectiveness of the C310S, G310S, C316S, G316S, C616W.

8.2 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 C310S, G310S, C316S, G316S, C616W as below.

- 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 C310S, G310S, C316S, G316S, C616W are with display characteristics equivalent to those of the predicate devices.

No animal or clinical testing is needed for C310S, G310S, C316S, G316S, C616W.

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 uses of proposed devices (C310S, G310S, C316S, G316S, C616W) are equivalent to the predicate devices.
- The technological characteristics differences between proposed devices (C310S, G310S, C316S, G316S, C616W) and the predicate devices do not affect the safety

and effectiveness, so no new risk is raised.

- Demonstrated by the bench tests, the display characteristics of proposed devices (C310S, G310S, C316S, G316S, C616W) are equivalent to those of the predicate devices.