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

October 25, 2024

Re: K243031
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: September 26, 2024
Received: September 27, 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.

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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243031

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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K243031

510 (k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

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

Sep 23, 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
Telephone No.:	+86-024-88087610
Fax No.:	+86-024-88087629
Email Address:	liyf@beacon-display.cn

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., LCD Monitors C310S, G310S, C316S, G316S, C616W has been cleared by FDA through 510(k) No. K240310 (Decision Date - 03/29/2024).

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 (Substantial Equivalence) [21 CFR 807.92(a)(6)]

Table 1 General Comparison of C310S

ID	Comparison Item	Proposed Device	Predicate Device K240310	Explanation of Differences
		C310S	C310S	
	1.Display Performance/Specifications			
1.1	**Display technology**	Color (IPS)	Color (IPS)	same
1.2	**Screen size**	54.1cm/21.3” Aspect ratio:3:4	54.1cm/21.3” Aspect ratio:3:4	same
1.3	**Viewing angle (H/V)**	178°/178°	178°/178°	same
1.4	**Native resolution**	1536 x 2048	1536 x 2048	same
1.5	**Viewable image size (H x V)**	324.86 x 433.15 mm	324.86 x 433.15 mm	same
1.6	**Pixel pitch**	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm	same
1.7	**Response time (typical)**	25 ms (on / off)	25 ms (on / off)	same
1.8	**Brightness (typical)**	1100cd/m^2	1100cd/m^2	same
1.9	**Recommended brightness**	450 cd/m^2	450 cd/m^2	same
1.10	**Contrast ratio (typical)**	2000:1	2000:1	same
1.11	**Backlight type**	LED	LED	same
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	same
	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	same

2.2	**Digital Scanning Frequency (H, V)**	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	same
2.3	**Video bandwidth**	DVI: 214.25 MHz DisplayPort: 214.25 MHz	DVI: 214.25 MHz DisplayPort: 214.25 MHz	same
	3.Power Related Specifications			
3.1	**Power Requirements**	DC 24V/ 5.0A	DC 24V/ 5.0A	same
3.2	**Maximum power consumption**	100 W	100 W	same
3.3	**Power save mode**	Less than or equal to 0.5 W	Less than or equal to 0.5 W	same
3.4	**Power Management**	VESA DPMS and EPA power saving management, DisplayPort 1.2	VESA DPMS and EPA power saving management, DisplayPort 1.2	same
	4.Miscellaneous Features/Specifications			
4.1	**Calibration Tool**	Beacon Monitor Manage/ Calibration Feedback System	Beacon Monitor Manage	Different
4.2	**Sensors**	Backlight sensor Integrated front sensor Ambient sensor	Backlight sensor Integrated front sensor Ambient sensor	same
4.3	**USB Ports**	2 USB Upstream Port 4 USB Downstream Port	2 USB Upstream Port 4 USB Downstream Port	same
4.4	**Brightness stabilization**	Yes	Yes	same
4.5	**Net weight**	8.2 ± 0.5 kg	8.2 ± 0.5 kg	same
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	same
	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.	same

Table 2 General Comparison of C316S

ID	Comparison Item	Proposed Device	Predicate Device K240310	Explanation of Differences
		C316S	**C316S**	
	1.Display Performance/Specifications			
1.1	**Display technology**	Color (IPS)	Color (IPS)	same
1.2	**Screen size**	54.1cm/21.3” Aspect ratio:3:4	54.1cm/21.3” Aspect ratio:3:4	same
1.3	**Viewing angle (H/V)**	178°/178°	178°/178°	same
1.4	**Native resolution**	1536 x 2048	1536 x 2048	same
1.5	**Viewable image size (H x V)**	324.86 x 433.15 mm	324.86 x 433.15 mm	same
1.6	**Pixel pitch**	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm	same
1.7	**Response time (typical)**	25 ms (on / off)	25 ms (on / off)	same
1.8	**Brightness (typical)**	1100cd/m^2	1100cd/m^2	same
1.9	**Recommended brightness**	450 cd/m^2	450 cd/m^2	same
1.10	**Contrast ratio (typical)**	2000:1	2000:1	same
1.11	**Backlight type**	LED	LED	same

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	same
	2.Video Signals			
2.1	**Input video signals**	DVI-D (dual link) x 1, DisplayPort x 2	DVI-D (dual link) x 1, DisplayPort x 2	same
2.2	**Digital Scanning Frequency (H, V)**	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	same
2.3	**Video bandwidth**	DVI: 216 MHz DisplayPort: 216 MHz	DVI: 216 MHz DisplayPort: 216 MHz	same
	3.Power Related Specifications			
3.1	**Power Requirements**	DC 24V/ 5.0A	DC 24V/ 5.0A	same
3.2	**Maximum power consumption**	100 W	100 W	same
3.3	**Power save mode**	Less than or equal to 0.5 W	Less than or equal to 0.5 W	same
3.4	**Power Management**	VESA DPMS and EPA power saving management, DisplayPort 1.2	VESA DPMS and EPA power saving management, DisplayPort 1.2	same
	4.Miscellaneous Features/Specifications			
4.1	**Calibration Tool**	Beacon Monitor Manage/ Calibration Feedback System	Beacon Monitor Manage	Different
4.2	**Sensors**	Backlight sensor Integrated front sensor Ambient sensor Presence sensor Gravity sensor	Backlight sensor Integrated front sensor Ambient sensor Presence sensor Gravity sensor	same
4.3	**USB Ports**	1 USB-A 2 USB Upstream Port 4 USB Downstream Port	1 USB-A 2 USB Upstream Port 4 USB Downstream Port	same

4.4	**Brightness stabilization**	Yes	Yes	same
4.5	**Net weight**	8.6 ± 0.5 kg	8.6 ± 0.5 kg	same
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	same
	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.	same

Table 3 General Comparison of G310S

ID	Comparison Item	Proposed Device	Predicate Device K240310	Explanation of Differences
		G310S	**G310S**	
	1.Display Performance/Specifications			
1.1	**Display technology**	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	same
1.2	**Screen size**	54.1 cm / 21.3” (541 mm diagonal)	54.1 cm / 21.3” (541 mm diagonal)	same
1.3	**Viewing angle (H/V)**	178°/178°	178°/178°	same
1.4	**Native resolution**	1536 x 2048 (3:4 aspect ratio)	1536 x 2048 (3:4 aspect ratio)	same
1.5	**Viewable image size (H x V)**	324.86 x 433.15 mm	324.86 x 433.15 mm	same
1.6	**Pixel pitch**	0.2115 mm (H) x 0.2115 mm (V)	0.2115 mm (H) x 0.2115 mm (V)	same
1.7	**Response time (typical)**	25 ms (On/Off)	25 ms (On/Off)	same
1.8	**Brightness (typical)**	2500 cd/m^2	2500 cd/m^2	same
1.9	**Recommended brightness**	450 cd/m^2	450 cd/m^2	same

1.10	**Contrast ratio (typical)**	2500:1	2500:1	same
1.11	**Backlight type**	LED	LED	same
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	same
	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	same
2.2	**Digital Scanning Frequency (H, V)**	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	same
2.3	**Dot Clock**	DVI: 214.25 MHz DisplayPort: 214.25 MHz	DVI: 214.25 MHz DisplayPort: 214.25 MHz	same
	3.Power Related Specifications			
3.1	**Power Requirements**	DC 24V/ 5.0A	DC 24V/ 5.0A	same
3.2	**Maximum power consumption**	60 W	60 W	same
3.3	**Power save mode**	Less than or equal to 0.5 W	Less than or equal to 0.5 W	same
3.4	**Power Management**	VESA DPMS and EPA power saving management, DisplayPort 1.2	VESA DPMS and EPA power saving management, DisplayPort 1.2	same
	4.Miscellaneous Features/Specifications			
4.1	**Calibration Tool**	Beacon Monitor Manage/ Calibration Feedback System	Beacon Monitor Manage	Different
4.2	**Sensors**	Backlight sensor Integrated front sensor Ambient sensor	Backlight sensor Integrated front sensor Ambient sensor	same
4.3	**USB Ports**	2 USB Upstream Port 4 USB Downstream Port/ Rev. 2.0	2 USB Upstream Port 4 USB Downstream Port/ Rev. 2.0	same
4.4	**Brightness stabilization**	Yes	Yes	same
4.5	**Net weight**	8.2 ± 0.5	8.2 ± 0.5	same

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	same
	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.	same

Table 4 General Comparison of G316S

ID	Comparison Item	Proposed Device	Predicate Device K240310	Explanation of Differences
		G316S	**G316S**	
	1.Display Performance/Specifications			
1.1	**Display technology**	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	same
1.2	**Screen size**	54.1 cm / 21.3” (541 mm diagonal)	54.1 cm / 21.3” (541 mm diagonal)	same
1.3	**Viewing angle (H/V)**	178°/178°	178°/178°	same
1.4	**Native resolution**	1536 x 2048 (3:4 aspect ratio)	1536 x 2048 (3:4 aspect ratio)	same
1.5	**Viewable image size (H x V)**	324.86 x 433.15 mm	324.86 x 433.15 mm	same
1.6	**Pixel pitch**	0.2115 mm (H) x 0.2115 mm (V)	0.2115 mm (H) x 0.2115 mm (V)	same
1.7	**Response time (typical)**	25 ms (On/Off)	25 ms (On/Off)	same
1.8	**Brightness (typical)**	2500 cd/m^2	2500 cd/m^2	same
1.9	**Recommended brightness**	450 cd/m^2	450 cd/m^2	same
1.10	**Contrast ratio (typical)**	2500:1	2500:1	same
1.11	**Backlight type**	LED	LED	same

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	same
	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	same
2.2	**Digital Scanning Frequency (H, V)**	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	Landscape: Horizontal: 126.327KHz Vertical: 59.956Hz	same
2.3	**Dot Clock**	DVI: 216 MHz DisplayPort: 216 MHz	DVI: 216 MHz DisplayPort: 216 MHz	same
	3.Power Related Specifications			
3.1	**Power Requirements**	DC 24V/ 5.0A	DC 24V/ 5.0A	same
3.2	**Maximum power consumption**	60 W	60 W	same
3.3	**Power save mode**	Less than or equal to 0.5 W	Less than or equal to 0.5 W	same
3.4	**Power Management**	VESA DPMS and EPA power saving management, DisplayPort 1.2	VESA DPMS and EPA power saving management, DisplayPort 1.2	same
	4.Miscellaneous Features/Specifications			
4.1	**Calibration Tool**	Beacon Monitor Manage/ Calibration Feedback System	Beacon Monitor Manage	Different
4.2	**Sensors**	Backlight sensor Integrated front sensor Ambient sensor Presence sensor Gravity sensor	Backlight sensor Integrated front sensor Ambient sensor Presence sensor Gravity sensor	same
4.3	**USB Ports**	1 USB-A 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	same
4.4	**Brightness stabilization**	Yes	Yes	same
4.5	**Net weight**	8.6 ± 0.5	8.6 ± 0.5	same

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	same
	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.	same

Table 5 General Comparison of C616W

ID	Comparison Item	Proposed Device	Predicate Device K240310	Explanation of Differences
		C616W	**C616W**	
	1.Display Performance/Specifications			
1.1	**Display technology**	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	same
1.2	**Screen size**	30” (Aspect Ratio 16:10)	30” (Aspect Ratio 16:10)	same
1.3	**Viewing angle (H/V)**	H: 178°; V: 178°	H: 178°; V: 178°	same
1.4	**Native resolution**	3280 × 2080	3280 × 2080	same
1.5	**Viewable image size (H x V)**	645.504 x 409.344 mm	645.504 x 409.344 mm	same
1.6	**Pixel pitch**	0.197 mm (H) x 0.197 mm (V)	0.197 mm (H) x 0.197 mm (V)	same
1.7	**Response time (typical)**	28ms	28ms	same
1.8	**Brightness (typical)**	1300cd/m^2	1300cd/m^2	same
1.9	**Recommended brightness**	450 cd/m^2	450 cd/m^2	same
1.10	**Contrast ratio (typical)**	2000:1	2000:1	same
1.11	**Backlight type**	LED	LED	same

1.12	**Display colors**	10bit	10bit	same
	2.Video Signals			
2.1	**Input video signals**	DVI-D (dual link) x 1, DisplayPort x 2	DVI-D (dual link) x 1, DisplayPort x 2	same
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	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	same
2.3	**Video bandwidth**	DVI: 217.75/ 441.5 231.00 MHz DisplayPort: 441.5/ 231.00 MHz	DVI: 217.75/ 441.5 231.00 MHz DisplayPort: 441.5/ 231.00 MHz	same
	3.Power Related Specifications			
3.1	**Power Requirements**	100-240VAC 50/60Hz	100-240VAC 50/60Hz	same
3.2	**Maximum power consumption**	160W	160W	same
3.3	**Power save mode**	Less than 0.5 W	Less than 0.5 W	same
3.4	**Power Management**	VESA DPMS and EPA power saving management, DisplayPort 1.2	VESA DPMS and EPA power saving management, DisplayPort 1.2	same
	4.Miscellaneous Features/Specifications			
4.1	**Calibration Tool**	Beacon Monitor Manage/ Calibration Feedback System	Beacon Monitor Manage	Different
4.2	**Sensors**	Integrated front sensor Ambient sensor Presence sensor	Integrated front sensor Ambient sensor Presence sensor	same

4.3	**USB Ports**	1 USB-1 2 USB Upstream Port 4 USB Downstream Port/ Rev. 2.0	1 USB-1 2 USB Upstream Port 4 USB Downstream Port/ Rev. 2.0	same
4.4	**Brightness stabilization**	Yes	Yes	same
4.5	**Net weight**	18.7 kg	18.7 kg	same
4.6	**Dimensions w/o stand (W x H x D)**	With base: 687.14 x 531.11 ~ 631.11 x 264.00 mm	With base: 687.14 x 531.11 ~ 631.11 x 264.00 mm	same
	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.	same

The technological characteristics differences discussed above do not affect the safety and the effectiveness of the C310S, G310S, C316S, G316S, C616W. The major changes include: 1) calibration tools, which have been validated according to IEC 62304, and 2) its module, which also has been verified and validated through physical laboratory testing conducted according to the FDA Guidance, “Display Devices for Diagnostic Radiology”.

Based on the physical laboratory test results and software validation reports, all the differences between the proposed and predicate device do not raise any concerns regarding safety and effectiveness of the device.

Therefore, the proposed device is substantially equivalent to the predicate device in terms of its indications for use and technological characteristics.

8. Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

The following data were provided in support of the substantial equivalence determination:

1) Software Validation

The display embedded software contain software that belongs to Basic Documentation Level. The

software was designed and developed according to a software development process and was verified and validated.

Its calibration tools, DBI Calibration Feedback System(CFS), belong to Basic Documentation Level. The software programs were verified and validated according to IEC 62304. Software information is provided in accordance with FDA guidance:

- The content of premarket submissions for Device Software Functions (June 14, 2023)

2) Cybersecurity

Cybersecurity documents are provided in accordance with the below FDA guidance:

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (September 27, 2023)
- Postmarket Management of Cybersecurity in Medical Devices (December 28, 2016)

3) Bench Test - Performance Test

- Physical Laboratory Test items suggested in the FDA guidance “Display Devices for Diagnostic Radiology” were tested on the display embedded software using DBI Calibration Feedback System on C310S, G310S, C316S, G316S, C616W and the test result as follows:

Measurements	Description	Test result
1. Spatial resolution	Measurement of spatial resolution expressed as modulation transfer function (MTF)	PASS
2. Pixel defects	The maximum number allowed for each type of pixel defects/faults	PASS
3. Artifacts	Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in TG18 guideline	PASS
4. Temporal response	Measure the temporal response using the typical data provided by the panel manufacturer	PASS
5. Luminance (maximum, minimum, achievable, and recommended)	Meausure the maximum, minimum, achievable, and recommended luminance	PASS
6. Conformance to a grayscale-to luminance function	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)	PASS
7. Color tracking (primary colors and color gamut)	Measurement of Color tracking (primary colors and color gamut)	PASS

All display characteristics of the display embedded software have met the pre-determined criteria. Therefore, 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.

8. 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

- There are no significant differences between the proposed device and the predicate device that would negatively impact its use and safety.
- The proposed device has been proved to be as safe and effective as the predicate device, which was previously cleared in K240310.
- It shares the same indications for use and similar technological characteristics, with any differences supported by software validation reports and performance test results that demonstrate the proposed device's safety and effectiveness.
- The technological differences between the proposed device and its predicate device do not raise any new concerns regarding safety or effectiveness, and the proposed device can be considered substantially equivalent to the predicate device.