



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

August 30, 2024

Re: K233897

Trade/Device Name: 5MP Color LCD Monitors/ 5MP Monochrome LCD Monitors (C510S, G510S, CB5MP, MB5MP, C516S, G516S)

Regulation Number: 21 CFR 892.2050

Regulation Name: Medical image management and processing system

Regulatory Class: Class II

Product Code: PGY

Dear Li Yafei:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 6, 2024. Specifically, FDA is updating this SE Letter (typo in regulation name and number) as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jessica Lamb, Office of Radiological Health, 301-796-6167, jessica.lamb@fda.hhs.gov

Sincerely,

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



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February 6, 2024

Re: K233897

Trade/Device Name: 5MP Color LCD Monitors/ 5MP Monochrome LCD Monitors (C510S, G510S, CB5MP, MB5MP, C516S, G516S)

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope And Accessories

Regulatory Class: Class II

Product Code: PGY

Dated: December 11, 2023

Received: December 11, 2023

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>).

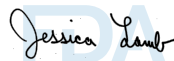
Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless 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,



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

Indications for Use

510(k) Number (if known)

K233897

Device Name

5MP Color LCD Monitors C510S, CB5MP, C516S.

5MP Monochrome LCD Monitors G510S, MB5MP, G516S.

Indications for Use (Describe)

C510S, G510S, CB5MP, MB5MP, C516S and G516S are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

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 04, 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: 5MP Color LCD Monitors C510S, CB5MP, C516S.
5MP Monochrome LCD Monitors G510S, MB5MP, G516S.
- Common Name: 5MP LCD Monitors C510S, G510S, CB5MP, MB5MP, C516S, G516S
- 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:

JVC Kenwood Corporation, 5MP Color LCD Monitor CL-S500, 5MP Monochrome LCD Monitor MS-S500 has been cleared by FDA through 510(k) No. K191137 (Decision Date - July 2, 2019).

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

5MP LCD Monitors C510S, G510S, CB5MP, MB5MP, C516S, G516S 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 2560 x 2048. The built-in brightness stabilization control circuit makes sure the brightness of these monitors is stable and the calibration is continuous, 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.

C510S, CB5MP, C516S have the same color LCD panel and similar functionality. The difference between C510S and CB5MP is only different customers which results in the two models. For C510S, CB5MP, C516S, the difference is the main board and design principle.

G510S, MB5MP, G516S have the same monochrome LCD panel and similar functionality. The difference between G510S and MB5MP is only different customers which results in the two models. For G510S, MB5MP, G516S, the difference is the main board and design principle.

6. Indications for use

C510S, G510S, CB5MP, MB5MP, C516S and G516S are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

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

C510S, CB5MP Color LCD monitors

Panel characteristics:	
Screen technology	21.3", TFT, color, LCD screen, anti-glare, hard coating
Active area (H x V)	422.4 x 337.92 mm
Pixel pitch	0.165 mm (H) x 0.165 mm (V)
Resolution	2560 x 2048
Contrast ratio	2000:1 (typical), 1600:1 (minimal)
Viewing angle(CR > 10)	Horizontal: 178° (Typical)
	Vertical: 178° (Typical)
Screen brightness	1150 cd/m ² (typical)
Refresh rate	50 Hz
Backlighting	LEDs
Lifetime of backlight	50,000 hours
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	<ul style="list-style-type: none"> • 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(R2012) + A1 CAN/CSA-C22.2 NO. 60601-1:14
Conformity	CCC, CE, FCC, TUV, CB, China energy
Dimension:	
With packing (W x H x D)	483 x 321 x 627 mm
Weight:	
Gross weight	Approximate 12.6 ± 0.5 kg
Net weight	Approximate 9.1 ± 0.5 kg

G510S, MB5MP Monochrome LCD Monitors

Panel characteristics :	
Screen technology	21.3", TFT, grayscale, LCD screen, anti-glare, hard coating
Active area (H x V)	422.4 x 337.92 mm
Pixel pitch	0.165 mm (H) x 0.165 mm (V)

Resolution	2560 x 2048
Contrast ratio	2000:1 (typical), 1600:1 (minimal)
Viewing angle(CR > 10)	Horizontal: 178° (Typical)
	Vertical: 178° (Typical)
Screen brightness	3000 cd/m ² (typical)
Refresh rate	50 Hz
Backlighting	LEDs
Lifetime of backlight	50,000 hours
Response time (T _R +T _F)	11 + 14 ms (typical)
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	<ul style="list-style-type: none"> • 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(R2012) + A1 CAN/CSA-C22.2 NO. 60601-1:14
Conformity	CCC, CE, FCC, TUV, CB, China energy
Dimension:	
With packing (W x H x D)	483 x 321 x 627 mm
Weight:	
Gross weight	Approximate 12.6 ± 0.5 kg
Net weight	Approximate 9.1 ± 0.5 kg

C516S Color LCD monitor

Panel characteristics :	
Screen technology	21.3", TFT, color, LCD screen, anti-glare, hard coating
Active area(H x V)	422.4 x 337.92 mm
Pixel pitch	0.165 mm (H) x 0.165 mm (V)
Resolution	2560 x 2048
Contrast ratio	2000:1 (typical), 1600:1 (minimal)
Viewing angle(CR > 10)	Horizontal: 178° (Typical)
	Vertical: 178° (Typical)
Screen brightness	1150 cd/m ² (typical)
Refresh rate	50 Hz
Backlighting	LEDs
Lifetime of backlight	50,000 hours

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	<ul style="list-style-type: none"> • 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(R2012) + A1 CAN/CSA-C22.2 NO. 60601-1:14
Conformity	CCC, CE, FCC, cTUVus, Energy Conservation Certification
Dimension:	
With packing(W x H x D)	483 x 321 x 627 mm
Weight:	
Gross weight	Approximate 13.3 ± 0.5 kg
Net weight	Approximate 9.3 ± 0.5 kg

G516S Monochrome LCD Monitor

Panel characteristics :	
Screen technology	21.3", TFT, grayscale, LCD screen, anti-glare, hard coating
Active area(H x V)	422.4 x 337.92 mm
Pixel pitch	0.165 mm(H) x 0.165 mm(V)
Resolution	2560 x 2048
Contrast ratio	2000:1(typical), 1600:1(minimal)
Viewing angle(CR > 10)	Horizontal: 178°(Typical)
	Vertical: 178°(Typical)
Screen brightness	3000 cd/m ² (typical)
Refresh rate	50 Hz
Backlighting	LEDs
Lifetime of backlight	50,000 hours
Response time(T _R +T _F)	11 + 14 ms(typical)
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	<ul style="list-style-type: none"> • 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(R2012) + A1 CAN/CSA-C22.2 NO. 60601-1:14
Conformity	CCC, CE, FCC, cTUVus, Energy Conservation Certification
Dimension:	
With packing(W x H x D)	483 x 321 x 627 mm
Weight:	
Gross weight	Approximate 13.3 ± 0.5 kg
Net weight	Approximate 9.3 ± 0.5 kg

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

8.1 Indication for use:

Table 1 Indication for use Comparison of C510S, G510S, CB5MP, MB5MP, C516S, G516S

ID	Comparison Item	Proposed Device 5MP Color LCD Monitors C510S, CB5MP, C516S. 5MP Monochrome LCD Monitors G510S, MB5MP, G516S.	Predicate Device 5MP Color LCD Monitor CL-S500, 5MP Monochrome LCD Monitor MS-S500
1	Indication for use	C510S, G510S, CB5MP, MB5MP, C516S and G516S are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	CL-S500 and MS-S500 are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

8.2 Comparison table

Table 2 General Comparison of C510S, CB5MP

ID	Comparison Item	Proposed Device 5MP Color LCD Monitors C510S, CB5MP	Predicate Device 5MP Color LCD Monitor CL-S500	Explanation of Differences
2	Display Performance/Specifications			
2.1	Screen Technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
2.2	Viewing angle (H, V)	CR>10 Horizontal: Typ.178 Vertical: Typ.178	CR>50 Horizontal: Typ.178 Vertical: Typ.178	Different screen provided by the different manufacturer
2.3	Resolution or matrix size	5MP(2560 x 2048)	5MP(2048 X 2560)	-
2.4	Aspect ratio	5:4	4:5	-
2.5	Display area	Horizontal: 422.4mm Vertical: 337.92mm	Horizontal: 337.92mm Vertical: 422.4mm	-
2.6	Pixel pitch	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	-
2.7	Response time (Typ.)	25ms (On/Off)	25ms (On/Off)	-
2.8	Maximum luminance	Min. 920cd/m ² Typ. 1,150cd/m ²	Min. 920cd/m ² Typ. 1,150cd/m ²	-
2.9	DICOM calibrated luminance	450cd/m ²	500cd/m ²	Difference complies the DICOM 3.14.

2.10	Contrast ratio	Min. 1600:1 Typ. 2000:1	Min. 1600:1 Typ. 2000:1	-
2.11	Backlighting	LED	LED	-
2.12	Grayscale 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 16,369 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,369 tones	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.
2.13	Luminance non-uniformity compensation	-	Digital Uniformity Correction System	Different design scheme
3	Video Signals			
3.1	Input video signals	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	-
3.2	Scanning Frequency (H, V)	Landscape: Horizontal: 104.852KHz Vertical: 50Hz	Portrait: Horizontal: 129.1KHz Vertical: 50Hz Landscape: Horizontal: 103.5KHz Vertical: 50Hz	Different design scheme
3.3	Dot Clock	285.2 MHz	285 MHz	-

4	Power Related Specifications			
4.1	Power Requirements	DC 24V, 5A	AC 100-240V, 50/60Hz	Difference between built-in power supply and built-out power supply
4.2	Power Consumption / Save Mode	100W Less than 0.5W	95W Less than 1W	Compared with the predicate device, the proposed device consumes more power in the operating mode and less power in the power saving mode.
4.3	Power Management	VESA DPMS and EPA power saving, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2a	Different design scheme
5	Miscellaneous Features/Specifications			
5.1	Calibration tools	Beacon Monitor Manage/ Calibration Feedback System	QA Medivisor/ Medivisor NXF-CAL	Different design scheme
5.2	Sensors	Built-in Front Sensor Built-in Ambient Light Sensor Built-in Backlight Sensor	Built-in Front Sensor Built-in Ambient Light Sensor	Different design scheme
5.3	USB Ports/Standard	2 upstream, 4 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
5.4	Dimensions with stand (W x H x D)	360.5 x 513.49/613.49 x 224 mm	361.5 x 517/612 x 196.5 mm	Different housing design due to the different panel size

Table 3 General Comparison of G510S, MB5MP

ID	Comparison Item	Proposed Device 5MP Monochrome LCD Monitors G510S, MB5MP	Predicate Device 5MP Monochrome LCD Monitor MS-S500	Explanation of Differences
2	Display Performance/Specifications			
2.1	Screen Technology	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
2.2	Viewing angle (H, V)	CR>10 Horizontal: Typ.178 Vertical: Typ.178	CR>50 Horizontal: Typ.178 Vertical: Typ.178	Different screen provided by the different manufacturer
2.3	Resolution or matrix size	5MP (2560 X 2048)	5MP (2048 X 2560)	-
2.4	Aspect ratio	5: 4	4:5	-
2.5	Display Area	Horizontal: 422.4mm Vertical: 337.92mm	Horizontal: 337.92mm Vertical: 422.4mm	-
2.6	Pixel pitch	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	-
2.7	Response Time (Typ.)	25ms (On/Off)	25ms (On/Off)	-
2.8	Maximum luminance	Min. 2,400cd/m ² Typ. 3,000cd/m ²	Min. 2,400cd/m ² Typ. 3,000cd/m ²	-
2.9	DICOM calibrated luminance	450cd/m ²	1,000cd/m ²	Difference complies the DICOM 3.14.

2.10	Contrast ratio	Min. 1600:1 Typ. 2000:1	Min. 1600:1 Typ. 2000:1	-
2.11	Backlighting	LED	LED	-
2.12	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 16,369 tones 8-bit (DVI): 256 from a palette of 16,369 tones	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.
2.13	Luminance non-uniformity compensation	-	Digital Uniformity Correction System	Different design scheme
3	Video Signals			
3.1	Input video signals	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	-
3.2	Scanning Frequency (H, V)	Landscape: Horizontal: 104.852KHz Vertical: 50Hz	Portrait: Horizontal: 129.1KHz Vertical: 50Hz Landscape: Horizontal: 103.5KHz Vertical: 50Hz	Different design scheme
3.3	Dot Clock	285.2 MHz	285 MHz	-
4	Power Related Specifications			

4.1	Power Requirements	DC 24V, 5.0A	AC 100-240V, 50/60Hz	Difference between built-in power supply and built-out power supply
4.2	Power Consumption / Save Mode	100W Less than 0.5W	80W Less than 1W	Compared with the predicate device, the proposed device consumes more power in the operating mode and less power in the power saving mode.
4.3	Power Management	VESA DPMS and EPA power saving, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2a	Different design scheme
5	Miscellaneous Features/Specifications			
5.1	Calibration tools	Beacon Monitor Manage/ Calibration Feedback System	QA Medivisor/ Medivisor NXF-CAL	Different design scheme
5.2	Sensors	Built-in Front Sensor Built-in Ambient Light Sensor Built-in backlight sensor	Built-in Front Sensor Built-in Ambient Light Sensor	Different design scheme
5.3	USB Ports/Standard	2 upstream, 4 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
5.4	Dimensions with stand (W x H x D)	360.5 x 513.49/613.49 x 224 mm	361.5 x 517/612 x 196.5 mm	Different housing design due to the different panel size

Table 4 General Comparison of C516S

ID	Comparison Item	Proposed Device 5MP Color LCD Monitors C516S	Predicate Device 5MP Color LCD Monitor CL-S500	Explanation of Differences
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2	Display Performance/Specifications			
2.1	Screen Technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
2.2	Viewing angle (H, V)	CR>10 Horizontal: Typ.178 Vertical: Typ.178	CR>50 Horizontal: Typ.178 Vertical: Typ.178	Different screen provided by the different manufacturer
2.3	Resolution or matrix size	5MP(2560 x 2048)	5MP(2048 X 2560)	-
2.4	Aspect ratio	5:4	4:5	-
2.5	Display area	Horizontal: 422.4mm Vertical: 337.92mm	Horizontal: 337.92mm Vertical: 422.4mm	-
2.6	Pixel pitch	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	-
2.7	Response time (Typ.)	25ms (On/Off)	25ms (On/Off)	-
2.8	Maximum luminance	Min. 920cd/m ² Typ. 1,150cd/m ²	Min. 920cd/m ² Typ. 1,150cd/m ²	-
2.9	DICOM calibrated luminance	450cd/m ²	500cd/m ²	Difference complies the DICOM 3.14.
2.10	Contrast ratio	Min. 1600:1 Typ. 2000:1	Min. 1600:1 Typ. 2000:1	-
2.11	Backlighting	LED	LED	-

2.12	Grayscale 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 16,369 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,369 tones	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.
2.13	Luminance non-uniformity compensation	-	Digital Uniformity Correction System	Different design scheme
3	Video Signals			
3.1	Input video signals	DVI-D x1 DisplayPort x2	DVI-D x1 DisplayPort x1	Different design scheme
3.2	Scanning Frequency (H, V)	Landscape: Horizontal: 104.852KHz Vertical: 50Hz	Portrait: Horizontal: 129.1KHz Vertical: 50Hz Landscape: Horizontal: 103.5KHz Vertical: 50Hz	Different design scheme
3.3	Dot Clock	285.2 MHz	285 MHz	-
4	Power Related Specifications			
4.1	Power Requirements	DC 24V, 5A	AC 100-240V, 50/60Hz	Difference between built-in power supply and built-out power supply

4.2	Power Consumption / Save Mode	100W Less than 0.5W	95W Less than 1W	Compared with the predicate device, the proposed device consumes more power in the operating mode and less power in the power saving mode.
4.3	Power Management	VESA DPMS and EPA power saving, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2a	Different design scheme
5	Miscellaneous Features/Specifications			
5.1	Calibration tools	Beacon Monitor Manage/ Calibration Feedback System	QA Medivisor/ Medivisor NXF-CAL	Different design scheme
5.2	Sensors	Built-in Front Sensor Built-in Ambient Light Sensor Built-in Backlight Sensor Built-in Presence Sensor Gravity Sensor	Built-in Front Sensor Built-in Ambient Light Sensor	Different design scheme
5.3	USB Ports/Standard	2 upstream, 4 downstream / Rev. 2.0 1 USB-A/ Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
5.4	Dimensions with stand (W x H x D)	360.5 x 513.49/613.49 x 224 mm	361.5 x 517/612 x 196.5 mm	Different housing design due to the different panel size

Table 5 General Comparison of G516S

ID	Comparison Item	Proposed Device 5MP Monochrome LCD Monitors G516S	Predicate Device 5MP Monochrome LCD Monitor MS-S500	Explanation of Differences
2	Display Performance/Specifications			
2.1	Screen Technology	TFT Monochrome LCD Panel (IPS)	TFT Monochrome LCD Panel (IPS)	-
2.2	Viewing angle (H, V)	CR>10 Horizontal: Typ.178 Vertical: Typ.178	CR>50 Horizontal: Typ.178 Vertical: Typ.178	Different screen provided by the different manufacturer
2.3	Resolution or matrix size	5MP (2560 X 2048)	5MP (2048 X 2560)	-
2.4	Aspect ratio	5: 4	4:5	-
2.5	Display Area	Horizontal: 422.4mm Vertical: 337.92mm	Horizontal: 337.92mm Vertical: 422.4mm	-
2.6	Pixel pitch	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	-
2.7	Response Time (Typ.)	25ms (On/Off)	25ms (On/Off)	-
2.8	Maximum luminance	Min. 2,400cd/m ² Typ. 3,000cd/m ²	Min. 2,400cd/m ² Typ. 3,000cd/m ²	-
2.9	DICOM calibrated luminance	450cd/m ²	1,000cd/m ²	Difference complies the DICOM 3.14.

2.10	Contrast ratio	Min. 1600:1 Typ. 2000:1	Min. 1600:1 Typ. 2000:1	-
2.11	Backlighting	LED	LED	-
2.12	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 16,369 tones 8-bit (DVI): 256 from a palette of 16,369 tones	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.
2.13	Luminance non-uniformity compensation	-	Digital Uniformity Correction System	Different design scheme
3	Video Signals			
3.1	Input video signals	DVI-D x1 DisplayPort x2	DVI-D x1 DisplayPort x1	-
3.2	Scanning Frequency (H, V)	Landscape: Horizontal: 104.852KHz Vertical: 50Hz	Portrait: Horizontal: 129.1KHz Vertical: 50Hz Landscape: Horizontal: 103.5KHz Vertical: 50Hz	Different design scheme
3.3	Dot Clock	285.2 MHz	285 MHz	-
4	Power Related Specifications			

4.1	Power Requirements	DC 24V, 5.0A	AC 100-240V, 50/60Hz	Difference between built-in power supply and built-out power supply
4.2	Power Consumption / Save Mode	100W Less than 0.5W	80W Less than 1W	Compared with the predicate device, the proposed device consumes more power in the operating mode and less power in the power saving mode.
4.3	Power Management	VESA DPMS and EPA power saving, DisplayPort 1.2	DVI DMPM, DisplayPort 1.2a	Different design scheme
5	Miscellaneous Features/Specifications			
5.1	Calibration tools	Beacon Monitor Manage/ Calibration Feedback System	QA Medivisor/ Medivisor NXF-CAL	Different design scheme
5.2	Sensors	Built-in Front Sensor Built-in Ambient Light Sensor Built-in Backlight Sensor Built-in Presence Sensor Gravity Sensor	Built-in Front Sensor Built-in Ambient Light Sensor	Different design scheme
5.3	USB Ports/Standard	2 upstream, 4 downstream / Rev. 2.0 1 USB-A/ Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
5.4	Dimensions with stand (W x H x D)	360.5 x 513.49/613.49 x 224 mm	361.5 x 517/612 x 196.5 mm	Different housing design due to the different panel size

The technological characteristics differences discussed above do not affect the safety and the effectiveness of the C510S, G510S, CB5MP, MB5MP, C516S, G516S.

8.3 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 C510S, G510S, CB5MP, MB5MP, C516S, G516S as below.

- Verify the conformance to DICOM GSDF in accordance with *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline).
- Measure the calibrated luminance according to the requirements of the "Luminance Response" test in 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.
- 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 TG-18.
- 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.

The test results showed that C510S, G510S, CB5MP, MB5MP, C516S, G516S are with display characteristics equivalent to those of the predicate devices, MS-S500, CL-S500 except some items, each of which was determined that it would not affect observer's performance.

No animal or clinical testing is needed for C510S, G510S, CB5MP, MB5MP, C516S, G516S.

9. Conclusion [21 CFR 807.92(b) (3)]

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Shenzhen Beacon Display Technology Co., Ltd. concludes that:

- The intended use of C510S, G510S, CB5MP, MB5MP, C516S, G516S is totally same as that of the predicate devices.
- The technological characteristics differences between C510S, G510S, CB5MP, MB5MP, C516S, G516S 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 C510S, G510S, CB5MP, MB5MP, C516S, G516S are equivalent to those of the predicate devices.