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

December 28, 2024

Re: K233119
Trade/Device Name: 8MP Color LCD Displays C811W, C811WT, PA27, PA27T
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: PZZ
Dated: September 27, 2023
Received: September 27, 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 and Part 809); 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,

Shyam Kalavar -S

Shyam Kalavar
Deputy Branch Chief
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
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.

510(k) Number *(if known)*
K233119

Device Name
8MP Color LCD Displays C811W, C811WT, PA27 and PA27T

Indications for Use *(Describe)*
8MP Color LCD Displays C811W, C811WT, PA27 and PA27T are intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide imaging scanners and viewed using IVD-labeled digital pathology image viewing software that have been validated for use with this device. They are an aid to the pathologist to review and interpret digital images of histopathology slides for primary diagnosis. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using 8MP Color LCD Displays C811W, C811WT, PA27 and PA27T. The displays are not intended for use with digital images from frozen section, cytology, or non-formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.

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

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

Dec. 27, 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: 8MP Color LCD Displays C811W, C811WT, PA27 and PA27T
- Common Name: 8MP Color LCD Display
- Classification Name: Digital Pathology Display
- Regulation Number: 21 CFR 864.3700
- Product code: PZZ
- Classification Panel: Pathology
- Device Class: II
- 510(k) Number: K233119

4. Identification of Predicate Device(s) [21 CFR 807.92(a) (3)]

The identified predicate within this submission is as follows:

Barco MDPC-8127, display used in Aperio GT 450 DX, referenced in 510(k) No. K232202 (Decision Date - 07/25/2023).

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

The C811WT, PA27T, C811W, PA27 are 8MP Color LCD Displays, specifically intended for review and interpretation of surgical pathology slides from IVD-labeled whole-slide imaging scanners that have been validated for use with the display.

The displays are equipped with a 27-inch color LCD panel with a fine pixel pitch. They use the latest generation of LED backlight panels. The built-in brightness stabilization control circuits make sure the brightness of these displays is stable in their life, so the products meet the demands of high precision medical imaging.

For C811WT, PA27T, C811W, PA27, the only difference is the capacitive touch screen.

C811WT, PA27T have the same capacitive touch screen. C811W, PA27 don't have a capacitive touch screen.

The difference between C811WT and PA27T is only different customers which results in the two models.

The difference between C811W and PA27 is only different customers which results in the two models.

Table 1: Differences between models

Model	Touch screen
C811WT	With touch screen
PA27T	
C811W	Without touch screen
PA27	

6. Intended Use [21 CFR 807.92(a)(5)]

8MP Color LCD Displays C811W, C811WT, PA27 and PA27T are intended for in vitro diagnostic use to display digital images of histopathology slides acquired from IVD-labeled whole-slide imaging scanners and viewed using IVD-labeled digital pathology image viewing software that have been validated for use with this device. They are an aid to the pathologist to review and interpret digital images of histopathology slides for primary diagnosis. It is the responsibility of the pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images using 8MP Color LCD Displays C811W, C811WT, PA27 and PA27T. The displays are not intended for use with digital images from frozen section, cytology, or non-formalin-fixed, paraffin embedded (non-FFPE) hematopathology specimens.

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

7.1 Comparison table of Technological Characteristics

Table 2: General Comparison of C811WT, PA27T

Attributes	**Proposed Device** **8MP Color LCD Display** (C811WT, PA27T)	**Predicate Device** **8MP Color LCD Display** Barco MDPC-8127	**Explanation of Difference**
Display Technology	TFT Color LCD Panel (AHVA)	TFT Color LCD Panel (IPS)	Both panels are from the same panel manufacturer and the same IPS like technology.
Screen size	684 mm (27")	684 mm (27")	-
Resolution	3840 x 2160 @ 60 Hz (16:9 aspect ratio)	3840 x 2160 @ 120 Hz (16:9 aspect ratio)	Different panel provided by the same manufacturer
Pixel pitch	0.15525 x 0.15525 mm	0.155 x 0.155 mm	-
Backlight type	LED	LED	-
Color Calibration	sRGB	sRGB	-
Calibrated luminance	500 cd/m^2	450 cd/m^2	Different display provided by the different manufacturer
Contrast Ratio (typical)	1000:1	1000:1	-
Display Interface	DVI-D x 1, HDMI x 1, DisplayPort x 1	DisplayPort x 2	Different design scheme.
Ambient light sensor	N/A	Yes	Different design scheme.
Touch screen technology	Capacitive touch screen	N/A	Different design scheme.
Calibration tools	Front sensor; Calibration Feedback System	Front sensor QAWeb	Different design scheme.

Table 3: General Comparison of C811W, PA27

Attributes	**Proposed Device** **8MP Color LCD Display** (C811W, PA27)	**Predicate Device** **8MP Color LCD Display** Barco MDPC-8127	**Explanation of Difference**
Display Technology	TFT Color LCD Panel (AHVA)	TFT Color LCD Panel (IPS)	Both panels are from the same panel manufacturer and the same IPS like technology.
Screen size	684 mm (27")	684 mm (27")	-
Resolution	3840 x 2160 @ 60 Hz (16:9 aspect ratio)	3840 x 2160 @ 120 Hz (16:9 aspect ratio)	Different panel provided by the same manufacturer
Pixel pitch	0.15525 x 0.15525 mm	0.155 x 0.155 mm	-
Backlight type	LED	LED	-
Color Calibration	sRGB	sRGB	-
Calibrated luminance	500 cd/m^2	450 cd/m^2	Different display provided by the different manufacturer
Contrast Ratio (typical)	1000:1	1000:1	-
Display Interface	DVI-D x 1, HDMI x 1, DisplayPort x 1	DisplayPort x 2	Different design scheme.
Ambient light sensor	N/A	Yes	Different design scheme.
Touch screen technology	N/A	N/A	-
Calibration tools	Front sensor; Calibration Feedback System	Front sensor; QAWeb	Different design scheme.

The technological characteristic differences discussed above do not affect the safety and the effectiveness of the C811WT, PA27T, C811W, PA27.

7.2 Performance Testing

According to FDA Guidance document titled “Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices Guidance for Industry and Food and Drug Administration Staff Document issued on: April 20, 2016” (TPA Guidance), Chapter IV (A) (11), the below-mentioned tests were performed on the proposed device and the predicate device to verify that the technical characteristics and performance of the proposed display are equivalent to the predicate device:

- User Controls
- Spatial Resolution
- Pixel defects
- Artifacts
- Temporal response
- Max and Min Luminance
- Grayscale
- Luminance Uniformity and Mura Test
- Stability of Luminance and Chromaticity with Temperature and Lifetime
- Bidirectional Reflection Distribution
- Gray Tracking
- Color Scale
- Color Gamut Volume

Test results are provided in the table below:

Table 4: C811W, C811WT, PA27 and PA27T Test Results

Test	Test Method/ Applicable Standards	C811W	C811WT	PA27	PA27T
1.User controls	2.1 Modified-Performance Modes, IDMS 1.03.	Luminance target, Maximum: 500 cd/m2 Display function: sRGB White point: D65 (6500K) Color space: sRGB 30 minutes of warm-up time	Luminance target, Maximum: 500 cd/m2 Display function: sRGB White point: D65 (6500K) Color space: sRGB 30 minutes of warm-up time	Luminance target, Maximum: 500 cd/m2 Display function: sRGB White point: D65 (6500K) Color space: sRGB 30 minutes of warm-up time	Luminance target, Maximum: 500 cd/m2 Display function: sRGB White point: D65 (6500K) Color space: sRGB 30 minutes of warm-up time
2.Spatial resolution	7.7 Effective Resolution, IDMS 1.03.	Vertical and Horizontal MTFs are 0.861 and 0.862 at Nyquist	Vertical and Horizontal MTFs are 0.877 and 0.885 at Nyquist	Vertical and Horizontal MTFs are 0.861 and 0.862 at Nyquist	Vertical and Horizontal MTFs are 0.877 and 0.885 at Nyquist

		frequency	frequency	frequency	frequency
3.Pixel defects (count and map)	7.6 Defective Pixels, IDMS 1.03.	Total number of bright and dark pixels <= 5	Total number of bright and dark pixels <= 5	Total number of bright and dark pixels <= 5	Total number of bright and dark pixels <= 5
4. Artifacts	10.4 Artifacts and Irregularities, IDMS 1.03.	Deviation <0.54%	Deviation <0.62%	Deviation <0.34%	Deviation <0.68%
5. Temporal response	10.2.3 Gray-to-Gray Response Time, IDMS 1.03.	Tmax:20.87ms Tmin:9.88ms	Tmax:20.09ms Tmin:3.84ms	Tmax:22.87ms Tmin:6.11ms	Tmax:22.09ms Tmin:3.56ms
6. Maximum, minimum luminance and calibrated luminance	2.4 Vantage-Point Suite of Measurement, IDMS 1.03.	Maximum:523.6cd/m^2 Minimum:0.501cd/m^2	Maximum:502.9cd/m^2 Minimum:0.4805cd/m^2	Maximum:510cd/m^2 Minimum:0.499cd/m^2	Maximum:502.6cd/m^2 Minimum:0.515cd/m^2
7. Grayscale	6.1 Grayscale, IDMS 1.03.	Maximum deviation:5.94 %	Maximum deviation:5.33 %	Maximum deviation:5.52%	Maximum deviation:6.07 %
8. Luminance uniformity and Mura test	8.1.2 Sampled Vantage-Point Uniformity, IDMS 1.03.	11.16% non-uniformity on 100% video level	6.89% non-uniformity on 100% video level	9% non-uniformity on 100% video level	9.26% non-uniformity on 100% video level
9. Stability of luminance and chromaticity response with temperature and lifetime	10.1 Warm-up time, IDMS 1.03.	Deviation from target luminance (500 cd/m^2): 0.48% Variations for chromaticity: < 0.55%	Deviation from target luminance (500 cd/m^2): 0.66% Variations for luminance and chromaticity: < 0.64% deviation	Deviation from target luminance (500 cd/m^2): 0.66%, Variations for chromaticity: < 0.3%	Deviation from target luminance (500 cd/m^2): 0.63% Variations for luminance and chromaticity: < 0.7% deviation
10.Bidirectional reflection distribution function	11.12 Diagnostic: Characterizing Hemisphere Uniformity, IDMS 1.03.	Specular reflection coefficient: 4.4%, Diffuse reflection coefficient: 0.92%:	Specular reflection coefficient: 4.19%, Diffuse reflection coefficient: 0.8%:	Specular reflection coefficient: 4.4%, Diffuse reflection coefficient: 0.92%:	Specular reflection coefficient: 4.19%, Diffuse reflection coefficient: 0.8%:
11. Gray Tracking	6.15 Gray-scale Color Changes, IDMS v1.03.	0.0006 Δu'v'	0.0016Δu'v':	0.0006 Δu'v'	0.0014Δu'v':
12. Color scale	6. Gray- and Color-Scale Measurement and 5.4 Color-Signal White, IDMS 1.03.	Maximum color error:<2ΔE Average color error:<1ΔE	Maximum color error:<2ΔE Average color error:<1ΔE	Maximum color error:<3ΔE Average color error:<2ΔE	Maximum color error:<3ΔE Average color error:<2ΔE

13. Color gamut volume	5.18 Volume-Color-Reproduction Capability, IDMS 1.03.	2D color gamut overlapped with sRGB:99.5%	2D color gamut overlapped with sRGB:99.6%	2D color gamut overlapped with sRGB:98.7%	2D color gamut overlapped with sRGB:99.6%

The test results showed that C811WT, PA27T, C811W, PA27 displays have equivalent characteristics and performance to the predicate device, MDPC-8127 except some items, which do not affect the safety and effectiveness of the device.

No animal or clinical testing is needed for C811WT, PA27T, C811W, PA27.

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:

- Device and predicate device have the same intended use.
- The technological characteristic differences from predicate device do not affect the safety and effectiveness, no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of 8MP Color LCD Displays are equivalent to the predicate device.

The tests have demonstrated that the proposed device is as safe and effective as the predicate device. Additionally, it has been demonstrated that the proposed device may be used for primary diagnosis in the following validated FDA-cleared WSI systems and digital pathology viewing software:

- Aperio GT 450 DX with Aperio WebViewer DX, cleared under K232202