August 27, 2020

Shenyang Torch-Bigtide Digital Technology Co., Ltd.
Fu Ailing
Document Engineer
No. 18-6B, Yaoyang Road, Huishan Economic Development Area, Shenbei New District
Shenyang, Liaoning 110164
China

Re: K201162
Trade/Device Name: Essence 55SP Large Monitor System
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-Ray Tube Display
Regulatory Class: Class II
Product Code: DXJ
Dated: July 22, 2020
Received: July 29, 2020

Dear Ms. Fu Ailing:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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

Jennifer Shih
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201162

Device Name
Essence 55SP Large Monitor System

Indications for Use *(Describe)*
The Essence 55SP Large Monitor System (Essence 55SP) is intended to be used by health care professionals to integrate the video output from various commercially-available instruments commonly used in a medical procedure laboratory into a single video display.

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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007_510 (k) Summary

510(k) Summary

[As required by 21 CFR 807.92]

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

April 15, 2020

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

Name of Sponsor: Shenyang Torch-Bigtide Digital Technology Co., Ltd.
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3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name/Model: Essence 55SP Large Monitor System (Essence 55SP)
Common Name: Essence 55SP Large Monitor System
Classification Name: Display, Cathode-Ray, Tube, Medical
Regulation Number: 21 CFR 870.2450
Product code: DXJ
Classification Panel: Cardiovascular
Device Class: II

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

The identified predicate within this submission is as follow:
Shenyang Torch-Bigtide Digital Technology Co., Ltd., Essence 55S Large Monitor System has been cleared by FDA through 510(k) No. K172969 (Decision Date - February 6, 2018).

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

The system consists of the following components:

- A 55” TFT color LCD Monitor: HL5501SP
- Video wall controller (AVS-540) (optional)
- Optical graphic extension module-fibres detachable (M1-201SA-TR) (optional)
- A common PC (optional)
- Cables (optional)

The Essence 55SP Large Monitor System is a large color LCD monitor for viewing images derived from several video sources on a single display and to rearrange these images to the situational requirements of the user. Thanks to the advantages of the large widescreen monitor, the data can be collected from the video sources using the optional video wall controller AVS-540 and fed into the large display via the DVI lines and / or DP.
DVI lines mean the assemblies consisting of DVI cable and related connectors; DP means the assembly consisting of DP cable and related connectors.

The optical graphic extension module M1-201SA-TR can be used to convert / transmit the video signal, and the common PC can be taken as a video device.

The difference between the Essence 55SP and the legally marketed device Essence 55S is additional glass. Essence 55S is without glass and Essence 55SP with glass, so Essence 55SP is named with the letter “P”.

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

Indications for Use:
The Essence 55SP Large Monitor System (Essence 55SP) is intended to be used by health care professionals to integrate the video output from various commercially -available instruments commonly used in a medical procedure laboratory into a single video display.

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

The Essence 55SP Large Monitor System (Essence 55SP) uses a color LCD panel employing In-Plane Switching (IPS) technology to allow wide viewing angles. It is used in landscape mode.

When the various video sources from medical and other devices are being collected, they are being fed into the large Display via the corresponding lines and / or DP. The optional optical graphic extension module can be used as an optional part of the system to convert / transmit the video signal, and the optional PC can be taken as a video device.

The Essence 55SP Large Monitor System (Essence 55SP) may be provided in different housing colors and with different logos. The cosmetic differences do not affect the function and performance of the system.

Panel Type	TFT Color LCD Panel (IPS)
Panel Size	139.7 cm / 55” (1, 397 mm diagonal)
Display Size (H x V)	1209.6 mm x 680.4 mm
Pixel Pitch	0.315 x 0.315 mm
Native Resolution	3840 x 2160 pixels
Display Colors	1.07 billion colors
Viewing Angle (H,V)	178^0, 178^0
Brightness (Typ.)	540 cd/m^2
Recommended Brightness for Calibration	400 cd/m^2
Brightness Uniformity	DIN V 6868-57
Contrast Ratio (Typ.)	1400:1
Response Time (Typ.)	18 ms
Scanning Frequency (H, V)	131.3 KHz, 59.5 – 60.5 Hz
Dot Clock	277 MHz
Input Terminals	DVI-D (dual link) x 2; DisplayPort x 2; DVI single link (HDMI) x 2
Power Requirements	100-240 VAC, 50/60 Hz, 3.2 - 1.2A
Power Consumption / Save Mode	300 W / Less than 40 W
Power Management	DVI DMPM
Sensor	Backlight Sensor x 3

Net Weight	49.5 + / - 2 Kg
Hole Spacing	VESA standard 400 x 400 mm
Degree of Protection	IP20
Operating Temperature	5℃ - 40℃
Storage Temperature	-20℃ - 70℃
Operating Humidity	20% to 80% rel. H., non condensing
Storage Humidity	10% to 95% rel. H., non condensing
Operating Pressure	700 hPa - 1060 hPa
Storage Pressure	700 hPa - 1060 hPa
Certifications and Standards*	CE: 93/42/EEC: Medical Device Directive Test Report CE Declaration CCC Certificate BIS Certificate - INDIA CB-Test Certificate: IEC 60601-1:2005 + A1:2012 (Ed. 3.1) CB-Test Report: IEC 60601-1:2005 + A1:2012 (Ed. 3.1) NRTL Certificate (US/C): ANSI/AAMI ES60601-1:2005/(R2012) + CAN/CSA C22.2-60601-1-14
Supplied Accessories	AC power cord
Optional accessories	● Video wall controller (AVS-540) ● Optical graphic extension module-fibres detachable (M1-201SA-TR) ● A common PC ● Cables ● CD (user's manual)
Warranty	Three years
Order No.	HL5501SP
Dimmensions (Unit:mm)	1287.2 x 761.2 x 86.3 mm

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

8.1 Intended uses:

Table 1 Intended Use Comparison

ID	Comparison Item	Proposed Device Essence 55SP Large Monitor System	Predicate Device Essence 55S Large Monitor System
1	Indications for Use	The Essence 55SP Large Monitor System (Essence 55SP) is intended to be used by health care professionals to integrate the video output from various commercially-available instruments commonly used in a medical procedure laboratory into a single video display.	The Essence 55S Large Monitor System (Essence 55S) is intended to be used by health care professionals to integrate the video output from various commercially-available instruments commonly used in a medical procedure laboratory into a single video display.

8.2 Comparison table

Table 2 General Comparison

ID	Comparison Item	Proposed Device Essence 55SP Large Monitor System	Predicate Device Essence 55S Large Monitor System	Explanation of Difference
2	**Display Performance/Specifications**			
2.1	Cabinet Color	Black Grey	Black Grey	-
2.2	Panel Type	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
2.3	Panel Size	139.7 cm / 55” (1, 397 mm diagonal)	139.7 cm / 55” (1, 397 mm diagonal)	-
2.4	Display Size (H x V)	1209.6 mm x 680.4 mm	1209.6 mm x 680.4 mm	-
2.5	Pixel Pitch	0.315 x 0.315 mm	0.315 x 0.315 mm	-

2.6	Native Resolution	3840 x 2160 pixels	3840 x 2160 pixels	-
2.7	Display Colors	1.07 billion colors	1.07 billion colors	-
2.8	Viewing Angle (H,V)	$178^{0,}$ 178^{0}	$178^{0,}$ 178^{0}	-
2.9	Brightness (Typ.)	540 cd/m^2	560 cd/m^2	The same screen is used, but 55SP is with additional glass.
2.10	Recommended Brightness for Calibration	400 cd/m^2	400 cd/m^2	-
2.11	Brightness Uniformity	DIN V 6868-57	DIN V 6868-57	-
2.12	Contrast Ratio (Typ.)	1400:1	1400:1	-
2.13	Response Time	6.5 ms (Midtone)	6.5 ms (Midtone)	-
3	**Video Signal Input**			
3.1	Scanning Frequency (H, V)	131.3 KHz, 59.5 – 60.5 Hz	131.3 KHz, 59.5 – 60.5 Hz	-
3.2	Dot Clock	277 MHz	257.4 MHz	EDID is changed, which does not raise any new issue of substantial equivalence.
3.3	Input Terminals	DVI-D (dual link) x 2; DisplayPort x 2; DVI single link (HDMI) x 2	DVI-D (dual link) x 2; DisplayPort x 2; DVI single link (HDMI) x 2	-
4	**Power Related Specifications**			
4.1	Power Requirements	AC 100-240 V, 50 / 60Hz, 3.2 - 1.2A	AC 100-240 V, 50 / 60Hz, 3.2 - 1.2A	-
4.2	Power Consumption / Save Mode	300 W / Less than 40 W	300 W / Less than 40 W	-
4.3	Power Management	DVI DMPM	DVI DMPM	-
5	**Miscellaneous Features/Specifications**			
5.1	Sensor	Backlight Sensor x 3	Backlight Sensor x 3	-

5.2	Net Weight	49.5 + / - 2 Kg	38 + / - 1 Kg	The 55SP is with additional glass.
5.3	Hole Spacing	VESA standard 400 x 400 mm	VESA standard 400 x 400 mm	-
5.4	Supplied Accessories	AC power cord, CD (user' manual)	AC power cord, CD (user' manual)	-
5.5	Optional accessories	Video wall controller (AVS-540), Optical graphic extension module-fibres detachable (M1-201SA-TR), a common PC, Cables	Video wall controller (AVS-540), Optical graphic extension module-fibres detachable (M1-201SA-TR), a common PC, Cables	-
5.6	Order No.	HL5501SP	HL5501S	Different coding rule
5.7	Dimmensions (Unit:mm)	1287.2 x 761.2 x 86.3 mm	1287.2 x 761 x 85.6 mm	The 55SP is with additional glass.

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the Essence 55SP.

8.3 Performance Testing

The following tests were successfully performed to validate the Essence 55SP Large Monitor System.

- Display bench tests
- Display validation tests
- System tests

The test results showed that the Essence 55SP Large Monitor System is with display characteristics equivalent to those of the predicate device, Essence 55S Large Monitor System except some items, each of which was determined that it would not affect observer's performance.

No animal or clinical testing is needed for the Essence 55SP.

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, Shenyang Torch-Bigtide Digital Technology Co., Ltd. concludes that:

- The intended use of Essence 55SP Large Monitor System (Essence 55SP) is totally same as that of the predicate device.
- The technological characteristics differences between 55SP Large Monitor System and 55S Large Monitor System do not raise different questions of safety and effectiveness.
- Demonstrated by the bench tests, the display characteristics of Essence 55SP Large Monitor System are substantially equivalent to those of the predicate device.