February 6, 2018

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

Re: K172969
Trade/Device Name: Essence 55S Large Monitor System
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical cathode-ray tube display
Regulatory Class: Class II
Product Code: DXJ
Dated: December 12, 2017
Received: December 20, 2017

Dear Fu Ailing:

This letter corrects our substantially equivalent letter of January 26, 2018.

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172969

Device Name

Essence 55S Large Monitor System

Indications for Use *(Describe)*

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.

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

[As required by 21 CFR 807.92]

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

August 9, 2017

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 55S Large Monitor System
Common Name: Essence 55S 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 predicates within this submission are as follows:

Eizo GmbH Siemensallee 84, D-76187 Karlsruhe, Germany, RadiForce Large Monitor System has been cleared by FDA through 510(k) No. K112645 (Decision Date - September 22, 2011).

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

The system consists of the following components:

- A 55” TFT color LCD Monitor: HL5501S
- Video wall controller (AVS-540) (optional)
- Optical graphic extension module-fibres detachable (M1-201SA-TR) (optional)
- A common PC (optional)
- Cables (optional)

The Essence 55S 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.

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.

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

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.

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

The Essence 55S Large Monitor System (Essence 55S) 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 55S Large Monitor System (Essence 55S) 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.)	560 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.)	6.5 ms (Midtone)
Scanning Frequency (H, V)	131.3 KHz, 59.5 – 60.5 Hz
Dot Clock	257.4 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 -1.2 A
Power Consumption / Save Mode	300 W / Less than 40 W
Power Management	DVI DMPM

Sensor	Backlight Sensor x 3
Net Weight	38 + / - 1 Kg
Hole Spacing	VESA standard 400 x 400 mm
Degree of Protection	IP20
Operating Temperature	0℃- 40℃（+32 to + 104 ℉）
Storage Temperature	-20℃- 60℃（+4 to +140 ℉）
Operating Humidity	15% to 85% rel. H., non condensing
Storage Humidity	10% to 90% rel. H., non condensing
Operating Pressure	700 hPa - 1060 hPa
Storage Pressure	700 hPa - 1060 hPa
Certifications and Standards*	CE(Medical Device Directive), EN60601-1, ANSI/AAMI ES60601-1, CSA C22.2 No. 601-1, FCC-B, RoHS, China RoHS, CCC
Supplied Accessories	AC power cord, CD (user's manual)
Optional accessories	● Video wall controller (AVS-540) ● Optical graphic extension module-fibres detachable (M1-201SA-TR) ● A common PC ● Cables
Warranty	Three years
Order No.	HL5501S
Dimmensions (Unit:mm)	1287.2 x 761 x 85.6 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 55S Large Monitor System	Predicate Device RadiForce Large Monitor System
1	Intended Use	The Essence 55S Large Monitor System (Essence 55S) is intended to be used by health	The RadiForce Large Monitor System is intended to be used by health care professionals to

		care professionals to integrate the video output from various commercially-available instruments commonly used in a medical procedure laboratory into a single video display.	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 55S Large Monitor System	Predicate Device RadiForce Large Monitor System	Explanation of Difference
2	**Display Performance/Specifications**			
2.1	Cabinet Color	Black Grey	Anthracite Gray	Different design scheme
2.2	Panel Type	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (MVA)	Different screen
2.3	Panel Size	139.7 cm / 55” (1, 397 mm diagonal)	143 cm / 56.2” (1, 430 mm diagonal)	Different screen
2.4	Display Size (H x V)	1209.6 mm x 680.4 mm	1244 x 700 mm	Different screen
2.5	Pixel Pitch	0.315 x 0.315 mm	0.324 x 0.324 mm	Different screen
2.6	Native Resolution	3840 x 2160 pixels	3840 x 2160 (16:9 aspect ration)	–
2.7	Display Colors	1.07 billion colors	16.77 million colors	Different screen
2.8	Viewing Angle (H,V)	178^0, 178^0	176^0, 176^0	Different screen
2.9	Brightness (Typ.)	560 cd/m^2	450 cd/m^2	Different screen
2.10	Recommended Brightness for Calibration	400 cd/m^2	300 cd/m^2	Different screen

2.11	Brightness Uniformity	DIN V 6868-57	DIN V 6868-57	_
2.12	Contrast Ratio (Typ.)	1400:1	1200:1	Different screen
2.13	Response Time (Typ.)	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, 59.7-60.3 Hz	–
3.2	Dot Clock	257.4 MHz	257 MHz	_
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	Different design scheme
4	**Power Related Specifications**			
4.1	Power Requirements	AC 100-240 V, 50 / 60Hz, 3.2 - 1.2A	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	Different design scheme
4.2	Power Consumption / Save Mode	300 W / Less than 40 W	500 W / Less than 41 W	Different design scheme
4.3	Power Management	DVI DMPM	DVI DMPM	_
5	**Miscellaneous Features/Specifications**			
5.1	Sensor	Backlight Sensor x 3	Backlight Sensor x 2	Different design scheme
5.2	Net Weight	38 + / - 1 Kg	48.2 + / - 1.8 kg	Different design scheme
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, dual link signal cable (DVI-D ~ DVI-D), Utility Disk (user's manual)	Determined by customers' requirements
5.5	Optional accessories	Video wall controller (AVS-540), Optical graphic extension module-fibres detachable (M1-201SA-TR), a common PC,	Large Monitor Manager LMM56800 /LMM0802, cable DVI~HDMI, adapter DVI~HDMI, Analog ~DVI converter PDC0100, DVI Transmission Link	Determined by customers' requirements

		Cables	TDL3600-QL (Quad Link)	
5.6	Order No.	HL5501S	6GF6200-8AA01 (LS560W without Stand)	Different coding rule
5.7	Dimmensions (Unit:mm)	1287.2 x 761 x 85.6 mm	1319 x 776 x 146 mm	Different housing design due to the different panel size

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

8.3 Performance Testing

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

- Display bench tests
- Display validation tests
- System tests

The test results showed that the Essence 55S Large Monitor System is with display characteristics equivalent to those of the predicate device, RadiForce 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 55S.

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 55S Large Monitor System (Essence 55S) is totally same as that of the predicate device.
- The technological characteristics differences between 55S Large Monitor System and RadiForce Large Monitor System do not affect the safety and effectiveness, no new risk is raised.
- Demonstrated by the bench tests, the display characteristics of Essence 55S

Large Monitor System are equivalent to those of the predicate device.