Qingdao Hisense Medical Equipment Co., Ltd.
℅ Lu Zhonghao
Quality Engineer
No. 399 Songling Road, Laoshan District
Qingdao, Shandong, 266100
CHINA

November 17, 2022

Re: K222208
Trade/Device Name: Hisense LCD monitor HMD2C21A, HMD4C27S, HMD6C30D
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: October 7, 2022
Received: October 18, 2022

Dear Lu Zhonghao:

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 and Part 809); 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,

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

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)*

K222208

Device Name Hisense
LCD monitor(HMD2C21A,HMD4C27S,HMD6C30D)

Indications for Use *(Describe)*

These products are intended to be used in displaying radiological images for review, analysis and diagnosis by trained medical practitioners. They do not support the display of mammography images for diagnosis.

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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Section5: 510(k) Summary

(K222208)

1. In accordance with 21 CFR 807.92 the following summary of information is provided:

<table>
<tr><td>Date</td><td>Oct. 7, 2022</td></tr>
<tr><td>Submitter</td><td>Qingdao Hisense Medical Equipment Co.,Ltd.
Address: No. 399 Songling Road, Laoshan District 266100, Qingdao, Shandong, P. R. China</td></tr>
<tr><td>Contact Person:</td><td>Primary Contact Person
Lu zhonghao
Quality Engineer
Qingdao Hisense Medical Equipment Co. Ltd.
Mail:luzhonghao@hisense.com
Tel: +86-532-83091111
Fax:+86-532-83091111
Secondary Contact Person
Wu yalan
RA Manager
Qingdao Hisense Medical Equipment Co. Ltd.
Mail: wuyalan@hisense.com
Tel: +86-532-83091111
Fax:+86-532-83091111</td></tr>
<tr><td>Device Trade Name:</td><td>Hisense LCD monitor HMD2C21A, HMD4C27S, HMD6C30D</td></tr>
<tr><td>Common/Usual Name:</td><td>2M/4M/6M Color LCD monitor</td></tr>
<tr><td>Classification Name:</td><td>Display, Diagnostic Radiology 21CFR 892.2050</td></tr>
<tr><td>Product Code:</td><td>PGY</td></tr>
<tr><td>Predicate Device(s):</td><td>
<table>
<tr><th>No.</th><th>Trade Name</th><th>510(k) Number</th><th>Product Code</th><th>Manufacturer</th></tr>
<tr><td>1</td><td>JUSHA-C 270G</td><td>K183498</td><td>PGY</td><td>Nanjing Jusha Display Technology Co., Ltd</td></tr>
<tr><td>2</td><td>C44W+</td><td>K202374</td><td>PGY</td><td>shenzhen Beacon Display Technology Co., Ltd.</td></tr>
<tr><td>3</td><td>RadiForce RX660</td><td>K163335</td><td>PGY</td><td>EIZO Corporation</td></tr>
</table>
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Device Description:	The Hisense LCD monitors are intended for trained medical practitioners and provides the image viewing and medical diagnostic functions. HMD2C21A, HMD4C27S, HMD6C30D are developed with different resolution:1600 x 1200, 2560 x 1440, 3280 × 2080. So the LCD monitors can be used in different environment according to different resolution requirement. The three models also developed with same features such as energy saving, ambient light induction, front-facing sensor calibration, etc. In particular, HMD4C27S, HMD6C30D have body-inductive energy-saving and auto awake function. The Hisense LCD monitor complies with standards as following: 1. EN 60601-1:2006+A1:2013+A12:2014 & IEC60601-1:2005+CORR.1:2006+CORR.2:2007 +AM1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance 2. IEC 60601-1-2:2014 & EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests.
Intended Use:	These products are intended to be used in displaying radiological images for review, analysis and diagnosis by trained medical practitioners. They do not support the display of mammography images for diagnosis.
Technology:	1)HMD2C21A is a 2M color LCD diagnostic monitor. It strictly complies with the DICOM standard and has the features of high-resolution, high-brightness display. It uses OSD menu software, monitor control software, and quality control software to achieve functional stability. 2) HMD4S27S is a 4M color, one-screen and dual-display diagnostic monitor. It strictly complies

	with the DICOM standard and integrates the functions of image browsing, reading and writing clinical reports, etc. It uses OSD menu software, monitor control software, and quality control software to achieve functional stability. 3)HMD6C30D is a 6M color, one-screen and dual-display diagnostic monitor. The built-in DICOM standard LUT ensures the long-term stability and consistency of the display, and truly restores the original information of the image. It uses OSD menu software, monitor control software, and quality control software to achieve functional stability.
Determination of Substantial Equivalence:	**Summary of Non-Clinical Tests:** The Hisense LCD monitor (HMD2C21A, HMD4C27S, HMD6C30D) complies with standards as following: 1. EN 60601-1:2006+A1:2013+A12:2014 & IEC60601-1:2005+CORR.1:2006+CORR.2:2007 +AM1:2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance 2. IEC 60601-1-2:2014 & EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests. The Hisense LCD monitor HMD2C21A, HMD4C27S, HMD6C30D are substantially equivalent to JUSHA-C270G, C44W+, RadiForce RX660. They have equivalent characteristics and functions according to comparison table, please refer to ***2. Product Comparison*** The following quality assurance measures were applied to the development of the system: ·Electrical Safety & EMC test ·Performance test

	·Risk Management & Analysis ·Design Reviews ·Raw materials verification ·Final acceptance test ·etc. **Summary of Clinical Tests:** The subject of this premarket submission, Hisense LCD monitor, don't require clinical studies to support substantial equivalence. The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device. Therefore, the subject device is determined as safe and effectiveness.
Conclusion	Qingdao Hisense Medical Equipment Co., Ltd. Considers the Hisense HMD2C21A, HMD4C27S and HMD6C30D LCD monitor to be as safe, as effective, and performance is substantially equivalent to the predicate devices.

2 Product Comparison

This comparison identifies the similarities and differences of the proposed HMD2 C21A, HMD4C27S and HMD6C30D LCD monitor device to the legally marketed predicate JUSHA-C270G, C44W+ and RadiForce RX660 LCD Monitor.

2.1 HMD2C21A and its predicate

Tabel1 HMD2C21A Detailed Comparison with Predicate

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K183498
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd
	Device type/model	HMD2C21A	JUSHA-C270G
1.Display Performance/Specifications			
1.1	Screen size	21,3 inches (540 mm)	21.3"
1.2	Screen Technology	Color LCD panel (IPS)	Color TFT LCD Panel
1.3	Viewing Angle	Horizontal: 178°; vertical: 178° (CR ≥ 10)	Horizontal 178°,Vertical 178°
1.4	Pixel array	1600 pixels (H) x 1200 pixels (V)	1600 x 1200/1200 x 1600

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K183498
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd
	Device type/model	HMD2C21A	JUSHA-C270G
1.5	Display Area	432 (H) x 324 (V) (mm)	432.0 (H) x 324.0(V) mm
1.6	Pixel Pitch	0.270 (H) x 0.270 (V) (mm)	0.270x0.270 mm
1.7	Subpixel driving	Not Applicable	Not Applicable
1.8	Contrast Ratio	1800:1 (typ.)	1400:1
1.9	Frame rate	60Hz	37.9~75kHz;60Hz
1.10	Maximum Brightness(typ)	1000 cd/m^2	1000cd/m^2
1.11	Recommended brightness	400cd/m^2	350cd/m^2
1.12	Backlight type	LED	LED
1.13	Ambient light sensing	Built-in ambient light sensor	Ambient luminance self-adaptation(ABA)
1.14	Response Time	16 ms (typ.)	16 ms(8ms+8ms)
1.15	Aspect Ratio	4:3	4:3
1.16	Luminance calibration	Front-facing sensor Upper Computer Software	Built in calibration sensor provided
1.17	Touch-screen	Not Applicable	Not Applicable
2.Video Signals			
2.1	Input Video Signal	DVI-D x 1 DisplayPort x 1	DVI-D x 1, DisplayPort x 1
2.2	Output Signal	DisplayPort x 1	DisplayPort x1
2.3	Video bandwidth	DVI: 215MHz DisplayPort : 215MHz	DVI: 215MHz DisplayPort : 215MHz
3.Power Related Specification			
3.1	Power Requirements	24 V DC, 1.9A	DC 24V
3.2	Power Consumption/ save mode	45.6W/Below 1W	50W/less than 0.5W
3.3	Power Management	DVI DMPM DisplayPort 1.2a	DVI DMPM DisplayPort 1.1a
4.Miscellaneous Features/Specifications			

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K183498
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd
	Device type/model	HMD2C21A	JUSHA-C270G
4.1	USB ports	1 uplink port and 2 downlink ports/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0
4.2	Display color	10bit	16-bit
4.3	User controls	Off the shelf	Off the shelf
4.4	Software/Firmware:	Built-in embedded software	Built-in embedded software
4.5	Dimensions w/o stand (W x H x D)	Without base:384 mm x 492 mm x 70mm With base:384 mm x 517.5-637.5 mm x 273.5 mm	Without stand: 382mm x490mm x77mm With stand: 382mm x635mm x238mm
4.6	Net weight	4.3 kg (excluding the base)	7.5 kg(without stand)
4.7	VESA standard	100 x 100 (mm)	100 x 100 (mm)
5. Intended use			
5.1	Indication for use	This product is intended to be used in displaying radiological images for review, analysis and diagnosis by trained medical practitioners. The product does not support the display of mammography images for diagnosis.	JUSHA-C270G LCD Monitor is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device does not support the display of mammography images for diagnosis.
6 Applicable standard			
6.1	Applicable standard	Compliance with IEC 60601-1 Compliance with IEC 60601-1-2	Compliance with IEC 60601-1 Compliance with IEC 60601-1-2

2.2 HMD4C27S and its predicate

Tabel2 HMD4C27S Detailed Comparison with Predicate

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K202374
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	shenzhen Beacon Display Technology Co., Ltd.
	Device type/model	HMD4C27S	C44W+
1.Display Performance/Specifications			
1.1	Screen size	27-inch	772 mm (30.4")
1.2	Screen Technology	Color LCD panel (IPS)	TFT LCD panel
1.3	Viewing Angle	Horizontal: 178°; vertical: 178° (CR ≥ 10:1) (typ.)	H:178°, V:178°, (CR＞10)
1.4	Pixel array	2560 x 1440	4MP(2560 x 1600)
1.5	Display Area	596.74 (H) x 335.66 (V) (mm)	641.28 (H) x 400.8 (V) mm
1.6	Pixel Pitch	0.2331 x0. 2331 (mm)	0.2505 x 0.2505 mm
1.7	Subpixel driving	Not Applicable	Not Applicable
1.8	Contrast Ratio	1000:1 (typ.)	1000:1
1.9	Frame rate / refresh rate	49-76Hz,71.3~112.6kH	31~140kHz，29-60Hz
1.10	Maximum Brightness(typ)	550cd/m^2	700cd/m^2
1.11	Recommended brightness	400 cd/m^2	500cd/m^2
1.12	Backlight type	LED	LED
1.13	Ambient light sensing	Built-in ambient light sensor	Yes
1.14	Response Time	16 ms (typ.)	6ms
1.15	Aspect Ratio	16:10	16:10
1.16	Luminance non-uniformity compensation	Not Applicable	Not Applicable
1.17	Touch-screen	Not Applicable	Not Applicable
2.Video Signals			
2.1	Input Video Signal	DVI-D x 2 DisplayPort x 2 HDMI	DVI-D x 2 DisplayPort x 2 VGA×1
2.2	Output Signal	DisplayPort	NA

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K202374
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	shenzhen Beacon Display Technology Co., Ltd.
	Device type/model	HMD4C27S	C44W+
2.3	Video bandwidth	DVI: 215MHz DisplayPort : 215MHz	DVI: 215MHz DisplayPort : 215MHz
3.Power Related Specification			
3.1	Power Requirements	24 V DC, 6.25A	DC 24 V/9A
3.2	Power Consumption/ save mode	70W/Below 0.5W	80W/ less than 5W
3.3	Power Management	DVI DMPM DisplayPort 1.2a	DVI DMPM, DisplayPort 1.2a
4.Miscellaneous Features/Specifications			
4.1	USB ports	1 uplink port and 2 downlink ports/ Rev. 2.0	1 upstream 2downstream/ Rev. 2.0
4.2	Display color	8bit	10-bit, 1,073,741,824color
4.3	Software/Firmware:	Built-in embedded software	Built-in embedded software
4.4	Dimensions w/o stand (W x H x D)	Without base:653.8 mm x 520mm x 60mm With base: 653.8 mm x 400mm x 60 mm	699.3 x513-633 x251.4mm Without packing 864 x600 x334mm(with packing)
4.5	Net weight	8.5 kg (excluding the base)	13±0.5kg(wet)
4.6	VESA standard	100 x 100 (mm)	VESA (100 mm)
5. Intended use			
5.1	Indication for use	This product is intended to be used in displaying radiological images for review, analysis and diagnosis by trained medical practitioners. The product does not support the display of mammography	These products are intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. They do not support the displaying of mammography

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K202374
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	shenzhen Beacon Display Technology Co., Ltd.
	Device type/model	HMD4C27S	C44W+
		images for diagnosis.	images for diagnosis.
6 Applicable standard			
6.1	Applicable standard	Compliance with IEC 60601-1 Compliance with IEC 60601-1-2	Compliance with IEC 60601-1 Compliance with IEC 60601-1-2

3.2 HMD6C30D and its predicate

Tabel3 HMD6C30D Detailed Comparison with Predicate

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K163335
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	EIZO Corporation
	Device type/model	HMD6C30D	RadiForce RX660
1.Display Performance/Specifications			
1.1	Screen size	30 inches	30"
1.2	Screen Technology	Color LCD panel (IPS)	IPS
1.3	Viewing Angle	Horizontal: 178°; vertical: 178° (CR ≥ 10)	H: 176°, V: 176°
1.4	Pixel array	3280 × 2080	6MP (3,280 x 2,048)
1.5	Display Area	645.504 (H) × 409.344 (V) (mm)	645.5 mm x 403.0 mm
1.6	Pixel Pitch	0.197 (H) x 0.197 (V) (mm)	0.1968 mm x 0.1968 mm
1.7	Subpixel driving	Not Applicable	Not Applicable
1.8	Contrast Ratio	2000:1 (typ.)	1500:1
1.9	Frame rate	48-62Hz	31 - 127 kHz / 22 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 – 30.5 Hz, 59 - 61 Hz
1.10	Maximum Brightness(typ)	1300cd/m^2	1000 cd/m^2
1.11	Recommended	400 cd/m^2	500 cd/m^2

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K163335
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	EIZO Corporation
	Device type/model	HMD6C30D	RadiForce RX660
	brightness		
1.12	Backlight type	LED	LED
1.13	Ambient light sensing	Built-in ambient light sensor	Yes
1.14	Response Time	30 ms (typ.)	25ms
1.15	Aspect Ratio	16:10	16:10
1.16	Luminance non-uniformity compensation	NA	Digital Uniformity Equalizer
1.17	Touch-screen	Not Applicable	Not Applicable
2.Video Signals			
2.1	Input Video Signal	DVI-D x 2, DisplayPort x 2, HDMI x 1	DVI-D (dual link) x 1, DisplayPort x 2
2.2	Output Signal	DisplayPort connector	DisplayPort x 1 (daisy chain
2.3	Video bandwidth	DVI: 215MHz DisplayPort : 215MHz	DVI: 215MHz DisplayPort : 215MHz
3.Power Related Specification			
3.1	Power Requirements	24 V DC, 6.25 A	AC 100 - 240 V: 50 / 60 Hz
3.2	Power Consumption/ save mode	150W/Below 0.5W	190 W / Less than 1.6 W
3.3	Power Management	DVI DMPM DisplayPort 1.2a	DVI DMPM, DisplayPort 1.2a
4.Miscellaneous Features/Specifications			
4.1	USB ports	1 uplink port and 2 downlink ports/ Rev. 2.0	2 upstream, 3 downstream / Rev. 2.0
4.2	Display color	10bit	10-bit
4.3	Software/Firmware:	Built-in embedded software	Built-in embedded software

ID	Elements of Comparison	Proposed device	Predicate Device
	510(k) Number	K222208	K163335
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	EIZO Corporation
	Device type/model	HMD6C30D	RadiForce RX660
4.4	Dimensions w/o stand (W x H x D)	Without base:700 mm x 478mm x 68mm With base:700 mm x 516-626 mm x 274 mm	682.5 x 441 x 88 mm
4.5	Net weight	17.1 kg (excluding the base)	10.1kg(without stand)
4.6	VESA standard	100 x 100 (mm)	100 x 100 (mm)
5. Intended use			
5.1	Indication for use	This product is intended to be used in displaying radiological images for review, analysis and diagnosis by trained medical practitioners. The product does not support the display of mammography images for diagnosis.	The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.
6 Applicable standard			
6.1	Applicable standard	Compliance with IEC 60601-1 Compliance with IEC 60601-1-2	Compliance with IEC 60601-1 Compliance with IEC 60601-1-2

3.Performance data

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

3.1Bench testing:

The bench tests were performed on the proposed devices HMD2C21A, HMD4C27S, HMD6C30D in accordance with Assessment of Display Performance for Medical Imaging Systems by AAPM Task Group 18 (TG18 guideline). Bench testing was conducted to demonstrate the HMD2C21A, HMD4C27S, HMD6C30D meets all performance standards as follows:

Table4 Bench test

Measurements Guidance	Recommended for Non-mammography Display Submissions	HMD2C21A, HMD4C27S,HMD6C30D Measurements
a. Spatial resolution	Yes	Measure Spatial resolution with TG18 Resolution
b. Pixel defects (maximum counts, allowed defect types, and locations)	Yes	Measure Pixel defects with TG18
c. Artifacts	Yes (Limited)	Measure Artifacts with TG18
d. Temporal response	Yes	Measure Temporal response with TG18
e. Luminance (maximum, minimum, achievable, and recommended)	Yes	Measure Luminance with TG18
f. Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF)	Yes	Measure Conformance to a grayscale-to-luminance function with TG18
g. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and four corners	No	-
h. Luminance uniformity or Mura test	No	-
i. Stability of luminance and chromaticity response with temperature and time of operation or on-time	No	-
j. Spatial noise	No	-
k. Reflection coefficient	No	-
l. Veiling glare or small-spot contrast	No	-
m. Color tracking (primary colors and color gamut)	Yes	Measure Color tracking with TG18
n. Gray tracking (gray shades and white point)	No	-

3.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the HMD2C21A, HMD4C27S, HMD6C30D. The devices comply with the IEC 60601-1 standard for safety and the IEC 60601-1-2 standard for EMC.

3.3 Animal and clinical study

The subject of this premarket submission, Hisense LCD monitor HMD2C21A, HMD4C27S, HMD6C30D do not require animal or clinical studies to support substantial equivalence.

4. Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, Qingdao Hisense Medical Equipment Co., Ltd. concludes that:

- The intended uses of proposed devices (HMD2C21A, HMD4C27S, HMD6 C30D) are equivalent to the predicate devices.
- The technological characteristics differences between proposed devices (HMD2C21A, HMD4C27S, HMD6C30D) 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 proposed devices (HMD2C21A, HMD4C27S, HMD6C30D) are equivalent to those of the predicate devices.