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

Re: K222132 November 8, 2022
Trade/Device Name: Hisense LCD monitor (HMD2G21S, HMD3G21S)
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 14, 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); 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)*
K222132

Device Name
LCD Monitor(HMD2G21S,HMD3G21S)

Indications for Use *(Describe)*
1) The 2MP Monochrome LCD Monitor HMD2G21S 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.

2)The 3MP Monochrome LCD Monitor HMD3G21S is intended to be used in displaying and viewing digital images for diagnosis X-ray or MRI, etc. by trained medical practitioners.
The device does 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

LCD monitor

Section5: 510(k) Summary

(K222132)

1. Applicant information

Date	Oct. 7, 2022
Submitter	Qingdao Hisense Medical Equipment Co.,Ltd. Address: No. 399 Songling Road, Laoshan District 266100, Qingdao, Shandong, P. R. China
Contact Person:	**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: Wu yalan@hisense.com Tel: +86-532-83091111 Fax:+86-532-83091111

2.Device information

Device Trade Name:	Hisense LCD monitor HMD2G21S,HMD3G21S
Common/Usual Name:	2M/3M Monochrome LCD Monitor
Classification	II
Classification Name:	Display, Diagnostic Radiology 21CFR 892.2050
Product Code:	PGY

3. Predicate Device(s):

Trade Name	JUSHA-M260G LCD Monitor
510(k) Number	K183497
Product Code	PGY
Manufacturer	Nanjing Jusha Display Technology Co., Ltd

Trade Name	JUSHA-M33C LCD Monitor
510(k) Number	K141690
Product Code	PGY
Manufacturer	Nanjing Jusha Display Technology Co., Ltd

4. Device Description

Hisense HMD2G21S, HMD3G21S LCD monitor complies with the DICOM Part 14 standard and is applicable to DSA, MRI, DR, CR, CT, and PET medical imaging. It is intended for trained medical practitioners and provides the image viewing and medical diagnostic functions.

5. Intended Use/Indication for Use

1) The 2MP Monochrome LCD Monitor HMD2G21S 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.

2) The 3MP Monochrome LCD Monitor HMD3G21S is intended to be used in displaying and viewing digital images for diagnosis X-ray or MRI, etc. by trained medical practitioners.
The device does not support the display of mammography images for diagnosis.

6. Substantial Equivalence Comparison

6.1 HMD2G21S and its predicate

Table 01: General Comparison Table

Elements of Comparison	Proposed device	Predicate Device	Remarks
510(k) Number	K222132	K183497	-
Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	-
Device type/model	HMD2G21S	JUSHA-M260G LCD Monitor	-
Intended use/ Indication for use	The 2MP Monochrome LCD Monitor HMD2G21S 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.	JUSHA-M260G 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.	same
Prescription or OTC	RX	RX	same

Elements of Comparison	Proposed device	Predicate Device	Remarks
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	same
Performance testing	FDA guidance “Display devices for Dignostic Radiology”	FDA guidance “Display devices for Dignostic Radiology”	same

Table 02: Detailed Comparison Table

ID	Elements of Comparison	Proposed device	Predicate Device	Remarks
	510(k) Number	K222132	K183497	-
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	-
	Device type/model	HMD2G21S	JUSHA-M260G LCD Monitor	-
1.Display Performance/Specifications				
1.1	Screen size	21,3 inches (540 mm)	21.3"	same
1.2	Screen Technology	Gray scale TFT LCD panel	Mono-TFT LCD Panel	same
1.3	Viewing Angle	Horizontal: 178°; vertical: 178° (CR ≥ 10)	Horizontal 178°,Vertical 178°	same
1.4	Pixel array	1600 pixels (H) x 1200 pixels (V)	1600 x 1200/1200 x 1600	same
1.5	Display Area	432 (H) x 324 (V) (mm)	432.0 (H) x 324.0(V) mm	same
1.6	Pixel Pitch	0,270 (H) x 0,270 (V) (mm)	0.27x0.27 mm	same
1.7	Subpixel driving	Not Applicable	Not Applicable	-
1.8	Contrast Ratio	1800:1 (typ.)	1400:1	the specification of the proposed device is superior to that of the predicate device
1.9	Frame rate / refresh rate	37.9~75kHz;60Hz	37.9~75kHz;60Hz	same
1.10	Maximum Brightness(typ	1900 cd/m^2	1000cd/m^2	the specification of the proposed

ID	Elements of Comparison	Proposed device	Predicate Device	Remarks
	510(k) Number	K222132	K183497	-
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	-
	Device type/model	HMD2G21S	JUSHA-M260G LCD Monitor	-
	)			device is superior to that of the predicate device
1.11	Recommended brightness for	400 cd/m^2	400cd/m^2	same
1.12	Backlight type	LED	LED	same
1.13	Ambient light sensing	Built-in ambient light sensor	Built in calibration sensor provided	same
1.14	Response Time	19 ms	16 ms	The difference does not affect diagnosis.
1.15	Aspect Ratio	4:3	4:3	same
1.16	Luminance calibration	Front-facing sensor Upper Computer Software	Built in calibration sensor provided	Same, only difference in words.
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	same
2.2	Output Signal	DisplayPort x 1	DisplayPort x1	same
2.3	Video bandwidth	DVI: 215MHz DisplayPort : 215MHz	DVI: 215MHz DisplayPort : 215MHz	same
3.Power Related Specification				
3.1	Power Requirements	24 V DC, 2,1 A	DC 12V	this difference doesn't affect product's safety.
3.2	Power Consumption/ save mode	50.4W/Below 0.5 W	50W/less than 0.5W	this difference doesn't affect product's safety.

ID	Elements of Comparison	Proposed device	Predicate Device	Remarks
	510(k) Number	K222132	K183497	-
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	-
	Device type/model	HMD2G21S	JUSHA-M260G LCD Monitor	-
3.3	Power Management	DVI DMPM DisplayPort 1.2a	DVI DMPM DisplayPort 1.1a	this difference doesn't affect product's safety.
4.Miscellaneous Features/Specifications				
4.1	USB ports	1 uplink port and 2 downlink ports/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0	same
4.2	Grayscale Tones(LUT)	14-bit:16384	14-bit:16384	same
4.3	User controls	Off the shelf	Off the shelf	same
4.4	Software/Firmware:	Built-in embedded software	Built-in embedded software	same
4.5	Dimensions w/o stand (W x H x D)	Without base:366 mm x 482 mm x 63 mm With base:366 mm x 502-616 mm x 244 mm	Without stand: 382mm x490mm x77mm With stand: 382mm x635mm x238mm	Different design scheme, the difference does not affect diagnosis.
4.6	Net weight	5 kg (excluding the base)	7.5 kg(without stand)	Different weight due to different components and parts
4.7	VESA standard	100 x 100 (mm)	100 x 100 (mm)	same

6.2 HMD3G21S and its predicate

Table 03: General Comparison Table

Elements of Comparison	Proposed device	Predicate Device	Remarks
510(k) Number	K222132	K141690	/
Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	/
Device type/model	HMD3G21S	JUSHA-M33C	/
Intended use/ Indication for use	The 3MP Monochrome LCD Monitor HMD3G21S is intended to be used in displaying and viewing digital images for diagnosis X-ray or MRI, etc. by trained medical practitioners. The device does not support the display of mammography images for diagnosis.	JUSHA-M33C 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.	same
Prescription or OTC	RX	RX	same
Electrical Safety	Compliance with IEC 60601-1	Compliance with IEC 60601-1	same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	same
Performance testing	FDA guidance “Display devices for Dignostic Radiology”	FDA guidance “Display devices for Dignostic Radiology”	same

Table 04: Detailed Comparison Table

ID	Elements of Comparison	Proposed device	Predicate Device	Remarks
	510(k) Number	K222132	K141690	-
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	-
	Device type/model	HMD3G21S	JUSHA-M33C	-
1.Display Performance/Specifications				
1.1	Screen size	21.3 inches (540 mm)	21.3inches	same
1.2	Screen Technology	Gray scale TFT LCD panel	Mono-TFT LCD Panel	same

ID	Elements of Comparison	Proposed device	Predicate Device	Remarks
	510(k) Number	K222132	K141690	-
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	-
	Device type/model	HMD3G21S	JUSHA-M33C	-
1.3	Viewing Angle	Horizontal: 178°; vertical: 178° (CR ≥ 10:1)	Horizontal 176°,Vertical 176°	the specification of the proposed device is superior to that of the predicate device
1.4	Pixel array	2048 pixels (H) x 1536 pixels (V)	2048 x1536/1536x 2048	same
1.5	Display Area	433.15 (H) x 324.86 (V) (mm)	433.152 (H) x 324.864 (V) (mm)	same
1.6	Pixel Pitch	0.2115 (H) x 0.2115 (V) (mm)	0.2115x0.2115 mm	same
1.7	Subpixel driving	Not Applicable	Not Applicable	-
1.8	Contrast Ratio	1500:1 (typ.)	1400:1	the specification of the proposed device is superior to that of the predicate device
1.9	Frame Rate and Refresh Rate	96.7kHz;60Hz	96.7kHz;60Hz	same
1.10	Maximum Brightness(typ)	2000cd/m^2	1700cd/m^2	the specification of the proposed device is superior to that of the predicate device
1.11	Recommended brightness	500d/cm^2	500cd/m^2	same
1.12	Backlight type	LED	LED	same
1.13	Ambient light sensing	Built-in ambient light sensor	Built in calibration sensor provided	same

ID	Elements of Comparison	Proposed device	Predicate Device	Remarks
	510(k) Number	K222132	K141690	-
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	-
	Device type/model	HMD3G21S	JUSHA-M33C	-
1.14	Response Time	28 ms (typ.)	40 ms	the specification of the proposed device is superior to that of the predicate device
1.15	Aspect Ratio	4:3	4:3	same
1.16	Luminance calibration	Front-facing sensor Upper Computer Software Body sensor	Built in calibration sensor provided	Same, only difference in words.
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	same
2.2	Output Signal	DisplayPort x 1	DisplayPort x1	same
2.3	Video bandwidth	DVI: 215MHz DisplayPort : 215MHz	DVI: 215MHz DisplayPort : 215MHz	same
3.Power Related Specification				
3.1	Power Requirements	24 V DC, 1.7 A	AC 100~240V 50~60Hz	this difference doesn't affect product's safety.
3.2	Power Consumption/ save mode	40.8 W/Below 0.5 W	45W/less than 3W	this difference doesn't affect product's safety.
3.3	Power Management	DVI DMPM DisplayPort 1.2a	DVI DMPM DisplayPort 1.1a	this difference doesn't affect product's safety.
4.Miscellaneous Features/Specifications				
4.1	USB ports	1 uplink port and 2 downlink ports/ Rev. 2.0	1 upstream (endpoint), 2 downstream/ Rev. 2.0	same

ID	Elements of Comparison	Proposed device	Predicate Device	Remarks
	510(k) Number	K222132	K141690	-
	Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Nanjing Jusha Display Technology Co., Ltd	-
	Device type/model	HMD3G21S	JUSHA-M33C	-
4.2	Grayscale Tones(LUT)	16384	65536	Different design scheme. The difference does not affect diagnosis.
4.3	User controls	Off the shelf	Off the shelf	same
4.4	Software/Firmware:	Built-in embedded software	Built-in embedded software	same
4.5	Dimensions w/o stand (W x H x D)	Without base:366 mm x 482 mm x 63 mm; With base:366 mm x 502-616 mm x 244 mm	Without stand:382mm x490mm x75mm With stand:382mm x533mm x238mm	Different design scheme, the difference does not affect diagnosis.
4.6	Net weight	6 kg(excluding the base)	7 kg(Without stand)	Different weight due to different components and parts
4.7	VESA standard	100 x 100 (mm)	100 x 100 (mm)	same

Discussion of Differences

About HMD2G21S and JUSHA-M260G

1) The proposed device is superior to that of the predicate device in Contrast Ratio, Maximum Brightness. The proposes device has better displaying image quality. And the predicate device is better than proposed device in Response Time, this difference doesn't affect diagnosis.
2) Because of different design scheme, the Power, Dimension and Net weight is not same. But this difference doesn't affect the diagnosis。

About HMD3G21S and JUSHA-M33C

1) The proposed device is superior to that of the predicate device in Viewing Angle, Contrast Ratio, Maximum Brightness. The proposes device has better displaying image quality. And the predicate device is better than proposed device in Response Time and Grayscale Tones, but this difference doesn't affect diagnosis.
2) Because of different design scheme, the Power, Dimension and Net weight is not same. But This difference doesn't affect the diagnosis.

7.Bench testing:

The bench tests were performed on the proposed devices HMD2G21S, HMD3G21S in accordance with Assessment of Display Performance for Medical Imaging Systems by AAPM Task Group 18 (TG18 guideline). The detail test item as below.

Measurements Guidance	HMD2G21S	HMD3G21S
a. Spatial resolution	By reporting modulation transfer function.	By reporting modulation transfer function
b. Pixel defects (maximum counts, allowed defect types, and locations)	Maximum number allowed for each type.	Maximum number allowed for each type.
c. Artifacts	Measure Artifacts with TG18	Measure Artifacts with TG18
d. Temporal response	Measure the rise and fall time constants for 5– 95% and 40–60% luminance transitions.	Measure the rise and fall time constants for 5– 95% and 40–60% luminance transitions.
e. Luminance (maximum, minimum, achievable, and recommended)	Measure the maximum, minimum, achievable, and recommended luminance.	Measure the maximum, minimum, achievable, and recommended luminance.
f. Conformance to a grayscale-to-luminance function (e.g., DICOM GSDF)	Luminance Response by AAPM-TG18.	Luminance Response by AAPM-TG18.
g. Luminance at 30° and 45° in diagonal, horizontal, and vertical directions at center and four corners	NA	NA
h. Luminance uniformity or Mura test	NA	NA
i. Stability of luminance and chromaticity response with temperature and time of operation or on-time	NA	NA
j. Spatial noise	NA	NA
k. Reflection coefficient	NA	NA
l. Veiling glare or small-spot contrast	NA	NA

Measurements Guidance	HMD2G21S	HMD3G21S
m. Color tracking (primary colors and color gamut)	NA, HMD2G21S is a monochrome LCD monitor，not color monitor	NA, HMD3G21S is a monochrome LCD monitor，not color monitor
n. Gray tracking (gray shades and white point)	NA	NA

8.Summary of Non-Clinical Tests

The Hisense LCD Monitor were evaluated for electrical, electromagnetic and performance, and have been found to comply with applicable 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 following quality assurance measures are applied to the development of the system:

(1) Risk Management

(2) Requirement review and Design reviews

(3) Integration testing

(4) Performance testing

(5) Safety testing

etc.

9.Clinical Testing

Not applicable.

The subject of this premarket submission did not 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.

10.Conclusion

Hisense considers the LCD Monitor HMD2G21S, HMD3G21S to be as safe, as effective, and performance is substantially equivalent to the predicate device.