Qingdao Hisense Medical Equipment Co., Ltd.
% Hanson Chen
Official Correspondent
Shenzhen Joyantech Consulting Co., Ltd.
1713A,17th Floor, Block A, Zhongguan Times Square,
Nanshan District, Shenzhen
Shenzhen, Guangdong GD755
CHINA

July 26, 2022

Re: K221567
Trade/Device Name: LCD monitor (HMD3C21S), LCD monitor (HMD5G21S)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: May 5, 2022
Received: May 31, 2022

Dear Hanson Chen:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K221567

Device Name
LCD Monitor HMD3C21S, LCD Monitor HMD5G21S.

Indications for Use *(Describe)*

HMD3C21S：

The 3MP Color LCD Monitor HMD3C21S is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

HMD5G21S：

The 5MP Monochrome LCD Monitor HMD5G21S is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

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. Contact Details

K221567

1.1 Applicant information

Applicant Name	Qingdao Hisense Medical Equipment Co., Ltd.
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Phone No.	+86-532-83091111
Contact person	Li Mingcheng
Contact person's e-mail	limingcheng@hisense.com
Date Prepared	May 5, 2022

1.2 Submission Correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	1713A, 17th Floor, Block A, Zhongguan Times Square, Liuxian Avenue, Xili Town, Nanshan District, Shenzhen, Guangdong, 518000, China
Phone No.	+86-755-86069197
Contact person	Hanson Chen
Contact person's e-mail	hanson@cefda.com
Website	http://www.cefda.com

2. Device information

Trade name	LCD monitor
Model	HMD3C21S, HMD5G21S
Classification	Ⅱ
Classification name	Medical image management and processing system
Product code	PGY
Regulation No.	892.2050

3. Legally Marketed Predicate Device

Trade Name	3MP Color LCD Monitors C32S+, C32SP+, 3MP Monochrome
510(k) Number	K201211
Product Code	PGY
Manufacturer	Shenzhen Beacon Display Technology Co., Ltd.

Trade Name	5MP Color LCD Monitor CL-S500, 5MP Monochrome LCD Monitor MS-S500
510(k) Number	K191137
Product Code	PGY
Manufacturer	JVC KENWOOD Corporation

4. Device Description

The LCD monitor employs high-luminance LCD panel, and is designed for medical image display.

5. Intended Use/Indication for Use

The 3MP Color LCD Monitor HMD3C21S is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

The 5MP Monochrome LCD Monitor HMD5G21S is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.

6. Substantial Equivalence Comparison

6.1 HMD3C21S and its predicate device:

Table 01: General Comparison Table

Elements of Comparison	Subject Device	Predicate Device	Remarks
510(k) Number	Pending	K201211	/
Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Shenzhen Beacon Display Technology Co., Ltd.	/
Device type/model	HMD3C21S	3MP Color LCD Monitors C32S+, C32SP+	/
Intended use/ Indication for use	The 3MP Color LCD Monitor HMD3C21S is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.	The 3MP Color LCD Monitors C32S+, C32SP+ are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The displays are not intended for mammography.	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 02: Detailed Comparison Table

Elements of Comparison	Candidate Device	Predicate Device	Remarks
510(k) Number	Pending	K201211	/
Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	Shenzhen Beacon Display Technology Co., Ltd.	/
Device type/model	HMD3C21S	3MP Color LCD Monitors C32S+, C32SP+	/
Display technology	Color LCD panel (IPS)	Color (IPS)	Same
Screen size (Display area)	540mm/21.3” 324.86 x 433.15 mm	54.1cm/21.3” 324.86 x 433.15 mm	Same
Backlight type	LED	LED	Same
Backlighting	1000 cd/m^2	1000 cd/m^2	Same
Frame Rate and Refresh Rate (Scanning Frequency)	60Hz	59-61Hz	Same
Pixel array (Resolution or Matrix Size)	1536 x 2048	1536 x 2048	Same
Pixel pitch	0.2115 x 0.2115 mm	0.2115 x 0.2115 mm	Same
Subpixel driving (spatial and temporal dithering)	NA, no such function.	Not available	/
Display interface (Input Video Signal)	DVI-D x 1, Displayport x 1	DVI-D x 1, Displayport x 1	Same
Video bandwidth	DVI: 215MHz DisplayPort: 215MHz	DVI: 216MHz DisplayPort: 216MHz	Similar
User control	Quality-control software The calibration function	Not available	/
Ambient light sensing	Built-in ambient light sensor	Ambient light sensor	Same
Touch-screen technology	NA, the screen is not touch-screen.	Not available	/
Luminance calibration tools	Front-facing sensor Body sensor Quality-control software	Integrated optical sensor External optical sensor Calibration software: Beacon Monitor Manage	Similar
Quality-	Quality-control software	Beacon Monitor	Difference

Elements of Comparison	Candidate Device	Predicate Device	Remarks
control procedures		Manage	design scheme
Software/Firmware:			
Viewing angle	Horizontal: 178° Vertical: 178°	178° / 178°	Same
Response time (typical)	25 ms	25 ms	Same
Contrast ratio (typical)	1500:1	1500:1	Same
Display colors	1073741824	1.073 billion	Same
Power requirements	DC 24V /3.1A	DC 12V /6.67A	Difference between voltage and electricity
Maximum power consumption	74.4W	80W	Difference design scheme
Power save mode	Less than 0.5W	Less than 5W	Difference design scheme
Sensors	Front-facing sensor Body sensor Ambient light sensor	Backlight sensor Integrated front sensor Ambient light sensor	Difference design scheme
USB ports	USB 2.0 x 3	USB 2.0: Type-B x 1	Difference design scheme
Net weight	10.31 KG	9.5 KG	Different weight due to different components and parts
VESA standard	100 x 100mm	100 x 100mm	Same
Dimensions	366 x 557~677 x 273, 366 x 482 x 63	369 x 220 x 511.5~596.15	Different housing design due to the different panel size

6.2 HMD5G21S and its predicate device:

Table 03: General Comparison Table

Elements of Comparison	Subject Device	Predicate Device	Remarks
510(k) Number	Pending	K191137	/
Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	JVC KENWOOD Corporation	/
Device type/model	HMD5G21S	MS-S500	/
Intended use/ Indication for use	The 5MP Monochrome LCD Monitor HMD5G21S is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	MS-S500 is intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. It is intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM.	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

Elements of Comparison	Subject Device	Predicate Device	Remarks
510(k) Number	Pending	K191137	/
Manufacturer	Qingdao Hisense Medical Equipment Co., Ltd	JVC KENWOOD Corporation	/
Device type/model	HMD5G21S	MS-S500	/
Display technology	Gray scale LCD panel (IPS)	TFT Monochrome LCD Panel (IPS)	Difference between gray and monochrome
Screen Size (Display Area)	Horizontal: 422.4mm Vertical: 337.92mm	Horizontal: 337.92mm Vertical: 422.4mm	Same
Backlight type	LED	LED	Same

Elements of Comparison	Subject Device	Predicate Device	Remarks
Brightness	3000 cd/m^2	3000 cd/m^2	Same
Frame Rate and Refresh Rate (Scanning Frequency)	50Hz	Portrait: Horizontal:129.1KHz Vertical:50Hz Landscape: Horizontal:103.5KHz Vertical:50Hz	Difference design scheme
Pixel array (Resolution or Matrix Size)	2048 x 2560	2048 x 2560	Same
Pixel pitch	0.165 x 0.165 mm	0.165 x 0.165 mm	Same
Subpixel driving (spatial and temporal dithering)	NA, no such function.	Not available	/
Display interface (Input Video Signal)	DVI-D x 1, Displayport x 1	DVI-D x 1, Displayport x 1	Same
Video bandwidth	DVI : 215MHz DisplayPort : 215MHz	Not available	/
User control	Quality-control software The calibration function	QA Medivisor / Medivisor NX F-CAL	Difference design scheme
Ambient light sensing	Built-in ambient light sensor	Built-in ambient light sensor	Same
Touch-screen technology	NA, the screen is not touch-screen.	Not available	/
Luminance calibration tools	Built-in calibration sensor Quality control software	Integrated optical sensor External optical sensor Calibration software: Beacon Monitor Manage	Difference design scheme
Software/Firmware:			
Viewing angle	Horizontal: 178° Vertical: 178°	Horizontal: 178° Vertical: 178°	Same
Aspect ratio	5:4	4:5	Same
Response time (typical)	25 ms	25 ms	Same
Contrast ratio (typical)	2000:1	2000:1	Same
Grayscale tones	256 gray scales/single	10-bit (DisplayPort):	Difference

Elements of Comparison	Subject Device	Predicate Device	Remarks
	subpixels (for DP 10-bit input)	1,024 from a palette of 16,369 tones 8-bit (DVI): 256 from a palette of 16,369 tones	design scheme
Power requirements	DC 24V, 3.3A	AC 100-240V, 50/60Hz	Difference between built-in power supply and built-out power supply
Maximum power consumption	79.2W	80W	Difference design scheme
Power save mode	Less than 0.5W	Less than 1W	Difference design scheme
Sensors	Front-facing sensor Ambient light sensor	Front sensor Ambient light sensor	Same
USB ports	1 uplink 2 downlink /Rev.2.0	1 upstream 2 downstream /Rev.2.0	Same
Dimensions	366 x 495~610 x 58, 366 x 496 x 58	361 x 517/612 x 196.5	Different housing design due to the different panel size

7. Performance Testing-Bench

The recommended physical laboratory tests were performed on the proposed devices HMD3C21S and HMD5G21S.

Measurements	HMD3C21S	HMD5G21S
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	Crosstalk and Ghost.	Crosstalk and Ghost.
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 at several (e.g. every 15 levels) grayscale intervals between 0 and 255.

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 gray scale-to-luminance function (for example, 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	By AAPM TG18.
h. Luminance uniformity or Mura test	NA	Luminance uniformity and Chromaticity uniformity by AAPM TG18.
i. Stability of luminance and chromaticity response with temperature and time of operation or on-time	NA	By AAPM TG18.
j. Spatial noise	NA	By noise power spectrum.
k. Reflection coefficient	NA	By specular reflection coefficient and diffuse reflection coefficient.
l. Veiling glare or small-spot contrast	NA	By AAPM TG18.
m. Color tracking (primary colors and color gamut)	Measure the primary colors and color gamut.	NA, HMD5G21S employs gray scale LCD panel.
n. Gray tracking (gray shades and white points)	NA	Measure the maximum chromaticity variation by IEC 62563-1.

8. Clinical testing

Not applicable.

9. Other information (such as required by FDA guidance/Test)

Not applicable.

10. Conclusions Drawn from Non-Clinical and Clinical Tests

The LCD monitor is substantially equivalent to the legally marketed predicate device 3MP Color LCD Monitors C32S+, C32SP+ (K201211) and 5MP Monochrome LCD Monitor MS-S500 (K191137).