DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Qingdao Hisense Medical Equipment Co., Ltd.
% Mr. Liu Zhitang
Regulatory Manager
Software Outsourcing Center 3rd Floor North Wing
No. 169 Songling Road, Laoshan
Qing dao, Shan dong 266101
P.R. CHINA

September 16, 2015

Re: K152030
Trade/Device Name: Hisense 2MP/3MP LCD Monitor (HMD2C21/HMD3C21)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: July 7, 2015
Received: July 22, 2015

Dear Mr. Zhitang:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152030

Device Name
Hisense 2MP/3MP LCD Monitor (HMD2C21/HMD3C21)

Indications for Use *(Describe)*
The 2MP/3MP LCD Monitor (HMD2C21/HMD3C21) is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

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)]

Jul 8th, 2015

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

Name of Sponsor:	Qingdao Hisense Medical Equipment Co., Ltd.
Address:	Software outsourcing center 3rd floor north wing, No.169 Songling Road, Laoshan Dist. 266101, Qingdao, China
Contact Name:	Liu Zhitang
Telephone No.:	+86 (0) 532-55753811

3. Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name:	Hisense LCD monitor models HMD2C21/ HMD3C21
Common Name:	Display system, medical image workstation, and others
Classification:	892.2050 system, image processing, radiological
Product code:	PGY
Classification Panel:	Radiology
Device Class:	II

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

The identified predicates within this submission are as follows:

BARCO N.V., Coronis 3MP (MDCG-3221) has been cleared by FDA through 510(k) No.K131246 (Decision Date –May 24, 2013),

BARCO N.V., Nio 2MP (MDNC-2221) has been cleared by FDA through 510(k) No K133663 (Decision Date –03/25/2014)

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

The 2MP/3MP LCD Monitor (HMD2C21/HMD3C21) is a display system for medical viewing, with high resolution 1600x1200(HMD2C21)/2048 x 1536(HMD3C21), built-in brightness stabilization circuit, front sensor and ambient light sensor, stable brightness and persistent calibration can be guaranteed. The display can support both landscape and portrait mode. The antiglare screen can prevent display from reflection under highlight conditions, make the image and display clearer.

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

The 2MP/3MP LCD Monitor (HMD2C21/HMD3C21) is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

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

The HMD3C21

Panel	21.2", TFT color LCD screen, antiglare
Brightness (typ.)	900 cd/m^2
CR (typ.)	1400:1
Viewing angle	R/L 176°， U/D 176° Typ.（CR > 10）
Pixel Pitch	0.21075 mm
Native resolution	2048 x 1536
Display area	431.6mm(H)x323.7mm (V)
Compatible video signals	640 x 480@60Hz(progressive) 2048x1536@60Hz (progressive)
Horizontal resolution	2048 x 1536
Aspect ratio	4:3
Screen size	21.2" real diagonal
Power	DC24V/3.5A
Power consumption	Max. 80 W
Input signals	DVI-D, Display Port
Digital input	TMDS（single）
Plug and play	VESA DDC 2B
Dimension	384.0mm (W) x 492.0mm (H) x70.0mm (D)（without Stand） 384.0 mm (W) x 637.5 mm (H) x 273.5mm (D)（with

	Stand）
Weight	6.1kg（without Stand） 10.4kg（with Stand）
Operating temperature and humidity:	Temperature: 0°C ~ 40°C Humidity: 20% ~80%
Storage temperature and humidity:	Temperature: -20°C ~ 60°C Humidity:10% ~90%

The HMD2C21

Panel	21.3”, TFT color LCD screen, antiglare
Brightness (typ.)	770 cd/m^2
CR (typ.)	1100:1
Viewing angle	R/L 176°， U/D 176° Typ.（CR > 10）
Pixel Pitch	0.27 mm
Native resolution	1600 x 1200
Display area	432.0mm(H)x324.0mm (V)
Compatible video signals	640 x 480@60Hz(progressive) 1600 x 1200@60Hz (progressive)
Horizontal resolution	1600 x 1200
Aspect ratio	4:3
Screen size	21.3” real diagonal
Power	DC24V/3.0A
Power consumption	Max. 70 W
Input signals	DVI-D, Display Port
Digital input	TMDS（single）
Plug and play	VESA DDC 2B
Dimension	384.0mm (W) x 492.0mm (H) x70.0mm (D)（without Stand） 384.0 mm (W) x 637.5 mm (H) x 273.5mm (D)（with Stand）
Weight	6.1kg（without Stand） 10.4kg（with Stand）
Operating temperature and humidity:	Temperature: 0°C ~ 40°C Humidity: 20% ~80%
Storage temperature and humidity:	Temperature: -20°C ~ 60°C Humidity:10% ~90%

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

8.1 Intended uses:

Table 1 Intended Use Comparison of HMD3C21

ID	Comparison Item	Proposed Device 3MP LCD Monitor（HMD3C21）	Predicate Device Nio 3MP(MDNC-3221)
1	**Intended Use**	The HMD3C21 is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.	"The Nio 3MP (MDNC-3221)" is intended to be used as a tool in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

Table 2 Intended Use Comparison of HMD2C21

ID	Comparison Item	Proposed Device 2MP LCD Monitor（HMD2C21）	Predicate Device Nio 2MP(MDNC-2221)
1	**Intended Use**	The HMD2C21 is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.	"The Nio 2MP (MDNC-2221)" is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

8.2 Comparison table

Table 3 General Comparison about HMD3C21 and Nio 3MP

ID	Comparison Item	Proposed Device 3MP LCD Monitor （HMD3C21）	Predicate Device Nio 3MP(MDNC-3221)
2	**Performance**		
2.1	Panel Size and Type	21.2”, TFT LCD display	21.3”,TFT LCD display
2.2	Pixel Pitch	0.21075 mm	0.2115 mm
2.3	Available Cabinet Colors	Red , Green , Blue	Red , Green , Blue

ID	Comparison Item	Proposed Device 3MP LCD Monitor （HMD3C21）	Predicate Device Nio 3MP(MDNC-3221)
2.4	Native Resolutions	2048 x1536	2048 x1536
2.5	Brightness	900 cd/m2	800 cd/m2
2.6	Contrast Ratio	1400:1	1400:1
2.7	Network Interface	USB(1 Up, 2 Downstream)	USB(1 Up, 2 Downstream)
2.8	Active Display Size	431.616mm x 323.712mm	433.2mm x 324.9mm
3	**Physical Specifications**		
3.1	Dimensions (Wx Hx D)	384.0mm (W) x 492.0mm (H) x 70.0mm (D)（without Stand） 384.0 mm (W) x 517.5-637.5 mm (H) x 273.5mm (D)（with Stand）	375mm x 488mm x 84mm (without Stand) Portrait: 375mm x 620~520mm x 235mm Landscape: 488mm x 563~463mm x 250mm (with Stand)
Temperature			
3.2	Operating	0°C ~ 40°C	0°C ~ 40°C
3.3	Transport/ Storage	-20°C ~ 60°C	-20°C ~ 60°C
Relative humidity			
3.4	Operating	20% ~80%	8% ~80%(non-condensing)
3.5	Transport/ Storage	10% ~90%	5% ~95%
4	**Power Supply**		
4.1	Power Capacity	＜80W	＜50W
4.2	Input Voltage	DC24V/3.5A	100~240v
5	**Human factors (operation characteristic)**		
5.1	Usability	Button operation, LED indicator	Button operation, LED indicator
5.2	Mode of operation	Continuous operation	Continuous operation
6	**Biocompatibility**		
6.1	Evaluation	The proposed device does not contain any components that come into direct or indirect contact with patients, so the evaluation doesn't be needed.	The proposed device does not contain any components that come into direct or indirect contact with patients, so the evaluation doesn't be needed.
7	**Sterility**		
7.1	Sterilization	The proposed device does not need sterilization.	The proposed device does not need sterilization.
8	**Electrical & Mechanical safety& Thermal safety**		
8.1	Type of protection	Class I	Class I

ID	Comparison Item	Proposed Device 3MP LCD Monitor （HMD3C21）	Predicate Device Nio 3MP(MDNC-3221)
	against electric shock		
8.2	Degree of protection against harmful ingress of liquid	Ordinary equipment.	Ordinary equipment.
8.3	Evaluation	The electrical, mechanical and thermal safety evaluation is conducted as per the requirements of the standard IEC 60601-1.	The electrical, mechanical and thermal safety evaluation is conducted as per the requirements of the standard IEC 60601-1.
9	**Electromagnetic Compatibility**		
9.1	EMC Evaluation	Complying with IEC 60601-1-2	Complying with IEC 60601-1-2

Table 4 General Comparison about HMD2C21 and Nio 2MP

ID	Comparison Item	Proposed Device 2MP LCD Monitor （HMD2C21）	Predicate Device Nio 2MP(MDNC-2221)
2	**Performance**		
2.1	Panel Size and Type	21.3”, TFT LCD display	21.3”,TFT LCD display
2.2	Pixel Pitch	0.27 mm	0.27 mm
2.3	Available Cabinet Colors	Red , Green , Blue	Red , Green , Blue
2.4	Native Resolutions	1600×1200	1600×1200
2.5	Brightness	770 cd/m2	800 cd/m2
2.6	Contrast Ratio	1100:1	1400:1
2.7	Network Interface	USB(1 Up, 2 Downstream)	USB(1 Up, 2 Downstream)
2.8	Active Display Size (H x V)	432.0mm x324.0mm	433.2mm x324.9mm
3	**Physical Specifications**		
3.1	Dimensions (W x H x D)	384mm (W) x 492mm (H) x 70mm (D)（without Stand） 384 mm (W) x 517.5-637.5 mm (H) x 273.5mm (D)（with Stand）	378mm x 491mm x 83.2mm (without Stand) Portrait: 378mm x 625~525mm x 235mm Landscape: 491mm x 565.5~465.5mm x 235mm (with Stand)
Temperature			

ID	Comparison Item	Proposed Device 2MP LCD Monitor （HMD2C21）	Predicate Device Nio 2MP(MDNC-2221)
3.2	Operating	0°C ~ 40°C	0°C ~ 35°C
3.3	Transport/ Storage	-20°C ~ 60°C	-20°C ~ 60°C
Relative humidity			
3.4	Operating	20% ~80%	8% ~80%(non-condensing)
3.5	Transport/ Storage	10% ~90%	5% ~85%
4	**Power Supply**		
4.1	Power Capacity	＜70W	＜50W
4.2	Input Voltage	DC24V/3A	100~240v
5	**Human factors (operation characteristic)**		
5.1	Usability	Button operation, LED indicator	Button operation, LED indicator
5.2	Mode of operation	Continuous operation	Continuous operation
6	**Biocompatibility**		
6.1	Evaluation	The proposed device does not contain any components that come into direct or indirect contact with patients, so the evaluation doesn't be needed.	The proposed device does not contain any components that come into direct or indirect contact with patients, so the evaluation doesn't be needed.
7	**Sterility**		
7.1	Sterilization	The proposed device does not need sterilization.	The proposed device does not need sterilization.
8	**Electrical & Mechanical safety& Thermal safety**		
8.1	Type of protection against electric shock	Class I	Class I
8.2	Degree of protection against harmful ingress of liquid	Ordinary equipment.	Ordinary equipment.
8.3	Evaluation	The electrical, mechanical and thermal safety evaluation is conducted as per the requirements of the standard IEC 60601-1.	The electrical, mechanical and thermal safety evaluation is conducted as per the requirements of the standard IEC 60601-1.
9	**Electromagnetic Compatibility**		
9.1	EMC Evaluation	Complying with IEC 60601-1-2	Complying with IEC 60601-1-2

8.4 Discussion of Differences:

It is reasonable that there are some differences between our new system and its predicate. All of parameters comply with 21CFR1020.33 and related IEC standards. We did not use any new technology in this system, so those differences between our new system and its predicate do not affect the safety and effectiveness (SE).

Review of ID 1 - Intended use, both of them are intended to be used in displaying and viewing digital images, excluding digital mammography, for review and analysis by trained medical practitioners. So the SE is not affected.

Review of ID 2 - Performance, except three items as below, both are the same, so the SE is not affected.

About HDM3C21 and Nio 3MP

1. Panel Size, The proposed device is 21.2'' and the predicate device is 21.3'', the different of the effective display area due to the different size of the pixel pitch, and the smaller the better in terms of the image quality. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.
2. Pixel Pitch, The proposed device is 0.21075 mm and the predicate device is 0.2115 mm, but the 0.21075 mm is better than 0.2115 mm in terms of the image quality. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.
3. Brightness, The proposed device is 900cd/m2 and the predicate device is 700cd/m2, but the 900 cd/m2 is better than 700cd/m2 mm in terms of the bright lifetime. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Review of ID 3 - Physical Specifications, Dimensions and Relative humidity are comparable, so the SE is not affected

Review of ID 4 - Power Supply, both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Review of ID 5 - Human factors, both are the same, so the SE is not affected.

Review of ID 6 - Biocompatibility, both are the same, so the SE is not affected.

Review of ID 7 - Sterility, both are the same, so the SE is not affected.

Review of ID 8 - Electrical & Mechanical safety& Thermal safety, both are the same, so the SE is not affected.

Review of ID 9 - EMC, both are the same, so the SE is not affected.

About HDM2C21 and Nio 2MP

Review of ID 1 - Intended use, both of them are intended to be used in displaying and viewing digital images, excluding digital mammography, for review and analysis by trained medical practitioners. So the SE is not affected.

Review of ID 2 - Performance, except two items as below, both are the same, so the SE is not affected.

4. Contrast Ratio, The proposed device is 1100:1 and the predicate device is 1400:1, but the different contrast ratio just affect in terms of the image quality. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.
5. Brightness, The proposed device is 770cd/m2 and the predicate device is 800cd/m2, but the different brightness just affect in terms of the bright lifetime. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Review of ID 3 - Physical Specifications, Dimensions and Relative humidity are comparable, so the SE is not affected

Review of ID 4 - Power Supply, both of them comply with IEC 60601-1 and IEC 60601-1-2. Therefore, they can be considered Substantially Equivalent in safety and effectiveness. So the SE is not affected.

Review of ID 5 - Human factors, both are the same, so the SE is not affected.

Review of ID 6 - Biocompatibility, both are the same, so the SE is not affected.

Review of ID 7 - Sterility, both are the same, so the SE is not affected.

Review of ID 8 - Electrical & Mechanical safety& Thermal safety, both are the same, so the SE is not affected.

Review of ID 9 - EMC, both are the same, so the SE is not affected.

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, Qingdao Hisense Medical Equipment Co., Ltd. concludes that :

The subject device has same intended use, similar product design, same performance effectiveness, performance safety as the predicate device. The differences above between the subject device and predicate device do not affect the basic design principle, usage, effectiveness and safety of the subject device. And no new risk is raised regarding to effectiveness and safety.