



Food and Drug Administration  
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D-VIEW Display Technology Co., Ltd.  
% Mr. Jianfei Sun  
Regulatory Manager  
3F, Building 4, No.12# Kechuang 13th Street, BDA area  
Beijing 100176  
CHINA

July 28, 2015

Re: K151854  
Trade/Device Name: 3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E) LCD display  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: PGY  
Dated: July 3, 2015  
Received: July 7, 2015

Dear Mr. Sun:

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,



For

Robert Ochs, Ph.D.  
Acting Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

**K151854**

Device Name

3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E) LCD display

Indications for Use (Describe)

The D-VIEW 3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E) LCD Display 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)]

July 3, 2015

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

Name of Sponsor: D-VIEW Display Technology Co.,Ltd.

Address: 3F, Building 4, No.12# Kechuang 13th Street , BDA area, Beijing,  
P.R.China

Contact Name: Jianfei Sun

Telephone No.: +8610 82379533 EXT. 5360

Fax No.: +8610 82379511

Email Address: sunjianfei@d-view.cn

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

Trade Name: D-VIEW

Common Name: 3MP (X213C3P0E X213G3P0E) and 2MP (X213C2P0E  
X213G2P0E) LCD display

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),  
 Classification: 892.2050 system, image processing, radiological  
 Product code: LLZ  
 Device Class: II

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

LCD display is a display system for medical viewing, with high resolution 1600 x 1200(X213C2P0E, X213G2P0E) and 2048 x 1536 (X213C3P0E, X213G3P0E), built-in brightness stabilization circuit, front sensor and ambient light sensor, stable brightness and persistent calibration can be guaranteed. These displays can support both landscape and portrait mode. The anti-reflection coated protective screen can prevent display from damage under hard using conditions, make the clean and disinfect easier.

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

The D-VIEW 3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E) LCD Display 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)]

Panel	21.3", TFT monochrome LCD screen, antiglare
Brightness (typ.)	1900cd/m2 (2MP: X213G2P0E) 900cd/m2 (2MP: X213C2P0E) 1700cd/m2 (3MP: X213G3P0E) 800cd/m2 (3MP: X213C3P0E)
CR (typ.)	1400:1
Viewing angle	R/L 176° , U/D 176° Typ. ( CR ≥ 10 )
Pixel Pitch	0.2115 × 0.0705mm ( 3MP ) 0.270 × 0.270mm ( 2MP )
Native resolution	2048 x 1536 (3MP) 1600 x 1200 (2MP)
Display area	433(V)mm × 324 mm(H)
Compatible video signals	3MP: 640 x 480@60Hz(progressive) 2048x1536@60Hz(progressive) 2MP:

	640 x 480@60Hz(progressive) 1600x1200@60Hz(progressive)
Horizontal resolution	3MP: 2048x1536@60Hz(progressive) 2MP: 1600x1200@60Hz(progressive)
Bandwidth	3MP: 267MHz 2MP: 162MHz
Aspect ratio	4:3
Screen size	21.3" real diagonal
Power	3MP, X213C3P0E: DC12V 3.5A 3MP, X213G3P0E: DC12V 2.2A 2MP, X213C2P0E: DC12V 3.5A 2MP, X213G2P0E: DC12V 2.2A
Input signals	DVI-I, DP
Digital input	TMDS ( dual )
Dimension	375 mm (W) x 434mm (H) x 70mm (D) ( without Stand ) 375 mm (W) x 589 mm (H) x 173mm (D) ( with Stand )
Weight	7.0±0.3kg ( without Stand ) 10.5kg±0.3kg ( with Stand )
Operating Atmospheric Pressure	70kPa ~ 106kPa
Operating temperature and humidity:	Temperature: 0°C ~40°C Humidity: 30% ~75%
Storage temperature and humidity:	Temperature: -20°C ~ 60°C Humidity: 0% ~90%

## 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 D-VIEW 3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E)	Predicate Device Coronis 3MP(MDCG-3221)

<b>1</b>	<b>Intended Use</b>	The D-VIEW 3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E) LCD Display is intended to be used in displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.	"The Coronis 3MP (MDCG-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.
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## 8.2 Comparison table

**Table 2 General Comparison**

ID	Comparison Item	Proposed Device D-VIEW 3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E)	Predicate Device Coronis 3MP(MDCG-3221)
<b>2</b>	<b>Performance</b>		
2.1	Panel Size and Type	21.3", TFT LCD display	21.3",TFT LCD display
2.2	Pixel Pitch	0.2115 × 0.0705mm (3MP) 0.270 × 0.270mm(2MP)	0.2115 mm
2.3	Available Cabinet Colors	Black	Black
2.4	Native Resolutions	1600 x 1200 (2MP) 2048 x 1536 (3MP)	2048 x1536
2.5	Brightness	1900cd/m2 (2MP, X213G2P0E) 900cd/m2 (2MP, X213C2P0E) 1700cd/m2 (3MP, X213G3P0E) 800cd/m2 (3MP, X213C3P0E)	1700 cd/m2
2.6	Contrast Ratio	1400:1	1300:1
2.7	Network Interface	USB(1 Up, 2 Downstream)	USB(1 Up, 2 Downstream)
2.8	Active Display Size	433mm × 324 mm	433.2mm x 324.9mm
<b>3</b>	<b>Physical Specifications</b>		
3.1	Dimensions (Wx Hx D)	375 mm (W) x 434mm (H) x 70mm (D) ( without Stand )	375mm x 488mm x 84mm (without Stand)

ID	Comparison Item	Proposed Device D-VIEW 3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E)	Predicate Device Coronis 3MP(MDCG-3221)
		375 mm (W) x 589 mm (H) x 173mm (D) ( with Stand )	Portrait: 375mm x 620~520mm x 235mm Landscape: 488mm x 563~463mm x 250mm (with Stand)
<b>Temperature</b>			
3.2	Operating	0°C ~ 40°C	0°C ~ 40°C
3.3	Transport/ Storage	-20°C ~ 60°C	-20°C ~ 60°C
<b>Relative humidity</b>			
3.4	Operating	30% ~75%(non-condensing)	8% ~80%(non-condensing)
3.5	Transport/ Storage	0% ~90%	5% ~95%
<b>4</b>	<b>Power Supply</b>		
4.1	PowerCapacity	<50W	<40W
4.2	Input Voltage	3MP, X213C3P0E: DC12V 3.5A 3MP, X213G3P0E: DC12V 2.2A 2MP, X213C2P0E: DC12V 3.5A 2MP, X213G2P0E: DC12V 2.2A Power adapter: MDS-150AAS12 B Input: 100-240VAC 50-60Hz 2.5-1A Output: 12VDC 10A	100~240v
<b>5</b>	<b>Human factors (operation characteristic)</b>		
5.1	Usability	Button operation, LED indicator	Button operation, LED indicator
5.2	Mode of operation	Continuous operation	Continuous operation
<b>6</b>	<b>Biocompatibility</b>		
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.
<b>7</b>	<b>Sterility</b>		

ID	Comparison Item	Proposed Device D-VIEW 3MP (X213C3P0E, X213G3P0E) and 2MP (X213C2P0E, X213G2P0E)	Predicate Device Coronis 3MP(MDCG-3221)
7.1	Sterilization	The proposed device does not need sterilization.	The proposed device does not need sterilization.
<b>8</b>	<b>Electrical &amp; Mechanical safety&amp; Thermal safety</b>		
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.
<b>9</b>	<b>Electromagnetic Compatibility</b>		
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 the item as below, it is the same, so the SE is not affected.

1. Contrast Ratio, The proposed device is 1400:1 and the predicate device is 1300:1, but the 1400:1 is better than 1300:1 in terms of the image quality. 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, Shenzhen Beacon Display Technology Co., Ltd concludes that D-VIEW 3MP (X213C3P0E、X213G3P0E) and 2MP (X213C2P0E、X213G2P0E) LCD display is substantially equivalent to predicate devices with regard to safety and effectiveness.