



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Barco N.V.  
Healthcare Division  
% Lieven De Wandel  
35 President Kennedypark  
Kortrijk B-8500  
Belgium

April 10, 2015

Re: K150821  
Trade/Device Name: Nio 3MP LED (MDNG-3220)  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: PGY  
Dated: March 12, 2015  
Received: March 27, 2015

Dear Lieven De Wandel:

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,

A handwritten signature in black ink that reads "Robert A. Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, semi-transparent watermark of the FDA logo.

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)

K150821

Device Name

Nio 3MP LED (MDNG-3220)

Indications for Use (Describe)

The Nio 3MP LED (MDNG-3220) Medical Flat Panel Display System 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.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 510(k) Summary (in accordance with 21 CFR 807.92)

1. Company	Barco N.V. Healthcare Division 35 President Kennedypark B-8500 Kortrijk BELGIUM		
2. Contact person	Lieven De Wandel Regulatory Affairs Officer		
3. Date of submission	March 12, 2015		
4. Device information	Trade name/model:	Nio 3MP LED (MDNG-3220)	
	Common name:	Nio 3MP LCD display	
	Classification name:	System, image processing, Radiological	
	Classification code:	PGY	
	Regulation number:	892.2050	
5. Predicate device	Nio 3MP (E-3620 MA) cleared under 510(K) K040041		
6. Device description	<p>The Nio 3MP LED (MDNG-3220) is a high-resolution flat panel LCD display system for reviewing medical images. It consists of an LCD display (MDNG-3220), an optional high-resolution display controller board and QA software.</p> <p>The display controller board is installed in a PACS workstation computer, connected to the display. The QA software helps to make and keep the displays DICOM compliant.</p> <p>The display uses LED backlight technology.</p>		
7. Intended Use of the Device	The Nio 3MP LED (MDNG-3220) Medical Flat Panel Display System 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.		
8. Comparison of technological characteristics	<b>Product acronym</b>	<b>MDNG-3220</b>	<b>E-3620 MA</b>
	Screen technology	TFT AM LCD Dual Domain IPS	TFT AM LCD Dual Domain IPS
	Active screen size (diagonal)	520 mm (20.8")	528 mm (20.8")
	Active screen size (H x V)	424 mm x 318 mm (16.69" x 12.52")	424 x 318 mm (16.7 x 12.5")
	Aspect ratio (H:V)	4:3	4:3
	Resolution	3MP (2048 x 1536)	3MP (2048 x 1536)
	Pixel pitch	0.207 mm	0.207 mm
	Color imaging	No	No
Gray imaging	Yes	Yes	

Viewing angle (H, V)	176°	170°
Uniform Luminance Technology (ULT)	Yes	Yes
Per Pixel Uniformity (PPU)	No	No
Ambient Light Compensation (ALC)	No	No
Backlight Output Stabilization (BLOS)	Yes	Yes
I-Guard	Yes	No
Maximum luminance	1200 cd/m <sup>2</sup>	1000 cd/m <sup>2</sup>
DICOM calibrated luminance (ULT off)	500 cd/m <sup>2</sup>	500 cd/m <sup>2</sup>
Contrast ratio (typical)	1200:1	900:1
Response time (Tr + Tf)	30 ms	50 ms
Scanning frequency (H; V)	15-129 kHz; 25-98 Hz	30-124 kHz; 50-85 Hz
Video input signals	DVI-D Dual Link / DisplayPort	DVI-D Dual Link
USB ports	1 upstream, 2 downstream	1 upstream, 2 downstream
USB standard	2.0	1.1
Power requirements (nominal)	100-240V	100-240V
Power consumption (nominal)	50W	54W
Power save mode	Yes	Yes
Net weight with stand	13 kg	13 kg
Net weight w/o stand	8 kg	9 kg

9. Performance testing

The bench tests mentioned below were performed to validate the device characteristics that differ from the predicate device:

Modification to device	Test performed	Criteria
LED backlight instead of CCFL	Optical tests, DICOM calibration and Luminance Uniformity tests	Pass the test
Different platform (including firmware)	Functional tests	Pass the test
Additional DisplayPort video input	Functional tests	Pass the test
Front sensor implementation	Front sensor qualification test	Maximum 5% deviation
Other material of front filter	Impact test	There shall be no cracking of the enclosure. There shall be no live parts that become accessible.
Other material for sheet metal parts	Vibration and drop tests	Pass the test

	<p>Additional tests performed: EMC test (IEC 60601-1-2)</p> <p>The tests showed that the device has similar or superior characteristics compared to the predicate device and did not reveal new issues of safety and performance.</p> <p>Animal or clinical testing have not been performed.</p>
10. Conclusion	<p>The Nio 3MP LED (MDNG-3220) was found to be substantially equivalent to the predicate device, due to the following reasons:</p> <ul style="list-style-type: none"> <li>a) Device and predicate device have the same intended use</li> <li>b) The technological characteristics differences from the predicate device do not affect safety or effectiveness</li> <li>c) Bench testing showed that the device has similar or superior characteristics compared to the predicate device and did not reveal new issues of safety and performance.</li> </ul>