



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Barco NV (Healthcare Division)  
% Lieven De Wandel  
Regulatory Officer  
President Kennedypark 35  
Kortrijk, 8500  
BELGIUM

July 19, 2017

Re: K171812  
Trade/Device Name: Nio Color 2MP (MDNC-2123)  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: PGY  
Dated: June 20, 2017  
Received: June 22, 2017

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,

 For

Robert Ochs, Ph.D.  
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)

K171812

Device Name

Nio Color 2MP (MDNC-2123)

Indications for Use (Describe)

The Nio Color 2MP LED Medical Flat Panel Display System is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

The display may be used in dental applications.

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.

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	16 June 2017		
4. Device information	Trade name/model: Nio Color 2MP (MDNC-2123) Common name: MDNC-2123 Classification name: System, image processing, Radiological Classification code: PGY Regulation number: 892.2050		
5. Predicate device	Nio Color 3MP (MDNC-3421) cleared under 510(K) K170837		
6. Device description	The MDNC-2123 is a derivative of the MDNC-3421. The modifications are: <ul style="list-style-type: none"> <li>✓ Change in LCD panel: INX 2MP panel instead of PSD 3MP panel</li> <li>✓ Change in chassis housing (light-weight design)</li> <li>✓ Change in packaging (smaller size)</li> <li>✓ Change in electronics board</li> <li>✓ Updated firmware</li> </ul>		
7. Intended Use of the Device	The Nio Color 2MP LED Medical Flat Panel Display System is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.  Note: There are no changes to the indications for use statement from that of the unmodified device.		
8. Comparison of technological characteristics	<b>Specification</b>	<b>MDNC-3421</b>	<b>MDNC-2123</b>
	Screen technology	IPS-TFT Color LCD	IPS-TFT Color LCD
	Active screen size (diagonal)	540 mm (21.3")	598 mm (23.6")
	Active screen size (H x V)	433 x 325 mm (17.0 x 12.8")	521 x 293 mm (20.5 x 11.5")
	Aspect ratio (H:V)	4:3	16:9
	Resolution	3MP (2048 x 1536)	2MP (1920 x 1080 pixels)

	Pixel pitch	0.2155 mm	0.2715 mm
	Color imaging	Yes	Yes
	Gray imaging	Yes	Yes
	Viewing angle (H, V)	176°	170°
	Per Pixel Uniformity (PPU)	No	No
	Ambient Light Compensation (ALC)	No	No
	Maximum luminance	800 cd/m <sup>2</sup>	460 cd/m <sup>2</sup>
	DICOM calibrated luminance (ULT off)	400 cd/m <sup>2</sup>	320 cd/m <sup>2</sup>
	Contrast ratio (typical)	1400:1	1000:1
	Response time (Tr + Tf)	40 ms	15 ms
	Video input signals	DVID Dual Link, DisplayPort	1x DVI 1x DisplayPort
	USB ports	1 upstream (endpoint), 2 downstream	1 upstream (endpoint), 2 downstream
	USB standard	2.0	2.0
	Power consumption (nominal)	50W	25W
	Dimensions with stand (W x H x D)	Portrait: 378 x 528~628 x 235 mm Landscape: 491 x 472~572 x 235 mm	Portrait: 560 x 412~512 x 202 mm Landscape: 338 x 571~624 x 202 mm
	Dimensions w/o stand (W x H x D)	Portrait: 378 x 491 x 84 mm Landscape: 491 x 378 x 84 mm	Portrait: 560 x 335 x 61 mm Landscape: 335 x 560 x 61 mm
	Net weight with stand	12.8 kg	DE WP version: 7.2 kg DE WH version: 5.9 kg
	Indications for use	The Nio Color 3MP LED Medical Flat Panel Display System is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners. The display may be used in dental applications.	The Nio Color 2MP LED Medical Flat Panel Display System is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners. The display may be used in dental applications.
9. Performance testing	The bench tests mentioned below were performed to validate the device characteristics that differ from the predicate device:		
	<b>Modification to device</b>	<b>Test performed</b>	
	Change in LCD panel	PPVR (Product Producibility Validation Report)	
	Change in chassis housing	Environmental tests	

	Change in packaging	Environmental tests
	Change in electronics board	Environmental tests Electrical Safety tests EMC tests
	Updated firmware	Firmware tests
	<p>The tests showed that the device has similar characteristics compared to the predicate device and did not reveal new issues of safety and performance.</p> <p>Animal testing has not been performed.</p>	
10. Conclusion	<p>The Nio Color 2MP 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 characteristics compared to the predicate device and did not reveal new issues of safety and performance.</li> </ul>	