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

April 5, 2017

Barco NV
% Ms. Helena Soenen
Regulatory Affairs Officer
President Kennedypark 35
Kortrijk 8500
BELGIUM

Re: K170837
Trade/Device Name: Nio Color 3MP (MDNC-3421)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: March 15, 2017
Received: March 21, 2017

Dear Ms. Soenen:

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.
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)*

K170837

Device Name
Nio Color 3MP (MDNC-3421)

Indications for Use *(Describe)*
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.

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 (in accordance with 21 CFR 807.92)

1. Company	Barco N.V. Healthcare Division 35 President Kennedypark B-8500 Kortrijk BELGIUM
2. Contact person	Helena Soenen Regulatory Affairs Officer
3. Date of submission	15 March 2017
4. Device information	Trade name/model: Nio Color 3MP (MDNC-3421) Common name: MDNC-3421 Classification name: System, image processing, Radiological Classification code: PGY Regulation number: 892.2050
5. Predicate device	Nio Color 3MP (MDNC-3321) cleared under 510(K) K131295
6. Device description	The MDNC-3421 is a derivative of the MDNC-3321. The modifications are: ✓ PLD panel instead of NLT panel ✓ Change in packaging (smaller size) ✓ Updated firmware ✓ Change in type of material from steel to aluminum (inside metal housing) ✓ For the dental radiology market, this display will be marketed with the screen in landscape orientation
7. Intended Use of the Device	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.

8. Comparison of technological characteristics

Specification	**MDNC-3421**	**MDNC-3321**
Screen technology	TFT AM Color LCD IPS	TFT AM Color LCD IPS
Active screen size (diagonal)	540 mm (21.3")	540 mm (21.3")
Active screen size (H x V)	433 x 325 mm (17.0 x 12.8")	433 x 325 mm (17.0 x 12.8")
Aspect ratio (H:V)	4:3	4:3
Resolution	3MP (2048 x 1536)	3MP (2048 x 1536)
Pixel pitch	0.2155 mm	0.2155 mm
Color imaging	Yes	Yes
Gray imaging	Yes	Yes
Viewing angle (H, V)	176°	176°

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Uniform Luminance Technology (ULT)	Yes	Yes
Per Pixel Uniformity (PPU)	No	No
Ambient Light Compensation (ALC)	No	No
Backlight Output Stabilization (BLOS)	Yes	Yes
Maximum luminance	800 cd/m²	800 cd/m²
DICOM calibrated luminance (ULT off)	400 cd/m²	400 cd/m²
Contrast ratio (typical)	1400:1	1400:1
Response time (Tr + Tf)	40 ms	40 ms
Video input signals	DVID Dual Link, DisplayPort	DVID Dual Link, DisplayPort
USB ports	1 upstream (endpoint), 2 dow nstream	1 upstream (endpoint), 2 dow nstream
USB standard	2.0	2.0
Power consumption (nominal)	50W	50W
Power save mode	Yes	Yes
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: 378 x 528~628 x 235 mm Landscape: 491 x 472~572 x 235 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: 378 x 491 x 84 mm Landscape: 491 x 378 x 84 mm
Net weight with stand	12.8 kg	12.8 kg
Intended 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 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.

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**
PLD panel instead of NLT panel	PPVR (Product Producibility Validation Report)
Change in packaging (smaller size)	Environmental tests
Updated firmware	Firmware tests
Change in type of material from steel to aluminum (inside metal housing)	Environmental tests
For the dental radiology market, this display will be marketed with the screen	Clinical study

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	in landscape orientation and for general radiology, this display will be marketed in portrait orientation.
	Additional tests performed: Electrical Safety test (IEC 60601-1), EMC test (IEC 60601-1-2) 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. Animal testing has not been performed.
10. Conclusion	The Nio Color 3MP was found to be substantially equivalent to the predicate device, due to the following reasons: a) Device and predicate device have the same intended use b) The technological characteristics differences from the predicate device do not affect safety or effectiveness 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.

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