Barco N.V.
Julie Vandecandelaere
Regulatory Affairs Officer
President Kennedypark 35
KORTRIJK, 8500
BELGIUM

December 11, 2023

Re: K233693
Trade/Device Name: Nio Color 8MP (MDNC-8132)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: November 17, 2023
Received: November 17, 2023

Dear Julie Vandecandelaere:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233693

Device Name

Nio Color 8MP (MDNC-8132)

Indications for Use *(Describe)*

The display is intended to be used for 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.

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

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510(k) Summary

Prepared on: 2023-11-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Barco N.V.
Applicant Address	President Kennedypark 35 Kortrijk 8500 Belgium
Applicant Contact Telephone	+32 (0)56 26 23
Applicant Contact	Ms. Julie Vandecandelaere
Applicant Contact Email	julie.vandecandelaere@barco.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Nio Color 8MP (MDNC-8132)
Common Name	Medical image management and processing system
Classification Name	Display, Diagnostic Radiology
Regulation Number	892.2050
Product Code	PGY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230520	Nio Color 2MP (MDNC-2521)	PGY

Device Description Summary

21 CFR 807.92(a)(4)

The Nio Color 8MP (MDNC-8132) is a medical computer display designed for general radiology applications. The device can also be used for home reading in radiology.

The display is a high-resolution LCD monitor with improved technical characteristics that are important for accurate medical image review: high luminance, good luminance uniformity, good luminance ratio and luminance stability. The medical display comes with special image-enhancing technologies to ensure consistent brightness over the lifetime of the display, noise-free images (=good luminance uniformity), ergonomic reading and automated compliance with DICOM and other medical image quality standards and guidelines. These technologies help the radiologist to make a swift and accurate diagnosis.

The displays can be used optionally with the downloadable QAWeb Enterprise software, listed under D332294 as a class 1 device with product code LHO. QAWeb Enterprise is a calibration software that is intended as a quality assurance software for the displays. QAWeb Enterprise software helps to keep the display DICOM compliant.

The display can be used optionally with the downloadable Intuitive Workflow Tools, cleared in K191845 as a class 2 device with product code PGY. The Intuitive Workflow Tools are accessories for image enhancement on diagnostic displays:

- SpotView: The Barco SpotView display feature allows focusing on a region of interest in an image by boosting the display's backlight such that the maximum luminance in provided inside the region of interest. SpotView also enables focused observation during reading by dimming images outside the region of interest and increasing the contrast in this region. Also magnification and inversion of pixels are possible with SpotView.

- AAM – Application Appearance Manager: This workflow tool allows you to set the luminance as well as the color space for each application that is on the workstation. There are often multiple windows open on a screen, but not all of them need the high brightness of the diagnostic applications.

These applications are addressed by the general term 'Intuitive Workflow Tools'.
The integration of the Intuitive Workflow Tools with the displays have been de-risked, verified and validated to ensure that they do not affect the safety and effectiveness of the displays.

The display can be used with or without the Barco MXRT display controller boards. The display controller board is installed in a PACS workstation computer, connected to the display. The display can optionally be used with a touchpad, which is a controlling device (e.g. like a mouse or trackball) that makes it easier to work with diagnostic images and to use the IWTs.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The display is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same.

Technological Comparison 21 CFR 807.92(a)(6)

Modifications between MDNC-8132 and MDNC-2521

The modifications are:
• New 32" 8 mega-pixel (3840*2160 resolution) LCD panel
• Updated multimedia board Hera 320D derived from Ares 300D, with similar functionality and design compared to MDNC-2521 (Ares 300D is the multimedia board from MDNC-2521 device)
• Addition of multimedia features (Webcam, speakers and microphone) for easier collaboration
• External power supply with similar functionality and design principle compared to MDNC-2521
• Updated display stand, with similar functionality and design principle compared to MDNC-2521
• New packaging, with similar functionality and design principle compared to MDNC-2521
• Updated firmware, with similar functionality and design principle compared to the respective predicate devices

The below performance bench tests are performed and corresponding results reported for the modified device MDNC-8132 in comparison to the already cleared device MDNC-2521 as per the Physical Laboratory Testing instructions in "Guidance for Industry and FDA Staff: Display Devices for Diagnostic Radiology", issued in 2022:

• Spatial resolution – MTF
• Pixel defects, Artifacts
• Temporal Response
• Maximum and Minimum Luminance
• Luminance response, Conformance to DICOM GSDF
• Angular Dependency of Luminance
• Luminance uniformity
• Reflection coefficient – Display Reflectance incl. Specular, Diffuse & Haze coefficients
• Veiling glare or small-spot contrast
• Color tracking

The tests showed that the MDNC-8132 has similar characteristics compared to already cleared device MDNC-2521 and did not reveal new issues of safety and performance.

Additionally, the MDNC-8132 is compliant to EMC and Safety standards, the environmental tests (climate, mechanical and packed) and software tests passed.

No animal testing or clinical testing has been performed.

As a conclusion we can state that the device MDNC-8132 is found to be substantially equivalent to the predicate device MDNC-2521, because:

- The indications for use are the same as the predicate device
- The technological characteristics discussed above do not raise questions of safety and effectiveness
- The bench tests show that the display characteristics are equivalent to those of the predicate device

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The below performance bench tests are performed and corresponding results reported for the modified device MDNC-8132 in comparison to the already cleared device MDNC-2521 as per the Physical Laboratory Testing instructions in "Guidance for Industry and FDA Staff: Display Devices for Diagnostic Radiology", issued in 2022:

- Spatial resolution – MTF
- Pixel defects, Artifacts
- Temporal Response
- Maximum and Minimum Luminance
- Luminance response, Conformance to DICOM GSDF
- Angular Dependency of Luminance
- Luminance uniformity
- Reflection coefficient – Display Reflectance incl. Specular, Diffuse & Haze coefficients
- Veiling glare or small-spot contrast
- Color tracking

The tests showed that the MDNC-8132 has similar characteristics compared to already cleared device MDNC-2521 and did not reveal new issues of safety and performance.

Additionally, the MDNC-8132 is compliant to EMC and Safety standards, the environmental tests (climate, mechanical and packed) and software tests passed.

No animal testing or clinical testing has been performed.

As a conclusion we can state that the device MDNC-8132 is found to be substantially equivalent to the predicate device MDNC-2521, because:

- The indications for use are the same as the predicate device
- The technological characteristics discussed above do not raise questions of safety and effectiveness
- The bench tests show that the display characteristics are equivalent to those of the predicate device