



Barco NV  
% Ms. Julie Vandecandelaere  
Regulatory Affairs Officer  
President Kennedypark 35  
Kortrijk, W-VL 8500  
BELGIUM

November 10, 2020

Re: K203106

Trade/Device Name: Nio Fusion 12MP (MDNC-12130)  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: Class II  
Product Code: PGY  
Dated: October 8, 2020  
Received: October 15, 2020

Dear Ms. 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 (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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 <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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.  
Director  
Division of Radiological Health  
OHT7: Office of In Vitro Diagnostics  
and Radiological Health  
Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K203106

Device Name

Nio Fusion 12 MP (MDNC-12130)

Indications for Use (Describe)

The display is intended to be used in displaying and viewing digital images, including standard and multiframe digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis 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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| <b>510(k) Summary (in accordance with 21 CFR 807.92)</b> |   |
|--|---|
| 1. Company   | Barco N.V.<br>Healthcare Division<br>35 President Kennedypark<br>B-8500 Kortrijk<br>BELGIUM   |
| 2. Contact person  | Julie Vandecandelaere<br>Regulatory Affairs Officer<br>Tel: +32 (0)56 26 13 19<br>julie.vandecandelaere@barco.com   |
| 3. Date of submission                                    | 08 October 2020   |
| 4. Device information                                    | Trade name/model: Nio Fusion 12MP (MDNC-12130)<br>Common name: MDNC-12130<br>Classification name: System, image processing, Radiological<br>Classification code: PGY<br>Regulation number: 892.2050   |
| 5. Predicate device                                      | Nio Color 5.8MP (MDNC-6121) cleared under 510(K) K170476.   |
| 6. Device description                                    | <p>The MDNC-12130 (Nio Fusion 12MP) is a medical computer display designed for both PACS and breast imaging applications. It consists of a 30.9" 12 mega-pixel (4200x2800 resolution) LCD panel with integrated LED backlight.</p> <p>The panel is integrated into the display housing body with an internal mechanics chassis structure, that also integrates the electronics, sensors and power supply. The display module is supported by a display stand.</p> <p>Internal sensors and controllers measure, control and stabilize the device. SoftGlow Lights are integrated as an ancillary function for user comfort and can be lit to illuminate the desk and to create some ambient lighting in the reading room.</p> <p>The 31" 12MP (4200x2800 resolution) MDNC-12130 display can be compared to a dual-head, 2 x 21" 5.8 MP (2100x2800 resolution) MDNC-6121 display system.</p> <p>The MDNC-12130 is a derivative of the MDNC-6121.</p> <p>The modified display is effectively identical to the predicate device except for the following changes:</p> <ul style="list-style-type: none"> <li>✓ 31" 12 mega-pixel (4200x2800 resolution) LCD panel, compared to 2 x 21inch 5.8 MP LCD panel of a dual-head MDNC-6121 display system</li> <li>✓ New housing, display stand and internal mechanics, with similar functionality and design principle compared to MDNC-6121 or any other Barco diagnostic display</li> </ul> |

|  | <ul style="list-style-type: none"> <li>✓ Change in electronics board, with similar functionality and design principle compared to MDNC-6121 or any other Barco diagnostic display; including:</li> <li>✓ Integration of the power supply adaptor into the device, compared to an external power adapter for MDNC-6121</li> <li>✓ Updated firmware, with similar functionality and design principle compared to MDNC-6121 or any other Barco diagnostic display</li> <li>✓ Change in packaging, with similar functionality and design principle compared to MDNC-6121 or any other Barco diagnostic display</li> <li>✓ Addition of SoftGlow Task Light and Wall Light ancillary function for user comfort</li> </ul>  |  |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
|--|--|--|----------------------------|------------------------------------|-------------|-----------------------------|------------------------------|---------------------------|--|--|--|---|---|--------------------|--|--|-------------------------------|----------------|----------------|--------------------------|----------------------------------|-----------------------------|--------------------|---|-----|------------|-----------------------------|--|--------------------------------|--|--|-----------------------------------|------------------------|------------------------|
| <p><b>7. Intended Use of the Device</b></p>                  | <p>The display is intended to be used in displaying and viewing digital images, including standard and multiframe digital mammography, for review, analysis, and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.</p> <p>Note: There are no changes to the indications for use statement from that of the unmodified device.</p>  |  |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| <p><b>8. Comparison of technological characteristics</b></p> | <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr style="background-color: #cccccc;"> <th style="text-align: center;">Item</th> <th style="text-align: center;">Predicate Device (K170476)</th> <th style="text-align: center;">Device for which listing is sought</th> </tr> </thead> <tbody> <tr> <td>Device name</td> <td>Nio Color 5.8MP (MDNC-6121)</td> <td>Nio Fusion 12MP (MDNC-12130)</td> </tr> <tr style="background-color: #cccccc;"> <td colspan="3"><b>Display Technology</b></td> </tr> <tr> <td></td> <td>a-Si TFT active matrix LCD with LED backlight</td> <td>a-Si TFT active matrix LCD with LED backlight</td> </tr> <tr style="background-color: #cccccc;"> <td colspan="3"><b>Screen size</b></td> </tr> <tr> <td>Active screen size (diagonal)</td> <td>541 mm (21.3")</td> <td>784 mm (30.9")</td> </tr> <tr> <td>Active screen size (HxV)</td> <td>324.45 x 432.6 mm (12.77" x 17")</td> <td>653 x 435 mm (25.7 x 17.1")</td> </tr> <tr> <td>Aspect ratio (H:V)</td> <td>3:4 for each display in portrait mode, 3:2 overall for dual head system</td> <td>3:2</td> </tr> <tr> <td>Resolution</td> <td>5.8 MP (2100 x 2800 pixels)</td> <td>Native 12MP (4200 x 2800 pixels)<br/>Configurable to 2 x 5.8MP (2100 x 2800 pixels)</td> </tr> <tr style="background-color: #cccccc;"> <td colspan="3"><b>Optical characteristics</b></td> </tr> <tr> <td>Maximum luminance (panel typical)</td> <td>1000 Cd/m<sup>2</sup></td> <td>1200 Cd/m<sup>2</sup></td> </tr> </tbody> </table> | Item   | Predicate Device (K170476) | Device for which listing is sought | Device name | Nio Color 5.8MP (MDNC-6121) | Nio Fusion 12MP (MDNC-12130) | <b>Display Technology</b> |  |  |  | a-Si TFT active matrix LCD with LED backlight | a-Si TFT active matrix LCD with LED backlight | <b>Screen size</b> |  |  | Active screen size (diagonal) | 541 mm (21.3") | 784 mm (30.9") | Active screen size (HxV) | 324.45 x 432.6 mm (12.77" x 17") | 653 x 435 mm (25.7 x 17.1") | Aspect ratio (H:V) | 3:4 for each display in portrait mode, 3:2 overall for dual head system | 3:2 | Resolution | 5.8 MP (2100 x 2800 pixels) | Native 12MP (4200 x 2800 pixels)<br>Configurable to 2 x 5.8MP (2100 x 2800 pixels) | <b>Optical characteristics</b> |  |  | Maximum luminance (panel typical) | 1000 Cd/m <sup>2</sup> | 1200 Cd/m <sup>2</sup> |
| Item   | Predicate Device (K170476)   | Device for which listing is sought   |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| Device name  | Nio Color 5.8MP (MDNC-6121)  | Nio Fusion 12MP (MDNC-12130)   |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| <b>Display Technology</b>                                    |  |  |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
|  | a-Si TFT active matrix LCD with LED backlight  | a-Si TFT active matrix LCD with LED backlight                                      |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| <b>Screen size</b>   |  |  |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| Active screen size (diagonal)                                | 541 mm (21.3")   | 784 mm (30.9")   |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| Active screen size (HxV)                                     | 324.45 x 432.6 mm (12.77" x 17")   | 653 x 435 mm (25.7 x 17.1")  |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| Aspect ratio (H:V)   | 3:4 for each display in portrait mode, 3:2 overall for dual head system  | 3:2  |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| Resolution   | 5.8 MP (2100 x 2800 pixels)  | Native 12MP (4200 x 2800 pixels)<br>Configurable to 2 x 5.8MP (2100 x 2800 pixels) |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| <b>Optical characteristics</b>                               |  |  |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |
| Maximum luminance (panel typical)                            | 1000 Cd/m <sup>2</sup>   | 1200 Cd/m <sup>2</sup>   |                            |                                    |             |                             |                              |                           |  |  |  |   |   |                    |  |  |                               |                |                |                          |                                  |                             |                    |   |     |            |                             |  |                                |  |  |                                   |                        |                        |

|   |   |  |  |
|---|---|--|--|
|   | DICOM calibrated luminance  | 600 Cd/m <sup>2</sup>  | 600 Cd/m <sup>2</sup>  |
|   | Contrast ratio (panel typical)  | 1400:1   | 1500:1   |
| <b>Frame rate and refresh rate</b>                                |   |  |  |
|   | Frame rate  | 60 Hz (60 frames per second)   | 60 Hz (60 frames per second)   |
|   | Response time ((Tr + Tf)/2) (typical) Gray-to-gray  | 12.5 ms  | 10 ms  |
| <b>Pixel array, pitch, subpixel pattern, pixel aperture ratio</b> |   |  |  |
|   | Pixel array   | 0.1545 x 0.1545 mm RGB pixel   | 0.1554 x 0.1554 mm RGB pixel   |
|   | Pixel pitch   | 0.1545 mm  | 0.1554 mm  |
|   | DPI (dots per inch)   | 164  | 164  |
|   | Subpixel pattern  | 0.0515 x 0.1554 mm x 3 (RGB)   | 0.0518 x 0.1554 mm x 3 (RGB)   |
|   | Pixel aperture ratio  | 53.6%  | 56.5%  |
| <b>Display Interface</b>  |   |  |  |
|   | Video input signals   | DVI-D Dual Link (2x)<br>DisplayPort (2x)   | 2 x DisplayPort 1.2  |
| <b>Ambient light sensing</b>                                      |   |  |  |
|   | Ambient Light Sensor  | Yes  | Yes  |
| <b>Luminance calibration tools</b>                                |   |  |  |
|   | Front sensor  | Yes  | Yes  |
|   | Luminance calibration and stabilization   | Integrated Front sensor with luminance stabilization firmware<br><br>QAWeb quality control software (external) | Integrated Front sensor with luminance stabilization firmware<br><br>QAWeb quality control software (external) |
| <b>Quality-control procedures</b>                                 |   |  |  |
|   | QA software   | QAWeb  | QAWeb  |
|   | The technological characteristics discussed above show that the device MDNC-12130 has similar technological characteristics as the predicate device MDNC-6121 and do not reveal new issues of safety and performance. |  |  |
| 9. Performance testing  | The below performance bench tests are performed and corresponding results reported for the modified device MDNC-12130 in comparison to the predicate device MDNC-6121, as   |  |  |

|                |   |
|----------------|---|
|                | <p>per the instructions in “<i>Guidance for Industry and FDA Staff: Display Devices for Diagnostic Radiology</i>”, issued on October 2, 2017:</p> <ul style="list-style-type: none"> <li>• Spatial resolution – MTF</li> <li>• Pixel defects, Artifacts</li> <li>• Temporal Response</li> <li>• Maximum and Minimum Luminance, Luminance response</li> <li>• Conformance to DICOM GSDF</li> <li>• Angular Dependency of Luminance</li> <li>• Luminance uniformity</li> <li>• Stability of Luminance and Chromacity over Time and Operating Temperature</li> <li>• Spatial Noise – NPS</li> <li>• Reflection coefficient – Display Reflectance with Specular, Diffuse &amp; Haze coefficients</li> <li>• Veiling glare or small-spot contrast</li> <li>• Color tracking, Gray tracking</li> </ul> <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>Additionally, the modified device MDNC-12130 is compliant to EMC and Safety standards.</p> <p>No animal testing or clinical testing has been performed.</p> |
| 10. Conclusion | <p>The Nio Fusion 12MP (MDNC-12130) was found to be substantially equivalent to the predicate device MDNC-6121, due to the following reasons:</p> <ol 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> </ol>  |

