

**510(K) SUMMARY**

In accordance with 21 CFR 807.92

**1. Date of preparation**

September 1, 2006

MAR 19 2007

**2. Company information**

BarcoView  
35 President Kennedypark  
B-8500 Kortrijk, Belgium  
Tel. +32-(0)56-233-211  
Fax +32-(0)56-233-457

**3. Contact person**

Lieven De Wandel  
Official correspondent

**4. Device information**

- Trade name: Nio 5MP-21"
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

**5. Predicate device**

- Name: Coronis 5MP
- 510(k) number: K042221
- Manufacturer: Barco NV

**6. Device description**

Nio 5MP-21" is a display system for medical viewing. It consists of 3 components:

MDNG-5121 CB is a 21.3" grayscale LCD display. BarcoMed Nio is a fast high-resolution display controller board that plugs into a PACS workstation computer. NioWatch is a softcopy QA software application for local calibration and QA control.

The display system can be a single-head system or multi-head system. In the last case it contains multiple displays and display controller boards.

**7. Intended use**

"The Nio 5MP-21" is intended to be used in displaying and viewing digital images, including digital mammography, for review and analysis by trained medical practitioners. The Nio 5MP-21", containing the display MDNG-5121 CB, the software NioWatch and the graphic board

BarcoMed Nio, will be marketed as separate device.

## **8. Summary of technological characteristics**

The device consists of three components:

- One 5-megapixel flat panel display (MDNG-5121 CB)
- One 10-bit display controller (BarcoMed Nio board)
- NioWatch software

The flat panel display has a resolution of 2560x2048 pixels. It can be used in landscape and portrait mode.

The BarcoMed Nio display controller board is an ultra-high speed board with an 8-bit in, 10-bit out lookup table, providing 256 simultaneous shades of gray.

The NioWatch software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, the display of the Nio 5MP-21" system uses the same LCD panel but does not have a built-in front sensor (I-Guard). The accompanying software application has a lower functionality. However, the basic specifications and functions of both systems are the same.

The device does not come into contact with the patient. It does not control any life sustaining devices either.

## **9. Conclusion:**

The Barco Nio 5MP-21" is substantially equivalent to the predicate device, Coronis 5MP.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco Nio 5MP-21" contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

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### **3. Contact person**

Lieven De Wandel

Official correspondent

### **4. Device information**

- Trade name: MDNG-5121 CB
- Common name: Display system, medical image workstation, and others
- Classification name: System, Image Processing
- Classification number: 21 CFR 892.2050 / Procode 90LLZ

### **5. Predicate device**

- Name: MFGD 5421
- 510(k) number: K042221
- Manufacturer: Barco NV

### **6. Device description**

MDNG-5121 CB is a 21.3" grayscale LCD display for medical viewing. It is combined with NioWatch, a user-friendly software application that allows to optimize the display for DICOM-compliant viewing.

### **7. Intended use**

"The MDNG-5121 CB is intended to be used in displaying and viewing digital images, including digital mammography, for review and analysis by trained medical practitioners. The MDNG-5121 CB, which is part of the Nio 5MP-21" system, will be marketed separately.

### **8. Summary of technological characteristics**

The flat panel display has a resolution of 2560x2048 pixels. It can be used in landscape or portrait mode.

The NioWatch software allows to set the display function, display test patterns, calibrate the display and view additional display and display controller information.

Compared to the predicate device, the MDNG-5121 CB display uses the same LCD panel but does not have a built-in front sensor (I-Guard).

The device does not come into contact with the patient. It does not control any life sustaining devices either.

## **9. Conclusion:**

The Barco MDNG-5121 CB is substantially equivalent to the predicate device, MFGD 5421.

The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and intended use.

Any difference between both devices does not affect safety or efficacy.

The 510(k) Pre-Market Notification for the Barco MDNG-5121 CB contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
9200 Corporate Blvd.  
Rockville MD 20850

Lieven De Wandel  
Official Correspondent,  
BarcoView  
Medical Imaging Systems  
35 President Kennedypark  
B-8500 Kortrijk  
BELGIUM

MAR 19 2007

Re: K062621  
Trade/Device Name: Nio 5MP-21  
Regulation Number: 21 CFR §892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: December 13, 2006  
Received: December 18, 2006

Dear Mr. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such 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.



*Protecting and Promoting Public Health*

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); 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.

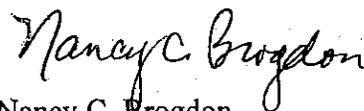
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

|                 |                                  |              |
|-----------------|----------------------------------|--------------|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology)          | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology)                      | 240-276-0120 |
| Other           |                                  | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,



Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**INDICATIONS FOR USE**

510(k) Number (if known): K062621

Device Name: Nio 5MP-21"

Indications for Use:

"The Nio 5MP-21" is intended to be used in displaying and viewing digital images, including digital mammography, for review and analysis by trained medical practitioners. The Nio 5MP-21", containing the display MDNG-5121 CB, the software NioWatch and the graphic board BarcoMed Nio, will be marketed as separate device.

Prescription Use XX

(Part 21 CFR 801 Subpart D)  
(21 CFR 801 Subpart C)

~~AND/OR~~

Over-The-Counter Use \_\_\_\_\_

(PLEASE DO NOT WRITE BELOW THIS LINE (CONTINUE ON ANOTHER PAGE IF NEEDED))

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K062621