

**1. Date of preparation**

NOV 16 2005

October 19, 2005

**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: Color Nio 2MP
- 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: Nio 2MP Medical flat panel display system
- 510(k) number: K042660
- Manufacturer: Barco NV

**6. Device description**

Color Nio 2MP is a display system for medical viewing. It consists of 3 components: E-2320 C is a 20.1" color LCD display. BarcoMed 2MP2CFe is a fast high-resolution display controller board that plugs into a PACS workstation computer. NioWatch is user-friendly software that allows to optimize the display for DICOM-compliant viewing.

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 Color Nio 2MP is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

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

The device consists of three components:

- One 2-megapixel flat panel display (E-2320 C)
- One 24-bit color display controller (BarcoMed 2MP2CFe board)
- NioWatch software

The flat panel display has a resolution of 1600x1200 pixels. It can be used in landscape and portrait mode.

The display controller board is an ultra-high speed board with a 32-bit in, 32-bit out look-up table.

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 Color Nio 2MP system has a color instead of grayscale LCD panel, while screen size and resolution are identical. The display controller board is a color board instead of a grayscale board.

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

## **9. Conclusion:**

The Barco Color Nio 2MP is substantially equivalent to the predicate device, Nio 2MP Medical flat panel display system.

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 Color Nio 2MP contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

## **1. Date of preparation**

October 19, 2005

## **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: E-2320 C
- 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: MFCD 2320
- 510(k) number: K040158
- Manufacturer: Barco NV

## **6. Device description**

E-2320 C is a 20.1" color LCD display for medical viewing. It is combined with NioWatch, a user-friendly software that allows to optimize the display for DICOM-compliant viewing.

## **7. Intended use**

The E-2320 C is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

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

The flat panel display has a resolution of 1600x1200 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 information.

Compared to the predicate device, the E-2320 C display contains a backlight sensor instead of a front sensor.

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

## **9. Conclusion:**

The Barco E-2320 C is substantially equivalent to the predicate device, MFCD 2320.

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 E-2320 C contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.



NOV 16 2005

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Lieven De Wandel  
BARCOVIEW  
Medical Imaging Systems  
35 President Kennedypark  
8500 Kortrijk  
BELGIUM

Re.: K052958  
Trade/Device Name: Color Nio 2MP and  
E-2320 C  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and  
communication system  
Regulatory Class: II  
Product Code: LLZ  
Dated: October 19, 2005  
Received: October 21, 2005

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 (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 (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); 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**

10(k) Number (if known): K052958

Device Name: Color Nio 2MP

**Indications for Use:**

"The Color Nio 2MP is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

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 OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy Beaton  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K052958

**INDICATIONS FOR USE**

10(k) Number (if known): K052958

Device Name: E-2320 C

**Indications for Use:**

"The E-2320 C is intended to be used in displaying and viewing digital images for review by trained medical practitioners. These devices must not be used in primary image diagnosis in mammography.

Prescription Use XX

(Part 21 CFR 801 Subpart D)

~~AND/OR~~

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

(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
(10(k) Number) K052958