510(k) Summary

In accordance with 21 CFR 807.92

K 052276

SEP 2 1 2005

1. Date of preparation

August 18, 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: Nio 2MP-20"
- 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

Nio 2MP-20" is a display system for medical viewing. It consists of 3 components:

E-2620 S is a 20.1" grayscale LCD display. BarcoMed Nio 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 Nio 2MP-20" 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-2620 S)
- One 10-bit display controller (BarcoMed Nio 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 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 2MP-20" system has a different LCD panel, while screen size and resolution are identical. The other components of the system 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 2MP-20" 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 Nio 2MP-20" contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

510(k) Summary

In accordance with 21 CFR 807.92

1. Date of preparation

August 18, 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-2620 S
- 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 2320 20-inch 2 Megapixel grayscale display
- 510(k) number: K033004
- Manufacturer: Barco NV

6. Device description

E-2620 S is a 20.1" grayscale 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-2620 S 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-2620 S display contains a backlight sensor instead of a front sensor, while their panels are identical.

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

9. Conclusion:

The Barco E-2620 S is substantially equivalent to the predicate device, MFGD 2320 20-inch 2 Megapixel grayscale display.

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-2620 S contains adequate information and data to enable FDA – CDRH to determine substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

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

Re: K052276
Trade/Device Name: Nio 2MP-20" and E-2620 S
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 18, 2005
Received: August 30, 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 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.

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

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): K052276

Device Name: Nio 2MP-20"

Indications for Use:

"The Nio 2MP-20" 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
510(k) Number K052276

INDICATIONS FOR USE

10(k) Number (if known): K052276

Device Name: E-2620 S

Indications for Use:

"The E-2620 S 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
510(k) Number K052276