K02 4358

510(k) Summary

as required by 807.92

MAR 2 5 2003

1. Company Identification

EIZO NANAO CORPORATION
153 Shimokashiwano-cho, Matto-shi, Ishikawa-ken, 924-8566, Japan
Tel: +81-76-274-2468
Fax: +81-76-274-2484

2. Official Correspondent

Hiroaki Hashimoto (Mr.)

3. Date of Submission

December 26, 2002

4. Device Trade name

20.1" Monochrome LCD Monitor, RadiForce G21

5. Common Name

Monitor, display, workstation, and others

6. Classification

Medical displays were classified in Class II per 21 CFR 890.2050.

7. Predicate Device

20.8" Monochrome LCD Monitor, FC-2091 manufactured by EIZO NANAO CORPORATION

8. Description of Device

20.1" Monochrome LCD Monitor, RadiForce G21 is a display for medical use. This product complies with radiation performance standards.

9. Intended Use

20.1" Monochrome LCD Monitor, RadiForce G21 is intended to be used in displaying for diagnosis of X ray or MRI, etc.

10. Compliance standards

Please refer to Appendix 1.

Appendix 1: Comparison Table with Predicate Device

Items	FC-2091	G21
510(k) Number	K022109	Not known
Panel Size and Type	53 cm (20.8") TFT monochrome LCD panel	51 cm (20.1") TFT monochrome LCD panel
Pixel Pitch	0.207 mm x 0.207 mm	0.255 mm x 0.255 mm
Available Cabinet Colors	Black	Black
Display Colors	1.531 grayscale tones	1.531 grayscale tones
Viewing Angles	H: 170°, V: 170°	H: 170°, V: 170°
Scanning Frequency (H, V)	92.86 - 96.72Hz, 60Hz	Analog: 31.5 kHz – 130kHz, 50 kHz – 85kHz Digital: 31.5 kHz – 75kHz, 60 Hz (VGA Text: 70Hz)
Native Resolutions	2048 x 1536 (landscape), 1536 x 2048 (portrait)	1600 x 1200 (landscape), 1200 x 1600 (portrait)
Brightness	650 cd/m^2	700 cd/m^2
Contrast Ratio	600 : 1 (typical)	1000 : 1 (typical)
DOT Clock	132MHz	Analog: 240MHz Digital: 162MHz
Response Time	50 ms (typical)	30 ms (typical)
Input Signals	DVI Standard 1.0	RGB Analog, DVI Standard 1.0
Input Terminals	DVI-D 24 pin	DVI-D 29 pin, BNC
USB Ports / Standard	1 upstream, 2 downstream / Rev. 1.1	1 upstream, 2 downstream / Rev. 1.1
Serial Ports	D-Sub 9 pin (Remote Out), Min DIN 6 pin (Remote In) Min DIN 8 pin (Photo Sensor)	D-Sub 9 pin (Remote Out), Min DIN 6 pin (Remote In) Mini DIN 8 pin (Photo Sensor)
Active Display Size (H x V)	424 mm x 318 mm (16.7" x 12.5")	408 mm x 306 mm (16.1" x 12.0")
Viewable Image Size	529 mm (20.8") (diagonal)	510 mm (20.1") (diagonal)
Power Management	DVI-DMPM	VESA DPMS, DVI-DMPM
Power Consumption	70 watts (typical)	55 watts (typical)
Power Save Mode	Less than 15 watts	Less than 8 watts
Dimensions (W x H x D)	With Stand: 368 mm x 520 – 592mm x 209 mm (14.5" x 20.5" x 23.3" x 8.2") Without Stand: 368 mm x 474 mm x 84 mm (14.5" x 18.7" x 3.3")	With Stand: 449 mm x 456 – 528 mm x 209 mm (17.7" x 18.0" x 20.8" x 8.2") Without Stand: 449 mm x 347 mm x 86.5 mm (17.7" x 13.7" x 3.4")
NET Weight	With Stand: 9.5 kg (20.9 lbs), Without Stand: 6.3 kg (13.9 lbs)	With Stand: 10.5 kg (23.1 lbs), Without Stand: 7.3 kg (16.1lbs)
Certifications & Standards	TUV/GM, CE, CB, EN60601-1, UL2601-1, CSA C22.2 No. 601-1, FCC-A, Canadian ICES-003-A, VCCI-A, FDA 510(k)	TUV/GM, c-TUV, CE, CB, EN60601-1, UL2601-1, CSA C22.2 No. 601-1, FCC-A, Canadian ICES-003-A, TUV/S, VCCI-A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 5 2003

EIZO NANAO Corporation
% Mr. Akira Wakayama
Safety Dept.
Cosmos Corporation
319 Akeno, Obata-cho
Watarai-gun, Mie-ken, 519-05
JAPAN

Re: K024358
Trade/Device Name: 20.1" Monochrome LCD Monitor, RadiForce G21
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 26, 2002
Received: December 30, 2002

Dear Mr. Wakayama:

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 (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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

December 25, 2002

STATEMENT OF INDICATIONS FOR USE

510(k) Number (If known): K024358

Device Name: 20.1" Monochrome LCD Monitor

Indications for Use:

20.1" Monochrome LCD Monitor, RadiForce G21 is intended to use in displaying for diagnosis of X-ray or MRI etc.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024358