K041597

JUN 2 4 2004

510(k) Summary
as required by 807.92

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

June 8, 2004

4. Device Trade name

Monochrome LCD Monitor, RadiForce G22

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

Manufacturer	:	EIZO NANAO CORPORATION
Device Name	:	20.8" Monochrome LCD Monitor
Model Name	:	FC-2091
510(k) No.	:	K022109

8. Description of Device

RadiForce G22 is a monitor for medical use. G22 provides 2 mega pixel (1200 x 1600) resolution and 10-bit (1,024 tones) simultaneous grayscale display for accurate diagnosis in CT, DSA, and MRI, etc, except for a digital mammography system.

9. Intended Use

Monochrome LCD Monitor, RadiForce G22 is intended to be used in displaying for diagnosis of in CT, DSA, and MRI, etc. These intended usages are same as that of the predicate model of FC2091, K022109.

10. Comparison of technological characteristics between new device and predicate device

Please refer to Appendix 1.

11. Compliance standards

Please refer to Appendix 1.

Appendix 1: Comparison table with predicate device

Items	FC-2091	G22
510(k) Number	K022109	Not known
Panel Size and Type	53 cm (20.8") TFT monochrome LCD panel	19.6" Class Monochrome LCD Monitor
Pixel Pitch	0.207 mm x 0.207 mm	0.294 mm x 0.294 mm
Available Cabinet Colors	Black	Black, Gray
Display Colors	1.531 grayscale tones	1,024 million grayscale tones from a pallet of 3,061
Viewing Angles	H: 170°, V: 170°	H: 170°, V: 170°
Scanning Frequency (H, V)	92.86 - 96.72 Hz, 60 Hz	75 kHz, 60 Hz
Native Resolutions	2048 mm x 1536 mm (landscape), 1536 mm x 2048 mm (portrait)	1200 mm x 1600 mm
Brightness	650 cd/m^2	800 cd/m^2
Contrast Ratio	600 : 1 (typical)	600 : 1 (typical)
DOT Clock	132MHz	162 MHz
Response Time	50 ms (typical)	40 ms (typical)
Input Signals	DVI Standard 1.0	DVI Standard 1.0
Input Terminals	DVI-D 24 pin	DVI-D 24 pin
USB Ports / Standard	1 upstream, 2 downstream / Rev. 1.1	1 upstream, 2 downstream / Rev. 2.0
Active Display Size (H x V)	424 mm x 318 mm	398 mm x 299 mm
Viewable Image Size	529 mm (20.8") (diagonal)	498 mm (diagonal)
Luminance Calibration	Software (Optional) Photo-sensor (Optional)	Software (Optional) Photo-sensor (Optional)
Power	AC100-120V/200-240V, 50/60Hz	AC100-120V/200-240V, 50/60Hz
Power Management	DVI-DMPM	DVI-DMPM
Power Consumption	70 watts (typical)	70 watts (typical)
Power Save Mode	Less than 15 watts	Less than 6 watts
Dimensions (W x H x D)	With Stand: 368 x 520 mm – 592 x 209 mm Without Stand: 368 mm x 474 mm x 84 mm	With Stand: 337 x 493 mm – 575 x 208.5 mm Without Stand: 337 mm x 441 mm x 78.5 mm
NET Weight	With Stand: 9.5 kg Without Stand: 6.3 kg	With Stand: 9.1 kg Without Stand: 5.9 kg
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, CE Medical Device Directive, CB (EN60601-1), cTUVus (UL2601-1, CSA C22.2 No. 601-1), FCC-B, Canadian ICES-003-A, VCCI-A, EIZO ECO Products 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2004

Mr. Hiroaki Hashimoto
Manager of Engineering
Management Section
EIZO NANAO Corporation
153 Shimokashiwano, Matto,
Ishikawa 924-8566
JAPAN

Re: K041597
Trade/Device Name: Monochrome LCD Monitor, RadiForce G22
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: June 8, 2004
Received: June 14, 2004

Dear Mr. Hashimoto:

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 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 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

June 8, 2004

Indications for Use

K041597

510(k) Number (if known): ~~Not known~~

Device Name: Monochrome LCD Monitor, RadiForce G22

Indications For Use:
RadiForce G22 is intended to be used in displaying for diagnosis in CT, DSA, or MRI, etc., except for a digital mammography system.

Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041597