510(k) Summary
as required by 807.92

K060845

APR 25 2006

1. Company Identification
EIZO NANAO CORPORATION
153 Shimokashiwano-cho, Hakusan-shi, Ishikawa-ken, 924-8566, Japan
Tel: +81-76-274-2468
Fax: +81-76-274-2484

2. Official Correspondent
Hiroaki Hashimoto (Mr.)
Manager of Engineering Management Section

3. Date of Submission
March 22, 2006

4. Device Trade name
Monochrome LCD Monitor, RadiForce GS310

5. Common/Usual Name
Image display system, medical image workstation, image monitor/display, and others

6. Classification Number
Medical displays classified in Class II per 21 CFR 892.2050.

7. Predicate Device

Manufacturer	:	EIZO NANAO CORPORATION
Device Name	:	Monochrome LCD Monitor
Model Name	:	RadiForce G33
510(k) No.	:	K052337

8. Description of Device
RadiForce GS310 is a 53cm (20.8") Monochrome LCD display for medical image viewing. GS310 displays high-definition medical imaging.

9. Intended Use
RadiForce GS310 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device is not specified for digital mammography system.

10. Technological Characteristics
GS310 employs smaller grayscale tones than that of G33. The sole modification is 3-bit ratio in sub-pixel opening areas for GS310. Comparison table of the principal characteristics of 2 devices in Attachment 1 shows that new and predicate devices are substantially equivalent in the areas of technical characteristics, general functions.

Appendix 1: Comparison Table with Predicate Device

Items	G33	GS310
510(k) Number	K052337	Not known
Panel Size and Type	53 cm (20.8") TFT Monochrome LCD panel	53 cm (20.8") TFT Monochrome LCD panel
Cabinet Color	Black	Black
Pixel Pitch	0.207 x 0.207mm	0.207 x 0.207mm
Ratio of Sub-pixel Opening Areas	4: 2: 1	4: 4: 4
Grayscale Tones	4,096 from a pallet of 8,161	1,024 from a pallet of 8,161
Viewing Angles	H: 170°, V: 170°	H: 170°, V: 170°
Scanning Frequency (H, V)	31-100kHz, 48-71.5Hz (VGA Text: 69-71Hz) Frame synchronous mode: 59-61Hz	31-100kHz, 48-71.5Hz (VGA Text: 69-71Hz) Frame synchronous mode: 59-61Hz
Native Resolutions	1536 x 2048 (landscape) 1536 x 2048 (portrait)	1536 x 2048
Brightness	700 cd/m² (Typical)	700 cd/m² (Typical)
Contrast Ratio	700: 1 (typical)	900: 1 (typical)
DOT Clock	165 MHz	165 MHz
Response Time	50 ms (typical)	50 ms (typical)
Active Display Size (H x V)	318 x 424 mm	318 x 424 mm
Viewable Image Size	529 mm (20.8") (diagonal)	529 mm (20.8") (diagonal)
Luminance Calibration	Built-in swing calibration sensor provided.	Built-in swing calibration sensor provided.
Input Signals	DVI Standard 1.0	DVI Standard 1.0
Input Terminals	DVU-D 24 pin	DVU-D 24 pin
USB Ports / Standard	1 upstream, 2 downstream	1 upstream, 2 downstream
Power	AC100-120V, 200-240V, 50/60Hz	AC100-120V, 200-240V, 50/60Hz
Power Management	DVI-DMPM	DVI-DMPM
Dimensions (W x H x D)	With Stand: 368 x 515.5 mm – 597.5 x 209 mm Without Stand: 368 x 486 x 90 mm	With Stand: 368 x 515.5 mm – 597.5 x 209 mm Without Stand: 368 x 486 x 90 mm
Certifications & Standards	TUV/GM, CE Medical Device Directive, CB (EN60601-1), cTUVus (UL2601-1, CSA C22.2 No. 601-1), VCCI-B, FCC-B, Canadian ICES-003-A, CCC	TUV/GM, CE Medical Device Directive, CB (EN60601-1), cTUVus (UL2601-1, CSA C22.2 No. 601-1), VCCI-B, FCC-B, Canadian ICES-003-A, CCC

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

APR 25 2006

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

Re: K060845
Trade/Device Name: Monochrome LCD Monitor, RadiForce GS310
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 9, 2006
Received: March 28, 2006

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 (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

510(k) Number (if known): Not known K060845

Device Name : Monochrome LCD Monitor, RadiForce GS310

Indications For Use:

RadiForce GS310 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. The device is not specified for 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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060845