K062053

# 510(k) Summary
as required by 807.92

AUG - 7 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
June 28, 2006

4. Device Trade name
Monochrome LCD Monitor, RadiForce GS320

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 G310 |
| 510(k) No. | : | K060845 |

8. Description of Device
RadiForce GS320 is a 54cm (21.3") Monochrome LCD display for medical image viewing. GS310 displays high-definition medical imaging.

9. Intended Use
RadiForce GS320 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
GS320 employs smaller grayscale tones than that of GS310. The only modification is that the panel size became big with 54cm(21.3") from 53cm(20.8"). 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 | GS310 | GS320 |
|---|---|---|
| 510(k) Number | K060845 | Not known |
| | | |
| Panel Size and Type | 53 cm (20.8") TFT Monochrome LCD panel | 54 cm (21.3") TFT Monochrome LCD panel |
| Cabinet Color | Black | It is same as the following. |
| | | |
| Pixel Pitch | 0.207 x 0.207mm | 0.2115 x 0.2115mm |
| Ratio of Sub-pixel Opening Areas | 4: 4: 4 | It is same as the following. |
| Grayscale Tones | 1,024 from a pallet of 8,161 | It is same as the following. |
| Viewing Angles | H: 170°, V: 170° | It is same as the following. |
| Scanning Frequency (H, V) | 31-100kHz, 48-71.5Hz<br>(VGA Text: 69-71Hz)<br>Frame synchronous mode: 59-61Hz | It is same as the following. |
| | | |
| Native Resolutions | 1536 x 2048 | It is same as the following. |
| Brightness | 700 cd/m² (Typical) | It is same as the following. |
| Contrast Ratio | 900: 1 (typical) | 850: 1 (typical) |
| DOT Clock | 165 MHz | It is same as the following. |
| Response Time | 50 ms (typical) | It is same as the following. |
| Active Display Size (H x V) | 318 x 424 mm | 324 x 433 mm |
| Viewable Image Size | 529 mm (20.8") (diagonal) | 541mm (21.3") (diagonal) |
| | | |
| Luminance Calibration | Built-in swing calibration sensor provided. | It is same as the following. |
| | | |
| Input Signals | DVI Standard 1.0 | It is same as the following. |
| Input Terminals | DVU-D 24 pin | It is same as the following. |
| USB Ports / Standard | 1 upstream, 2 downstream | 1 upstream, 2 downstream/Standard Rev.2.0 |
| | | |
| Power | AC100-120V, 200-240V, 50/60Hz | It is same as the following. |
| Power Management | DVI-DMPM | It is same as the following. |
| | | |
| Dimensions (W x H x D) | With Stand:<br>368 x 515.5 mm<br>– 597.5 x 209 mm<br>Without Stand:<br>368 x 486 x 90 mm | With Stand:<br>376 x 522.5 mm<br>– 604.5x 208.5 mm<br>Without Stand:<br>376 x 500 x 92 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

AUG - 7 2006

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

Re: K062053
Trade/Device Name: Monochrome LCD Monitor, RadiForce GS320
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 3, 2006
Received: July 20, 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.xxx | (Gastroenterology/Renal/Urology | 240-276-0115 |
| 21 CFR 884.xxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 894.xxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
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

K062053

# Indications for Use

510(k) Number (if known): ~~Not known~~ K062053

Device Name : Monochrome LCD Monitor, RadiForce GS320

Indications For Use:

RadiForce GS320 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062053