K07-0131

# 510(k) Summary
**as required by 807.92**

FEB 15 2007

**1. Submitter Information**

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

**2. Official Correspondent**

Hiroaki Hashimoto (Mr.)
Manager of Engineering Management Section

**3. Date of Submission**

January 9, 2007

**4. Device Trade name**

Monochrome LCD Monitor, RadiForce GX220 and RadiForce GS220

**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 G22 |
| 510(k) No. | : | K041597 |

**8. Description of Device**

RadiForce GX220 and Radiforce GS220 are a 54cm (21.3") Monochrome LCD display for medical image viewing. RadiForce GX220 and RadiForce GS220 display high-definition medical imaging. The model difference between GX220 and GS220 are the built-in swing calibration sensor and the protection panel equipped with GX220 as standard feature.

**9. Intended Use**

RadiForce GX220 and Radiforce GS220 are intended to be used in displaying for diagnosis in CT, DSA, or MRI, etc., except for a digital mammography system.

**10. Technological Characteristics**

RadiForce GX220 and RadiForce GS220 are substantially equivalent to G22 (K041597). RadiForce GX220 and GS220 employ smaller grayscale tones than that of G22. The panel size became big with 54cm (21.3") from 19.6". Additional product innovations include Digital Uniformity Equalizer (DUE), which enables compensates for luminance non-uniformity. The built-in swing calibration sensor and the Protection Panel are equipped with GX220 as standard feature. Comparison table of the principal characteristics in Attachment 1 shows that new and predicate devices are substantially equivalent in the areas of technical characteristics, general functions. Regarding to upgrade in software, refer to Software Information for RadiCX ver.2.5 used for built-in swing calibration sensor (GX220), or optional photo sensor (GS220). The device does not come into contact with the patient. It does not control any life-sustaining device either. Any difference between both devices not affects safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

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

FEB 15 2007

Re: K070131
Trade/Device Name: Monochrome LCD Monitor, RadiForce GX220 and RadiForce GS220
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 9, 2007
Received: January 16, 2007

Dear Mr. Hishimoto:

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

K070131

# Indications for Use

510(k) Number (~~if known): Not known~~ K070131

Device Name : Monochrome LCD Monitor, RadiForce GX220 and RadiForce GS220

Indications for Use:

RadiForce GX220 and RadiForce GS220 are 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K070131