K052344

510(k) Summary

as required by 807.92

SEP 14 2005

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.)
Manager of Engineering Management Section

3. Date of Submission

August 23, 2005

4. Device Trade name

Color LCD Monitor, RadiForce R31 & R31-C

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	:	20.8" Color LCD Monitor
Model Name	:	RadiForce R22
510(k) No.	:	K033466

8. Description of Device

RadiForce R31 and R31-C are 53cm (20.8") Color LCD displays for medical viewing. Each model produces hi-crisp images for modality applications and 3D image fusion. The model difference between R31 and R31-C are the panel protector provided with R31-C and brightness only.

9. Intended Use

RadiForce R31 and R31-C are intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. These devices must not be used for digital mammography system.

10. Technological Characteristics

R31 and R31-C employs the maximum resolution value same as that of R22. Comparison table of the principal characteristics of these devices in Attachment 1 shows the new and predicate devices are substantially equivalent in the areas of technical characteristics, general function. Regarding to the change in software, refer to Software Information for RadiCX used for optional calibration sensor kit. The device does not come into contact with the patient. It does not control any life-sustaining devices either. Any difference between these devices does not affect safety or efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

Eizo Nanao Corporation
% Mr. Shinich Yamanaka
Reviewer
Cosmos Corporation
319 Akeno, Obata-cho,
Watarai-gun, Mie-ken, 519-05
JAPAN

Re: K052344
Trade/Device Name: Color LCD Monitor, RadiForce R31
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 24, 2005
Received: August 29, 2005

Dear Mr. Yamanaka:

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 STATEMENT

510(k) Number (If known): K052344

Device Name : Color LCD Monitor, RadiForce R31

Indications for Use:

RadiForce R31 is intended to be used in displaying and viewing digital images for diagnosis of X-ray or MRI, etc. by trained medical practitioners. These devices must not be used for digital mammography system.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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 K052344