EIZO Corporation
Hiroaki Hashimoto
Senior Manager of Regulatory Compliance and Safety Department
153 Shimokashiwano
Hakusan, Ishikawa 924-8566
Japan

November 27, 2024

Re: K243221
Trade/Device Name: RadiForce RX570; RadiForce RX570-AR
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: October 7, 2024
Received: October 7, 2024

Dear Hiroaki 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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jessica Lamb
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243221

Device Name

RadiForce RX570;
RadiForce RX570-AR

Indications for Use *(Describe)*

This product is intended for use in clinical radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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U.S. Food and Drug Administration
Center for Devices and Radiological Health

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510(k) Summary

1. Submitter

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Phone: +81 (76) 274-2468
Contact Person: Hiroaki Hashimoto
Date of Prepared: October 7th, 2024

2. Device

- Name of Device: RadiForce RX570; RadiForce RX570-AR
- Common or Usual Name: 21.3 inch (54.1 cm) Color LCD Monitor
- Classification Name: Medical Image Management and Processing System (21 CFR 892.2050)
- Regulatory Class: II
- Product Code: PGY

3. Predicate Device

- Name of Device: RadiForce RX560, RX560-AR (K172738)
- Common or Usual Name: 54.1 cm (21.3 inch) class Color LCD Monitor
- Classification Name: Medical Image Management and Processing System (21 CFR 892.2050)
- Regulatory Class: II
- Product Code: PGY

- Name of Device: RadiForce GX540 (K151883)
- Common or Usual Name: 5MP Monochrome LCD Monitor
- Classification Name: Medical Image Management and Processing System (21 CFR 892.2050)
- Regulatory Class: II
- Product Code: PGY

4. Device Description

RadiForce RX570 is a color LCD monitor for viewing medical images including those of mammography. The color panel employs in-plane switching (IPS) technology allowing wide viewing angles and the matrix size (or resolution) is 2,048 x 2,560 pixels (5MP) with a pixel pitch of 0.165 mm.

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

There are two model variations, RX570 and RX570-AR. The difference of the two variations is the surface treatment of the display screens; the surface treatment of the RX570 is Anti-Glare (AG) treatment and that of the RX570-AR is Anti-Reflection (AR) coating.

Two RX570 monitors mounted on a single stand configuration is available identified by with "MD" like RX570-MD and RX570-AR-MD.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce RX570 based on the QC standards and guidelines and is capable of quantitative tests and visual tests defined by them. The RadiCS and its subset, RadiCS LE, are included in this 510(k) submission as an accessory to the RadiForce RX570.

RadiCS is Basic Documentation level and that it's being used unchanged from the predicate software. RadiCS supports the functions of the monitor RadiForce RX570 and it's not a medical imaging software.

5. Indications for use

This product is intended for use in clinical radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

6. Comparison of Technological Characteristics with the predicate device

The comparison table below enumerates information derived from the product brochure and measured values of the each device and different technological characteristics are discussed in it:

Attributes	Proposed Device: RadiForce RX570	Predicate Device: RadiForce RX560
Indications for Use		
	This product is intended for use in clinical radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.	This product is intended to be used in displaying and viewing digital images, including standard and multiframe digital mammography, for review, analysis and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.
Display Technology		
	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)
Screen size		
	54.1cm / 21.3" Aspect ratio: 4 : 5	54.1cm / 21.3" Aspect ratio: 4 : 5
Backlight type		
	LED	LED
Frame rate and refresh rate		
Digital Scanning Frequency (H / V)	31 - 135 kHz / 23 - 61 Hz Frame synchronous mode: 23.5 - 25.5 Hz, 47 - 51 Hz	31 - 135 kHz / 23 - 61 Hz Frame synchronous mode: 23.5 - 25.5 Hz, 47 - 51 Hz
Pixel pitch		
Pixel pitch	0.165 mm x 0.165 mm	0.165 mm x 0.165 mm
Subpixel pattern	RGB Vertical Stripe	RGB Vertical Stripe
Pixel aperture ratio	0.627	0.656
Subpixel driving (spatial and temporal dithering)		
Independent Subpixel drive	N/A	N/A
Dithering	3bit FRC	3bit FRC
Display Interface		
Input video signals	DVI-D (dual link) x 1, DisplayPort x 2	DVI-D (dual link) x 1, DisplayPort x 1
Output video signals	DisplayPort x 1 (daisy chain)	DisplayPort x 1 (daisy chain)
Video bandwidth		
	DVI : 25-290MHz DisplayPort : 25-290MHz	DVI: 290MHz DisplayPort: 290MHz

User controls		
OSD	CAL Switch / FineContrast / Color Mode	CAL Switch / FineContrast / Color Mode
	Mode Skip	Mode Skip
	Hybrid Gamma PXL	Hybrid Gamma PXL
	Brightness	Brightness
	Contrast	Contrast
	Temperature	Temperature
	Gamma	Gamma
	Hue	Hue
	Saturation	Saturation
	Gain	Gain
	SelfQC	SelfQC
	Sharpness Recovery	Picture Expansion
	DP Daisy Chain	Sharpness Recovery
	PinP	DP Daisy Chain
	Orientation(H/W Pivot)	Orientation (H/W Pivot)
	Power Save	Power Save
	DP Power Save	DP Power Save
	Language	EcoView Sense
	OSD Information	Language
	Indicator	OSD Information
	Input Selection	Indicator
	Key Lock	Input Selection
	LEA (Life Expectancy Analyzer)	Logo
	USB Selection for KVM Switch	Key Lock
	Grayscale Warning	LEA (Life Expectancy Analyzer)
		DDC for Medical
		Grayscale Warning
RadiCS	Complete QC Tests	Complete QC Tests
	Calibration	Calibration
	Task Setting	Task Setting
	History Management	History Management
	Asset Management	Asset Management

Ambient light sensing		
Ambient light sensor	Photo Diode Position: In the upper right bezel of the screen Software tool: RadiCS	Photo Diode Position: In the upper right bezel of the screen Software tool: RadiCS
Touch-screen technology		
	N/A	N/A
Luminance calibration tools		
	Integrated optical sensor External optical sensor Calibration software: RadiCS	Integrated optical sensor External optical sensor Calibration software: RadiCS
Quality-control procedures		
	Software: RadiCS AAPM On-line Report No. 03:2005 compliant	Software: RadiCS AAPM On-line Report No. 03:2005 compliant
Software/Firmware		
	N/A	N/A

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the RX570.

7. Performance Testing

The bench tests below were performed on the RadiForce RX570 following the instructions in "Guidance for Industry and FDA Staff: Display Devices for Diagnostic Radiology" issued on September 28, 2022:

- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- The maximum number allowed for each type of pixel defects/faults
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in TG18 guideline
- Measurement of temporal response
- Measurement of Luminance
- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of the angular dependency of luminance response in horizontal, vertical and diagonal directions
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in TG18 guideline
- Performance data on luminance stability
- Measurement of noise expressed as noise power spectrum (NPS)
- Measurement of display reflections including specular, diffuse and haze components
- Measurement of small-spot contrast ratio
- Measurement of Color tracking and Gray tracking

The test results showed that the RadiForce RX570 has display characteristics equivalent to those of the predicate device, RadiForce RX560 or RadiForce GX540.

Besides, the display characteristics of the RadiForce RX570 meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce RX570.

8. Conclusion

The RadiForce RX570 was determined to be substantially equivalent to the predicate device due to the following reasons:

- The stated intended use is substantially the same as that of the predicate device.
- It was confirmed that the technological characteristics differences from those of the predicate device do not affect the safety or the effectiveness.
- The bench tests demonstrated that the display characteristics are equivalent to those of the predicate device.