DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

EIZO Corporation
% Mr. Hiroaki Hashimoto
Manager
153 Shimokashiwano
Hakusan, Ishikawa 924-8566
JAPAN

November 18, 2014

Re: K143098
Trade/Device Name: 3MP Color LCD Monitor, RadiForce RS340
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: October 24, 2014
Received: October 28, 2014

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. 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.

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 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143098

Device Name
3MP Color LCD Monitor, RadiForce RS340

Indications for Use *(Describe)*
This product is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

EIZO Corporation, 153 Shimokashiwano, Hakusan, Ishikawa
924-8566 Japan

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510(k) Summary (in accordance with 21 CFR 807.92)

1. Company

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Fax: +81 (76) 274-2484

2. Contact Person

Hiroaki Hashimoto

3. Date of Summary

November 14th, 2014

4. Device Information

- Trade Name/Model: RadiForce RS340
- Common Name: 3MP Color LCD Monitor
- Classification Name: Display, Diagnostic Radiology
- Regulation Number: 21 CFR 892.2050, Product Code PGY

5. Predicate Device

- 3MP Color LCD Monitor, RadiForce RX340 (K113562)

6. Device Description

RadiForce RS340 is a color LCD monitor for viewing medical images other than those of mammography. The color panel employs in-plane switching (IPS) technology allowing wide viewing angles with the matrix size (or resolution) of 1,536 x 2,048 pixels (3MP).

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.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce RS340 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 RS340.

7. Intended Use

This product is intended to be used in displaying and viewing digital images for review, analysis and diagnosis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

8. Comparison of Technological Characteristics

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

Attributes	**RadiForce RS340**	**RadiForce RX340**	**Explanation of Differences**
Display Performance/Specifications			
Screen technology	IPS TFT Color LCD Panel	IPS TFT Color LCD Panel	-
Viewing angle (H, V)	H: 176°, V: 176°	H: 170°, V: 170°	Eizo uses typical data for very low contrast provided by the panel manufacturers
Active screen size	324.8 mm x 433.1 mm	323.7 mm x 431.6 mm	-
Resolution	3MP (1,536 x 2,048)	3MP (1,536 x 2,048)	
Aspect ratio	3 : 4	3 : 4	-
Pixel pitch	0.211 mm x 0.211 mm	0.21075 mm x 0.21075 mm	-
Maximum luminance	800 cd/m^2	1,000 cd/m^2	Though the smaller maximum luminance value usually results in shorter period during which the calibrated luminance can be guaranteed, the guaranteed operating periods of the both devices are the same.
DICOM calibrated luminance	400 cd/m^2	400 cd/m^2	–
Contrast ratio	1400 : 1	1400 : 1	Eizo uses typical contrast ratio data provided by panel manufacturers.
Backlighting	LED	LED	-
Display Colors	From a palette of 68 billion colors: - 10-bit input (DisplayPort): 1.07 billion colors (maximum) - 8-bit input: 16.77 million colors	From a palette of 68 billion colors: - 10-bit input (DisplayPort): 1.07 billion colors (maximum) - 8-bit input: 16.77 million colors	-
Luminance non-uniformity compensation	Digital Uniformity Equalizer	Digital Uniformity Equalizer	-
Video Signal Input			
Input video signals	DVI-D (dual link) x 1, DisplayPort x 1	DVI-D (dual link) x 1, DisplayPort x 1	-

Scanning Frequency (H, V)	31 - 127 kHz / 29 – 61.5 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	31 - 127 kHz, 29 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 29.5 - 30.5 Hz, 59 - 61 Hz	-
Power Related Specifications			
Power Requirements	AC 100 - 240 V: 50 / 60 Hz	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	-
Power Consumption / Save Mode	110 W / Less than 1.6 W	125 W / Less than 3 W	The proposed device consumes less power than the predicate device in the power saving mode.
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
Miscellaneous Features/Specifications			
QC software	RadiCS	RadiCS	-
Sensors	Backlight Sensor, Presence Sensor	Backlight Sensor, Presence Sensor, Integrated Front Sensor (IFS), Ambient Light Sensor	For the predicate device without IFS, the use of an external sensor is assumed for QC tests and calibration.
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o stand (W x H x D)	376 x 505 x 98 mm	376 x 505 x 98 mm	-

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the RS340.

9. Performance Testing

The following bench tests were performed on the RadiForce RS340.

- 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 luminance non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance as specified in *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions*
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in the TG18 guideline
- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- The maximum number allowed for each type of pixel defects/faults

The test results showed that the RadiForce RS340 has display characteristics equivalent to those of the predicate device, RadiForce RX340 except one item, which was determined that it would not affect observer's performance.

Besides, the display characteristics of the RadiForce RS340 meet the pre-defined criteria when criteria are set.

No animal or clinical testing was performed on the RadiForce RS340.

10. Conclusion

The RadiForce RS340 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 different from those of the predicate device do not affect the safety and the effectiveness.
- The bench tests demonstrated that the display characteristics are equivalent to those of the predicate device except one item, which was determined that it would not affect observer's performance.