December 18, 2023

EIZO Corporation
Hiroaki Hashimoto
Senior Manager
153 Shimokashiwano
Hakusan, Ishikawa 924-8566
Japan

Re: K231066
Trade/Device Name: CuratOR EX3242-FD
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: November 28, 2023
Received: November 28, 2023

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.

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.12.18 12:03:45 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
CuratOR EX3242-FD

Indications for Use *(Describe)*
This product is intended to provide color video displays of images from endoscopic/laparoscopic camera systems and other compatible medical imaging systems. This product is a wide-screen, high-definition monitor for real-time use during endoscopic/laparoscopic procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.

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.

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

Name Hiroaki Hashimoto
Department Regulatory Compliance and Safety

Telephone +81 (76) 274-2468

E-Mail hiroaki.hashimoto@eizo.com

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

510(k) Summary

1. Submitter

EIZO Corporation
153 Shimokashiwano, Hakusan,
Ishikawa 924-8566 Japan
Phone: +81 (76) 274-2468

Contact Person: Hiroaki Hashimoto
Date of Prepared: April 13th, 2023

2. Device

- Name of Device: CuratOR EX3242-FD
- Common or Usual Name: 81.3 cm (32.0 inch) class Color LCD Monitor
- Classification Name: Endoscope and accessories (21 CFR 876.1500)
- Regulatory Class: II
- Product Code: GCJ

3. Predicate Device

- Name of Device: OEV321UH (K220069)
- Common or Usual Name: Olympus 4K UHD LCD Monitor
- Classification Name: Endoscope and accessories
- (21 CFR 876.1500)
- Regulatory Class: II
- Product Code: GCJ

4. Device Description

CuratOR EX3242-FD 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 and the matrix size (or resolution) is 3,840 x 2,160 pixels (4K UHD) with a pixel pitch of 0.185 mm.

The CuratOR EX3242-FD is not a cyber device because it does not have the ability to connect to the internet.

5. 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	Subject Device	Predicate Device
Regulatory		
Device Name	CuratOR EX3242-FD	Olympus 4K UHD LCD Monitor OEV321UH
Regulatory Decision	This submission	K220069
Product Code	Same as predicate	GCJ
Regulatory Class	Same as predicate	II
Regulation Number	Same as predicate	876.1500
Regulation Name	Same as predicate	Endoscope and accessories
Classification Panel	Same as predicate	General and Plastic Surgery
Indications for Use	This product is intended to provide color video displays of images from endoscopic/laparoscopic camera systems and other compatible medical imaging systems. This product is a wide-screen, high-definition monitor for real-time use during endoscopic/laparoscopic procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.	The 4K UHD LCD Monitor is intended to provide 4K 2D color video displays of images from endoscopic/laparoscopic camera systems and other compatible medical imaging systems. The 4K UHD LCD Monitor is a wide- screen, high-definition, medical grade monitor for real-time use during endoscopic/laparoscopic procedures and is suitable for use in hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments.
Mode of Action	Same as predicate	This monitor displays color video images that are output

		from medical imaging systems on the LCD (liquid crystal display) panel. Liquid crystal and color filters are laid on the front of the flat light source (backlight) of the LCD panel. The LCD panel displays images by controlling the aperture of the liquid crystal according to input signals.
Intended Environment	Same as predicate	Hospital operating rooms, surgical centers, clinics, doctors' offices and similar medical environments
Intended Users	Same as predicate	Doctors and Assistants
System Parameters and Specifications		
Power	Same as predicate	AC 100-240V/ 50-60Hz
Dimensions (excluding max. protrusions)	760.8 × 463.8 × 91.6 mm	753.9 × 476.3 × 79.2mm
Display Dimension	Same as predicate	2D
Input Signals	12G-SDI, 3G-SDI, DisplayPort, HDMI, DVI-D, DC IN	12G-SDI1, 12G-SDI2, 3G-SDI, DisplayPort, HDMI, DVI-D, DC IN
Output Signals	12G-SDI, DVI-D OUT, +5V DC OUT	12G-SDI1, 12G-SDI2, 3G-SDI, CloneOUT, +5V DC OUT, +12V DC OUT
Display Device	Same as predicate	LCD panel (IPS)
Backlight Device	Same as Predicate	LED
Viewing Angle	Same as Predicate	Right>89[deg] (CR>10) Left>89[deg] (CR>10) Up>89[deg] (CR>10) Down>89[deg] (CR>10)
Active Screen Size	708(H)×399(V) mm	697(H)×392(V) mm
Resolution	Same as predicate	3840 × 2160 pixels
Luminance	850[cd/m2] typ.	≥280[cd/m2]
Primary Colors	Same as predicate	RGB
Gamma Curve	1.8, 2.0, 2.2, 2.4, 2.6, DICOM, HLG, PQ	1.8, 2.0, 2.2, 2.4, 2.6, DICOM, Endoscope, HLG
Color Space	sRGB, BT.2020, Native	Auto, BT.709, BT.2020, Native
Refresh Rate	Same as predicate	50/60Hz

Frame Rate	Same as predicate	50/60 fps
Display Format	Same as predicate	Normal, Multi display, Flip display

It is clear that the technological characteristics differences discussed above do not affect the safety and the effectiveness of the EX3242-FD.

6. Performance Testing

No bench, animal or clinical testing was performed on the CuratOR EX3242-FD.

7. Conclusion

The CuratOR EX3242-FD 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.