ACULA Technology Corp.
℅ Tzu-Wei Li
Third Party Contact
Center For Measurement Standards Of Industrial
Bldg. 16, 321 Kuang Fu Rd,sec2
HSINCHU,
TAIWAN

June 13, 2024

Re: K241499
Trade/Device Name: 21.3" 5MP Color LCD Display UMD5-21B01
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: PGY
Dated: May 28, 2024
Received: May 28, 2024

Dear Tzu-Wei Li:

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,

Jessica Lamb, Ph.D.,
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K241499

Device Name
21.3" 5MP Color LCD Display UMD5-21B01

Indications for Use *(Describe)*
UMD5-21B01 is indicated for use in displaying 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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K241499

510(k) Summary

I. SUBMITTER

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Date Prepared: Apr. 22, 2024

II. DEVICE

Name of Device: 21.3” 5MP Color LCD Display UMD5-21B01

Common or Usual Name: UMD5-21B01

Classification Name: Display, Diagnostic Radiology (21 CFR 892.2050)

Regulatory Class: II

Product Code: PGY

III. PREDICATE DEVICE

510(k) Number: K200864

Model Name: 5MP Color LCD Monitors C53S+, C53SP+,
5MP Monochrome LCD Monitors G53S+, G53SP+

Applicant: Shenzhen Beacon Display Technology Co., Ltd.

Common Name: 5MP LCD Monitors C53S+, C53SP+, G53S+, G53SP+

Classification Name: Display, Diagnostic Radiology

Regulation Number: 21 CFR 892.2050

Product Code: PGY Device Class: 2

IV. DEVICE DESCRIPTION

UMD5-21B01 is a 5 mega pixels 21.3” color LCD display for viewing medical images including mammography and digital breast tomosynthesis. The resolution of the display is 2,048 x 2,560 pixels (5MP) with a pixel pitch of 0.165 mm and wide angle LCD technology (IPS) support Dual-link DVI and Displayport signals from workstation or personal computer.

Since factory calibrated 3 display modes, each of which is characterized by a specific curve (including DICOM GSDF), a specific luminance range and a pre-defined color temperature, are stored in Lookup Table (LUT) within the display, the tone curve is e.g. DICOM compliant regardless of the display controller used.

AcuCal, a general name for the calibration and quality control functions of UMD-series product, includes corresponding firmware (AcuCal-Pro) and management application of PC (AcuCal Manage). AcuCal-Pro is the controlling firmware of this LCD display. AcuCal-Pro can perform the luminance calibration without PC or workstation and also includes the quality control scheme to make sure display quality, especially DICOM conformance. AcuCal Manage is a PC application for managing a group of displays.

V. INDICATIONS FOR USE

The UMD5-21B01 is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The comparison table below provides information to support the substantial equivalence between the proposed device Color LCD Display UMD5-21B01 and predicate device Color LCD Display C53S+, C53SP+ (K200864) in terms of intended use, application and technological characteristics.

Comparison Item	Proposed Device 21.3" 5MP Color LCD Display UMD5-21B01	Predicate Device 21.3" 5MP Color LCD Display C53S+, C53SP+	Explanation of Differences
510(k) number	Unknown	K200864	
Intended Use	The UMD5-21B01 is indicated for use in displaying radiological images (including full-field digital mammography and digital breast tomosynthesis) for review, analysis, and diagnosis by trained medical practitioners	The 5MP Color LCD Monitors C53S+, C53SP+ and 5MP Monochrome LCD Monitors G53S+, G53SP+ are intended to be used in displaying and viewing medical images for diagnosis by trained medical practitioners or certified personnel. They're intended to be used in digital mammography PACS, digital breast tomosynthesis and modalities including FFDM	Same
Screen Technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	Same
Viewing angle	CR>10 Horizontal: Typ.178 Vertical: Typ.178	CR>10 Horizontal: Typ.178 Vertical: Typ.178	Same
Resolution	5MP (2048 x 2560)	5MP (2048 x 2560)	Same
Aspect ratio	4:5	4:5	Same
Display area	Horizontal: 337.92mm Vertical: 422.4mm	Horizontal: 337.92mm Vertical: 422.4mm	Same
Pixel pitch	Horizontal: 0.165mm Vertical: 0.165mm	Horizontal: 0.165mm Vertical: 0.165mm	Same
Response time (Typ.)	25ms (On/Off)	25ms (On/Off)	Same

Maximum luminance	Min. 920cd/m2 Typ. 1,150cd/m2	Min. 920cd/m2 Typ. 1,150cd/m2	Same
DICOM calibrated luminance	500cd/m2	500cd/m2	Same
Contrast ratio	Min.1600：1 Typ. 2000：1	Min.1600：1 Typ. 2000：1	Same
Backlighting	LED	LED	Same
Grayscale Tones	10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,384 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,384 tones	10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,384 tones 8-bit(DVI): 16.77 million 256 from a palette of 16,384 tones	Same
Luminance non-uniformity Compensation	-	-	Same
Input Video Signals	DVI-D x1 DisplayPort x1	DVI-D x1 DisplayPort x1	Same
Scanning Frequency	Landscape: Horizontal: 104.852KHz Vertical: 50Hz	Landscape: Horizontal: 104.852KHz Vertical: 50Hz	Same
Dot Clock	285 MHz	285 MHz	Same
Power Requirements	AC100-240V, 50/60Hz	DC 12V, 6.67A	Different between built-in power supply and built-out power supply
Power Consumption / Save Mode	85W Less than 1W	80W Less than 5W	In comparison with predicate device, UMD5-21B01 maximum power is higher, but it consumes less power in standby

			mode.
Power Management	DVI DPMS, DisplayPort 1.2a	DVI DPMS, DisplayPort 1.2	Different spec. version between DisplayPort 1.2 and DisplayPort 1.2a
QC Software	AcuCal	Beacon Monitor Manage	Different design
Sensors	Built- in Front Sensor Built-in ambient Light Sensor Built-in Backlight Sensor	Built- in Front Sensor (Only for C53SP+) Built-in ambient Light Sensor Built-in Backlight Sensor	Same
USB Ports / Standard	1 upstream, 3 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	In comparison with predicate device, UMD5-21B01 has one more downstream USB Port for service use
Dimensions w/o Stand (W x H x D)	359 x 458 x 75.9 mm	395.3 x 549.6/629.6 x 234.8 mm	Different industrial design

According to the above table, UMD5-21B01 is a medical device which has the same intended use as the predicate device. The difference in the above statement does not change the intended use. As a result, both devices have fundamentally the same intended use.

VII. PERFORMANCE DATA

The performance data bench tests below were performed on the UMD5-21B01 following the instructions in "*Guidance for Industry and Food and Drug Administration Staff: Display Devices for Diagnostic Radiology*":

- Measurement of spatial resolution expressed as modulation transfer function (MTF)
- Measurement of pixel aperture ratio
- 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 Assessment of Display Performance for Medical Imaging Systems by AAPM Task Group 18 (TG18 guideline)
- Measurement of temporal response Performance data (provided by Innolux, LCD panel vender)
- Measurements of the maximum and minimum luminance that the device outputs as used in the application under recommended conditions and the achievable values
- Verification of the conformance to DICOM GSDF as specified in TG18 guideline
- Measurement of the angular dependency of luminance response in horizontal, vertical and diagonal directions
- Measurement of noise expressed as noise power spectrum (NPS)
- Measurement of display reflections including specular, diffuse and glare components
- Measurement of small-spot contrast ratio
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in TG18 guideline
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in TG18 guideline

XIII. CONCLUSIONS

After analyzing all testing data and comparing it with the predicated device, it can be concluded that UMD5-21B01 is substantially equivalent to the predicate device (K200864) with respect to technological characteristic, application and intended use.

The specifications of the primary component employed by the proposed device are the same as those of the predicate device, and other differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.