May 21, 2024

ACULA Technology Corp
Sheng-Sung Jian
Director of R&D
11, Alley 21, Lane 20, Rd. Dashing, Luchu Dist.
TAOYUAN, 33862
TAIWAN

Re: K233336
Trade/Device Name: 21.3" 3MP Color LCD Display UMD3-21B01 (MD3-21B01)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: PGY
Dated: April 12, 2024
Received: April 16, 2024

Dear Sheng-Sung Jian:

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,

for

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)*

K233336

Device Name
21.3" 3MP Color LCD Display UMD3-21B01(MD3-21B01)

Indications for Use *(Describe)*
The 3MP Color LCD Display UMD3-21B01 (MD3-21B01) is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

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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# 510(k) Summary

## I. SUBMITTER

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Phone: +886-3-3135577

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Contact Person: Sheng-Sung Jian

Email: SSJian@acula.com.tw

Date Prepared: September 19, 2023

## II. DEVICE

Name of Device: 21.3” 3MP Color LCD Display UMD3-21B01 (MD3-21B01)

Common or Usual Name: UMD3-21B01 (MD3-21B01)

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

Regulatory Class: II

Product Code: PGY

## III. PREDICATE DEVICE

510(k) Number: K201211

Model Name: C32S+, C32SP+

Applicant: Shenzhen Beacon Display Technology Co., Ltd.

Common Name: 3MP LCD Monitors C32S+, C32SP+

Classification Name: Display, Diagnostic Radiology

Regulation Number: 21 CFR 892.2050

Product Code: PGY Device Class: 2

## IV. DEVICE DESCRIPTION

UMD3-21B01 (MD3-21B01) is a 3 mega pixels 21.3” color LCD display for viewing medical images, not including mammography. The resolution of the display is 1,536 x 2,048 pixels (3MP) with a pixel pitch of 0.2115 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 MD-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 Mange is a PC application for managing a group of displays.

** UMD3-21B01 and MD3-21B01 refer to the same monitor. UMD3-21B01 is registered trade name for Acula Technology Corporation. MD3-21B01 is the model name for Acula Technology Corporation.

## V. INDICATIONS FOR USE

The 3MP Color LCD Display UMD3-21B01 (MD3-21B01) is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography.

## 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 UMD3-21B01 (MD3-21B01) and predicate device Color LCD Display C32S+, C32SP+ (K201211) in terms of intended use, application and technological characteristics.

| Comparison Item | Proposed Device 21.3" 3MP Color LCD Display UMD3-21B01 (MD3-21B01) | Predicate Device 21.3" 3MP Color LCD Display C32S+, C32SP+ | Explanation of Differences |
|---|---|---|---|
| 510(k) number | Unknown | K201211 | |
| Intended Use | The 3MP Color LCD Display UMD3-21B01 (MD3-21B01) is indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The display is not intended for mammography. | The 3MP Color LCD Monitors C32S+, C32SP+ are indicated for use in displaying radiological images for review, analysis, and diagnosis by trained medical practitioners. The displays are not intended for mammography. | Same |
| Display technology | Color (IPS) | Color (IPS) | Same |
| Screen size | 54.1cm / 21.3”<br>Aspect ratio: 3:4 | 54.1cm / 21.3”<br>Aspect ratio: 3:4 | Same |
| Viewing angle | Horizontal: Typ.178<br>Vertical: Typ.178 | Horizontal: Typ.178<br>Vertical: Typ.178 | Same |
| Native resolution | 1536 x 2048 | 1536 x 2048 | Same |
| Viewable image size | Horizontal: 324.86mm<br>Vertical: 433.15mm | Horizontal: 324.86mm<br>Vertical: 433.15mm | Same |

| | | | |
|---|---|---|---|
| Pixel pitch | Horizontal: 0.2115mm<br>Vertical: 0.2115mm | Horizontal: 0.2115mm<br>Vertical: 0.2115mm | Same |
| Response time (typical) | 25ms (On/Off) | 25ms (On/Off) | Same |
| Brightness (typical) | 1,000cd/m2 | 1,000cd/m2 | Same |
| Recommended brightness for | 500cd/m2 | 500cd/m2 | Same |
| Contrast ratio (typical) | 1500：1 | 1500：1 | Same |
| Backlight type | LED | LED | Same |
| Display colors | 10-bit (DisplayPort): 1.073 billion 1024 from a palette of 16,384 tones<br>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 |
| Input Video Signal | DVI-D (dual link) x1<br>DisplayPort x1 | DVI-D (dual link) x1<br>DisplayPort x1 | Same |
| Scanning Frequency (H, V) | 31 - 97 kHz/59 - 61 Hz | 31 - 97 kHz/59 - 61 Hz | Same |
| Video bandwidth | DVI: 216 MHz<br>DisplayPort: 216 MHz | DVI: 216 MHz<br>DisplayPort: 216 MHz | Same |
| Power Requirements | AC100-240V, 50/60Hz | DC 12 V / 6.67 A | Difference between built-in power supply and built-out power supply |
| Maximum Power Consumption | 80W | 80W | Same |

| | | | |
|---|---|---|---|
| Power save mode | Less than 1W | Less than 5W | In comparison with predicate device, UMD3-21B01 (MD3-21B01) consumes less power in power save mode. |
| Power Management | DVI DMPM, DisplayPort 1.2a | DVI DMPM, DisplayPort 1.2 | Same |
| Quality-control Software | AcuCal | Beacon Monitor Manage | Different design scheme |
| Sensors | Backlight sensor<br>Integrated front sensor<br>Ambient light sensor | Backlight sensor<br>Integrated front sensor<br>Ambient light sensor | Same |
| Luminance calibration tools | -Integrated optical sensor<br>-External optical sensor<br>-Calibration software: AcuCal-Pro | -Integrated optical sensor<br>-External optical sensor<br>-Calibration software: Beacon Monitor Manage | Different design scheme |
| USB Ports | 1 upstream, 3 downstream / Rev. 2.0 | Upstream<br>USB 2.0: Type-B x 1 | In comparison with predicate device, UMD3-21B01 (MD3-21B01) has one more downstream USB Port for service use |
| Brightness stabilization | Yes | Yes | Same |
| Digital uniformity equalizer | Yes | Yes | Same |

| | | | |
|---|---|---|---|
| Net weight | 10.9 kgs | 9.5 kgs | Different industrial design |
| Hole Spacing (VESA Standard) | 100 x 100mm | 100 x 100mm | Same |
| Dimensions w/o Stand (W x H x D) | 354.2 x 472.7 x 78.8 mm | 369 x 220 x 511.5 ~ 596.15 mm | Different industrial design |

According to the above table, UMD3-21B01 (MD3-21B01) 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 tests below were performed on the UMD3-21B01 (MD3-21B01) 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 the chromaticity 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 UMD3-21B01 (MD3-21B01) is substantially equivalent to the predicate device (K201211) with respect to technological characteristic, application and intended use. Some of the technological characteristics of UMD3-21B01 (MD3-21B01) are different from the predicate device, but they do not affect the safety and effectiveness, so no new risk is raised.

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.