The Linden Group Corp.
% Mr. Marc Leppla
Director
QUBYX Software Technologies Inc.
501 Silverside Road, Suite 105
WILMINGTON DE 19809

March 16, 2020

Re: K191705
Trade/Device Name: OptikView GUP2103CMI
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: PGY
Dated: February 20, 2020
Received: February 24, 2020

Dear Mr. Leppla:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191705

Device Name
OptikView GUP2103CMI

Indications for Use *(Describe)*
The OptikView GUP2103CMI with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners.
The device can NOT be used in primary image diagnosis in mammography.
The device can NOT be used for a life-support system.
The device is intended for prescription use.

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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510(K) Summary as required by 807.92

K191705

1. Company Identification

The Linden Group Corp.
2B Wing Drive
Cedar Knolls, NJ 07927 USA

2. Official Correspondent

Dr. Marc Leppla
President and CTO (Chief Technical Officer) leppla@qubyx.com

3. Date of Submission

07/19/2018

4. Device Trade name

OptikView GUP2103CMI

5. Common/Usual Name

Image display system, Color LCD Monitor, image monitor/display

6. Classification Number

Medical displays classified in Class II per 21 CFR 892.2050
Classification Name: Picture Archiving and Communications System

7.Predicate device

Name: Nio Color 3MP (MDNC-3421)
Manufacturer: BARCO NV
510(k) number: K170837
Classification Number: Medical displays classified in Class II per 21 CFR 892.2050
Classification Name: Picture Archiving and Communications System

8. Device description

The OptikView GUP2103CMI with QUBYX PerfectLum is a 21" color display for medical viewing.

It is combined with QUBYX PerfectLum and PerfectLum remote management, a user-friendly DICOM calibration and AAPM TG18 verification software suite. The software allows setting the display function to DICOM, displaying test pattern and performing acceptance and constancy tests.

The main difference from the predicate monitor is enhanced screen luminance. All other technological characteristics are similar to the predicate device

9. Indications for use

The OptikView GUP2103CMI with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners.
The device can NOT be used in mammography.
The device can NOT be used for a life-support system.
The device is intended for prescription use.

10. Comparison of technological characteristics

Specification	**GUP2103CMI**	**Nio Color 3MP (MDNC-3421)**
Screen technology	Color TFT Normally Black	TFT AM Color LCD IPS
Active screen size (diagonal)	540 mm (21.3")	540 mm (21.3")
Active screen size (H x V)	433.15 (H) x 324.86 (V) mm	433 x 325 mm (17.0 x 12.8")
Aspect ratio (H:V)	4:3	4:3
Resolution	3MP (2048 x 1536 pixels)	3MP (2048 x 1536)
Pixel pitch	0.2155 mm	0.2155 mm
Color imaging	Yes	Yes
Gray imaging	Yes	Yes
Viewing angle (H, V)	178°	176°
Backlight Output Stabilization	Yes	Yes
Maximum luminance	1000 cd/m2	800 cd/m2
DICOM calibrated luminance	500 cd/m2	400 cd/m2
Contrast ratio (typical)	1400:1	1400:1
Response time (Tr + Tf)	30 ms	40 ms
Video input signals	DVI-D Dual Link, DisplayPort, VGA	DVI-D Dual Link, DisplayPort
USB ports	1 upstream (endpoint), 2 downstream	1 upstream (endpoint), 2 downstream
USB standard	2.0	2.0
Power consumption (nominal)	80W	50W
Power save mode	Yes	Yes
Dimensions with stand (W x H x D)	Portrait: 377 x 473~607,5	Portrait: 378 x 528~628
Net weight with stand	11,3 kg	12.8 kg
Intended use	The OptikView GUP2103CMI is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners. The device can NOT be used in primary image diagnose in mammography The device can NOT be used for a life-support system.	The Nio Color 3MP LED Medical Flat Panel Display System is intended to be used for displaying and viewing digital images (excluding digital mammography) for review and analysis by trained medical practitioners.

11. Details of testing:

To verify DICOM conformance, a DICOM conformance test was performed, using QUBYX PerfectLum software and an X-Rite i1 Display Pro measurement device.
The test procedure was generated by the software in accordance with the requirements of the DICOM standard. It consisted of measurement steps, where the meter measured display's characteristics and the software recorded them. Then the software analyzed the results in comparison with target values, defined by DICOM standard, and generated the report, stating that the display is DICOM-conformant.

The display device has successfully passed DICOM conformance test, so it is compliant with DICOM Part 14 GSDF standard. So is the predicate device, so the two devices are substantially equivalent in this regard.

To verify AAPM TG18 conformance, an acceptance test was performed, using QUBYX PerfectLum software and an X-Rite i1 Display Pro measurement device.
The test procedure was generated by the software in accordance with the requirements of the AAPM TG18 standard and consisted of measurement and visual parts.

During the measurement steps, the meter measured display's characteristics and the software recorded them. During the visual steps, the user analyzed test patterns, generated by the software in accordance with AAPM standard. The software recorded the user's answers. Then the software analyzed the results in comparison with target values, defined by AAPM standard, and generated the report, stating that the display passes AAPM TG18 acceptance test.

The display device has successfully passed AAPM TG18 acceptance test, so it is compliant with AAPM TG18 standard and can be used as a primary category display for interpretation of medical images. The same is true for the predicate device, so the two devices are substantially equivalent in this regard.

Both devices have the same indications for use, except for predicate device it is not specified that it will not contact with the patient.
We can conclude that the new and predicate devices are substantially equivalent in terms of performance, indications for use, and principles of operation.

International standards: TÜV (ANSI/AAMI ES60601-1 and CAN/CSA C22.2 NO.60601-1); CE (IEC/EN 60601-1; EN60601-1-2); BSMI; CCC

12. Conclusion:

The comparison table shows that the subject device (OptikView GUP2103CMI) has the same intended use as the predicate. The main difference from the predicate monitor is enhanced screen luminance. All other technological characteristics are similar to the predicate device.

Both devices are compliant with DICOM Part 14 GSDF and AAPM TG18 standards. To verify DICOM and AAPM compliance for the subject device, AAPM acceptance test and DICOM conformance test were also performed
by QUBYX.