K131601
6.1
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JUL 07 2014

510(K) Summary

as required by 807.92

1. Company Identification
QUBYX Limited
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2. Official Correspondent
Mr. Marc Leppla
President and CTO (Chief Technical Officer)
leppla@qubyx.com

3. Date of Submission
May 21, 2013

4. Device Trade name
DELL U3014 with QUBYX PerfectLum bundle

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

7. Predicate device 1
Name: UltraSharp U3011
Manufacturer: DELL Inc.
510(k) number: K111385

Predicate device 2
Name: MD301 C4
Manufacturer: NEC Display Solutions Ltd.
510(k) number: K111237

8. Device description

The DELL U3014 with QUBYX PerfectLum is a 30" color display for medical viewing. It provides 2560x1600 resolution with an adjustable Look Up Table and a 10 bit panel.

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.

9. Intended use

The DELL U3014 with QUBYX PerfectLum is intended to be used for displaying and viewing of digital images, for review and analysis by trained medical practitioners.

The DELL U3014 must only be used in conjunction with QUBYX PerfectLum. The

device must not be used in primary image diagnosis in mammography.
The device can not be used for a life-support system and does not contact with the patient.

10. Comparison table – predicate device 1

	DELL U3014 with PerfectLum	Predicate device DELL U3011 with PerfectLum 510(k) number: K111385
Panel Type	IPS	IPS
Panel size	30" viewable	30" viewable
Native Resolution	2560 x 1600	2560 x 1600
Aspect Ratio	16:10	16:10
Pixel Pitch	0.25 mm	0.25 mm
Brightness (typical)	350 cd/m2	370 cd/m2
Contrast Ratio (typical)	1:1000	1:1000
Viewing Angle (typical)	178° Vert., 178° Hor.	178° Vert., 178° Hor.
Displayable Colors	1.07 billion colors	1.07 billion colors
Backlight	RGB LED	CCFL
DICOM calibration and AAPM verification software	bundled	bundled
Indications for Use	The DELL U3014 with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners. The DELL U3014 can be used only in conjunction with QUBYX PerfectLum. 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 does not contact with the patient.	The DELL U3011 with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners. The DELL U3011 can be used only in conjunction with QUBYX PerfectLum. The device can not be used in primary image diagnosis in mammography. The device can not be used for a life-support system.

Conclusion

DELL U3014 is the direct successor of the DELL U3011 model in the product line of UltraSharp displays, so the DELL U3014 with PerfectLum has exactly the same technical characteristics that predicate device 1 (DELL U3011 with PerfectLum) except maximum luminance (maximum luminance of the U3011 model is 370 cd/m2, while maximum luminance of the U3014 display is 350 cd/m2) and backlight type.

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

Details of testing:

To verify DICOM conformance, a DICOM conformance test was performed, using QUBYX PerfectLumsoftware 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.
The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and indented use

11. Comparison table – predicate device 2

	DELL U3014 with PerfectLum	Predicate device NEC MD301C4,510(k) number: K111237
Panel Type	IPS	IPS
Panel size	30" viewable	29.8" viewable
Native Resolution	2560 x 1600	2560 x 1600

Aspect Ratio	16:10	16:10
Pixel Pitch	0.25 mm	0.25 mm
Brightness (typical)	350 cd/m2	350 cd/m2
Contrast Ratio (typical)	1:1000	1:1000
Viewing Angle (typical)	178° Vert., 178° Hor.	178° Vert., 178° Hor.
Displayable Colors	1.07 billion colors	1.07 billion colors
Backlight	RGB LED	LED
DICOM calibration and AAPM verification software	bundled	no software, pre-calibrated to DICOM, compliant with AAPM TG 18
Indications for Use	The DELL U3014 with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners. The DELL U3014 can be used only in conjunction with QUBYX PerfectLum. 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 does not contact with the patient.	MD3OIC4 is intended to be used for displaying and viewing of digital images for diagnosis by trained physicians. Caution: MD3OIC4 cannot be used for a life-support system. This unit is designed as component of a final system which is compliance to IEC60601-1-1 requirements. MD3OI C4 must not be used in digital mammography.

Conclusion

DELL U3014 with PerfectLum and NEC MD301C4 have substantially equivalent technical characteristics, such as resolution, luminance, pixel pitch, viewing angle. The diagonal size of the NEC MD301C4 monitor is 0.2" smaller than that of the subject 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 performed by QUBYX. AAPM and DICOM conformance of the subject device is tested and verified by University of Arizona.

Details of testing:

To verify DICOM conformance, a DICOM conformance test was performed, using QUBYX PerfectLumsoftware 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 are intended to be used for displaying and viewing of digital images for diagnosis by trained physicians; both cannot be used for a life-support system and must not be used in digital mammography. The predicate device is designed as component of a final system which is compliant with IEC60601-1-1 requirements, while the indications for use for the new device do not specify what final system it will be used in. The DELL U3014 with PerfectLum is not intended for use in direct contact with the patient, while indications for use of the predicate device do not specify that.

We believe that these differences do not effect the safety and effectiveness of the DELL U3014 with PerfectLum to be substantially equivalent to the predicate device. The new and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application and indented use.

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

July 7, 2014

QUBYX Limited
% Ms. Alice Kotlyarenko
Marketing and Sales Assistant
80, rue Marechal Joffre
06000 Nice
FRANCE

Re: K131601
Trade/Device Name: Dell U3014 with QUBYX PerfectLum Bundle
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: June 6, 2013
Received: June 17, 2014

Dear Ms. Kotlyarenko:

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,

Michael D. O'Hara For

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K131601

Device Name: Dell U3014 with QUBYX PerfectLum bundle

Indications for Use: The DELL U3014 with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners.
The DELL U3014 can be used only in conjunction with QUBYX PerfectLum.
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 does not contact with the patient.
The device is intended for prescription use.

Prescription Use ___Yes___ AND/OR Over-The-Counter Use ___No___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K131601