K111385

JAN 30 2012

510(K) Summary of Safety and Effectiveness

as required by 807.92

1. Company Identification
QUBYX Limited
80, rue Marechal Joffre
06000 Nice, France
Tel: +33 4 97 03 23 00

2. Official Correspondent
Mr Marc Leppla
President and CTO (Chief Technical Officer)
leppla@qubyx.com

3. Date of Submission
May 05, 2011

4. Device Trade name
DELL UltraSharp U3011 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
Name: LCD3090WQXI
Manufacturer: NEC Display Solutions Ltd
510(k) number: K083916

K29

8. Device description
The DELL UltraSharp U3011 with QUBYX PerfectLum is a 30" color display for medical viewing. It provides 4 mega pixel (2560x1600) resolution with a adjustable Look Up Table and a 10 bit Panel.
It is combined with QUBYX PerfectLum 3.0 and PerfectLum remote QA, a user-friendly DICOM calibration and AAPM TG18 verification software suite. The software allows to set the display function to DICOM, display testpattern and perform acceptance and constancy tests.

9. Intended use

The DELL UltraSharp U3011 with QUBYX PerfectLum is intended to be used in displaying and viewing of digital images, for review and analysis by trained medical practitioners.

The DELL UltraSharp U3011 must only be used in conjunction with QUBYX PerfectLum 3.0

These devices must not be used in primary image diagnosis in mammography.

The device can not be used for a life-support system.

10. Conclusion

Compared to the predicate device, the U3011 uses a 10 bit instead of a 8 bit panel. The U3011 offer a typical brightness of 370 cd/m2 and the NEC 3090WQXi of 350 cd/m2. The Color Gamut is 102% for the NEC 3090WQXi and 117% for the DELL U3011.

The new and predicate device are substantially equivalent in the areas of technical characteristics, general function, application and indented use.

Comparison table

	DELL U3011 with PerfectLum version 3	Predicate device NEC LCD3090WQXI 510(k) number: K083916
Panel Type	IPS	IPS
Panel size	30" viewable	29.8" viewable
Native Resolution	2560 x 1600	2560 x 1600
Pixel Pitch	0.25 mm	0.25 mm
Brightness (typical)	370 cd/m2	350 cd/m2
Contrast Ratio (typical)	1000:1	1000:1
Viewing Angle (typical)	178° Vert., 178° Hor.	178° Vert., 178° Hor.
Displayable Colors	1.07 billion colors	16.7 million
DICOM calibration software and AAPM verification software	bundled	optional

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JAN 30 2012

Dr. Marc Leppla
President and CTO
QUBYX Limited
80 rue Marechal Joffre
06000 NICE
FRANCE

Re: K111385
Trade/Device Name: qubyx's DELL UltraSharp U3011 with QUBYX PerfectLum Bundle
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 13, 2011
Received: December 13, 2011

Dear Dr. 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. 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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

K111385

Indications for Use Form

510(k) Number: K111385

Device Name: qubyx's DELL UltraSharp U3011 with QUBYX PerfectLum Bundle

Indications for Use: The DELL UltraSharp U3011 with QUBYX PerfectLum is intended to be used in displaying and viewing of digital images, for review and analysis by trained medical practitioners.

The DELL UltraSharp U3011 must only be used in conjunction with QUBYX PerfectLum 3.0

These devices must not be used in primary image diagnosis in mammography.

The device can not be used for a life-support system.

Prescription Use No		Over-The-Counter Use Yes
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K111385