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

Qubyx Ltd.
% Mr. Marc Leppla
Director, CTO
80, rue Marechal Joffre
Nice, 06000
FRANCE

November 17, 2015

Re: K152847
Trade/Device Name: DIVA ZSP5812CMI with QUBYX PerfectLum Bundle
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY
Dated: September 16, 2015
Received: September 29, 2015

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. 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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152847

Device Name

DIVA ZSP5812CMI with QUBYX PerfectLum bundle

Indications for Use *(Describe)*

The DIVA ZSP5812CMI with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners.
The DIVA ZSP5812CMI 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary 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

09/16/2015

4. Device Trade name

DIVA ZSP5812CMI 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: EIZO RadiForce RX650
Manufacturer: EIZO Corporation
510(k) number: K134002

8. Device description

The DIVA ZSP5812CMI with QUBYX PerfectLum is a 58" 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.

9. Indications for use

The DIVA ZSP5812CMI with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners.
The DIVA ZSP5812CMI 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.

	Subject Device	Predicate device
	DIVA ZSP5812CMI with PerfectLum	**EIZO RadiForce RX650**
510(k) number:		K134002
Panel Type	MVA	IPS
Panel size	58" viewable	30" viewable
Native Resolution	3840 x 2160	3280×2048 0.197 x
Pixel Pitch	0.334 x 0.334 mm	0.197 mm
Brightness (typical)	400 cd/m2	400 cd/m2
Viewing Angle (typical)	178° Vert., 178° Hor.	176° Vert., 176° Hor.
Displayable Colors	1G colors (8-bit+FRC)	10-bit colors (DisplayPort) : 1.07 billion (maximum) colors; 8-bit colors: 16.77 million
DICOM calibration software and AAPM verification software	bundled	bundled
Backlight	LED	LED
DICOM precalibrated	YES	YES
Power Requirements	AC 100 to 240 V, 50 / 60 Hz	AC 100-120 V, 200-240 V, 50 / 60 Hz
Power Consumption	310W	225W
Certification and Compliance	cTÜVus (UL 60601-1, CAN/CSA C22.2 No.60601-1), CB (IEC 60601-1), TUV/RH (EN 60601- 1), FCC, CE, RoHS, WEEE	FCC Class B certified, C-Tick, ICES-003 Class B, CCC, UL 60601-1, RoHS, WEEE, GOST-R, DICOM Part 14, FDA 510k, EN 60601-1, IEC 60601-1, VCCI Class B, CSA C22.2 No. 60601-1, China RoHS
Indications for Use	The DIVA ZSP5812CMI with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, for review and analysis by trained medical practitioners. The DIVA ZSP5812CMI 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 EIZO RadiForce RX650 is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

Conclusion:

The comparison table shows that the subject device (DIVA ZSP512CMI with PerfectLum) has the same intended use as the predicate. Although the devices have some different technological characteristics, these differences do not make the sub ect device less safe and reliable, so the subject device fits for diagnostic use as the predicate device does.

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.
We can conclude that the new and predicate devices are substantially equivalent in terms of performance, indications for use, and principles of operation.