



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

February 25, 2016

Re: K160328
Trade/Device Name: DIVA ZSP2105CMI with QUBYX PerfectLum bundle
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: PGY,
Dated: January 22, 2016
Received: February 5, 2016

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned above the typed name and title.

FOR

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160328

Device Name

DIVA ZSP2105CMI with QUBYX PerfectLum bundle

Indications for Use (Describe)

The DIVA ZSP2105CMI with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, including those of mammography, for review, analysis and diagnosis by trained medical practitioners.

The DIVA ZSP2105CMI can be used only in conjunction with QUBYX PerfectLum.

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.

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510(K) Summary as required by 807.92

1. Company Identification

The Linden Group Corp.
2b Wing Dr Cedar Knolls
NJ 079271020
US

2. Official Correspondent

Mr. Marc Leppla (President and CTO of QUBYX Ltd.)
Contact details: email: leppla@qubyx.com Tel: +33 497032300

3. Date of Submission

22/01/2016

4. Device Trade name

DIVA ZSP2105CMI with QUBYX PerfectLum bundle

5. Common/Usual Name

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

6. Classification Number

Medical displays classified in Class II per 21 CFR 892.2050

7. Predicate device

Name: EIZO RadiForce GX540
Manufacturer: EIZO Corporation
510(k) number: K151883

Description of the device:

The DIVA ZSP2105CMI with QUBYX PerfectLum is a 21.3" monochrome display for medical viewing. It can be used for diagnostic viewing or normal reviewing purpose of medical images like computed tomography images, digitalized x-ray images, etc. 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 GSDF, displaying test patterns and performing acceptance and constancy tests according to AAPM TG18.

Indications for use:

The DIVA ZSP2105CMI with QUBYX PerfectLum is intended to be used for displaying and viewing of digital images, including those of mammography, for review, analysis and diagnosis by trained medical practitioners.

The DIVA ZSP2105CMI must only be used in conjunction with QUBYX PerfectLum. The device does not contact with the patient and can not be used for a life-support system. The device is intended for prescription use.

Device comparison table:

	Subject Device DIVA ZSP2105CMI with PerfectLum	Predicate device EIZO RadiForce GX540
510(k) number	K160328	K151883
Panel Type	IPS	IPS

Panel size	21.3"	21.3"
Native Resolution	2560 x 2048	2560 x 2048
Pixel Pitch	0.165mm x 0.165mm	0.165mm x 0.165mm
Brightness (typical)	1200 cd/m2	1200 cd/m2
Viewing Angle (typical)	170° Vert., 170° Hor.	176° Vert., 176° Hor.
Displayable Colors	1024 grayscale (10-bit)	10-bit (DisplayPort): 1,024 from a palette of 16,369 tones 8-bit: 256 from a palette of 16,369 tones
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	100W	108W
Certification and Compliance	CE (Medical Device Directive), 93/42/EEC, EN60601-1, EN60601-2, FCC Class B, cTUVus (UL 60601-1, CAN/CSA C22.2 No.60601-1), CNS14336-1, CNS13438), VCCI by ITE, Apr.2010, Class B (Regulation of VCCI V-2 and VCCI-3 and VCCI V-4), RoHS, WEEE	CE (Medical Device Directive), EN60601-1, UL60601-1, CSA C22.2 No. 601-1, IEC60601-1, VCCI-B, FCC-B, Canadian ICES-003-B, C-tick, RoHS, China RoHS, WEEE, CCC, GOST-R
Indications for Use	The DIVA ZSP2105CMI with QUBYX PerfectLum is intended to be used for displaying and viewing medical images, including those of mammography,	The EIZO RadiForce GX540 is intended to be used in displaying and viewing digital images, including standard and

	<p>for review, analysis and diagnosis by trained medical practitioners. The DIVA ZSP2105CMI can be used only in conjunction with QUBYX PerfectLum. The device can not be used for a life-support system. The device does not contact with the patient.</p>	<p>multi-frame digital mammography, for review, analysis and diagnosis by trained medical practitioners. It is specially designed for breast tomosynthesis applications.</p>
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The comparison table shows that the subject device (DIVA ZSP2105CMI with PerfectLum) has the same intended use as the predicate one.

Although the devices have some different technological characteristics, these differences do not make the subject 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 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.

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