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

September 16, 2016

VISUS Technology Transfer GmbH
% Axel Schreiber. M.D., Ph.D.
Vice President Research and Development
Universitaetsstrasse 136
Bochum, 44799
GERMANY

Re: K162008
Trade/Device Name: JiveX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 14, 2016
Received: July 20, 2016

Dear Dr. Schreiber:

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,

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

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)*
K162008

Device Name
JiveX

Indications for Use *(Describe)*
JiveX is a software only Picture Archiving and Communication System intended to display, process, read, report, communicate, distribute, store, and archive medical data which is available as DICOM or HL7 data, including mammographic images, and bio signals. JiveX also converts case related non-image documents, archives them as DICOM data and serves as a vendor neutral archive.
It supports the physician in diagnosis.
For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images must be used. Also monitors (displays) and printers which received FDA clearance for Mammography must be used.
Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.
Note: Web-based image distribution and mobile device display are not intended for diagnostic purposes.

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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

General Information

Manufacturer	VISUS Technology Transfer GmbH, Universitätsstr. 136 44799 Bochum, Germany
Registration Number	3007667119
Contact Person	Axel Schreiber, MD, PhD Vice President R&D Telephone +49 234 93693-0 Email: schreiber@visus.com
Date Prepared	September 16th, 2016
Trade Names	JiveX
Common Name	Picture Archiving and Communication Systems (PACS)
Classification Panel	Radiology
CFR Section	21 CFR §892.2050
Device Class	Class II
Product Code	LLZ

Safety and Effectiveness Information for Determination of Substantial Equivalence

Device Description and Intended Use
JiveX is a software only Picture Archiving and Communication System intended to display, process, read, report, communicate, distribute, store, and archive medical data which is available as DICOM or HL7 data, including mammographic images, and bio signals. JiveX also converts case related non-image documents, archives them as DICOM data and serves as a vendor neutral archive.
It supports the physician in diagnosis.
For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images must be used. Also monitors (displays) and printers which received FDA clearance for Mammography must be used.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.
Note: Web-based image distribution and mobile device display are not intended for diagnostic purposes.

A Communication Server is communicating, storing, and archiving DICOM data and also renders images for the web based image distribution.
Fat clients, rich in rendering and image manipulation functionality, are medical diagnostic and viewing workplaces. When using FDA cleared monitors diagnosis on digital mammography images is possible.
The web based clients are intended for image distribution on either personal computers or mobile devices.

Technological Characteristics
JiveX is a client server solution that is mainly implemented in Java. Clients run on personal computers with MS windows operating systems. The mobile client runs on iPAD. The server also runs on MS Windows operating systems using server hardware either directly or via virtual machines.
JiveX is a software only medical device.

The following table compares JiveX 5.0 with the predicate devices JiveX 4.7

	JiveX 5.0	**SE: JiveX 4.7**
510(k) number	K162008	K142750
Manufacturer	VISUS Technology Transfer GmbH	VISUS Technology Transfer GmbH
Design/Architect.	client / server	client / server
Operating systems	Server: Win. 7/8.1/10 Srv. 2008/ 2012 Client: Win. 7/8.1/10	Server: Win. XP/7/8.1/ Srv. 2003/2008/ 2012 Client: Win. XP/7/8.1
Image communication	TCP/IP, DICOM, proprietary internal image transfer protocol, proprietary interface to accept JPEG from an iPhone via web interface	TCP/IP, DICOM, proprietary internal image transfer protocol
Accepted Image Formats	DICOM data + data accepted as non DICOM and converted to DICOM for storage: PDF, standard and proprietary ECG formats	DICOM data + data accepted as non DICOM and converted to DICOM for storage: PDF, standard and proprietary ECG formats
Supported storage solutions	Local storage on HDD/RAID/DVD, Network: NAS, SAN, long term storage solutions	Local storage on HDD/RAID/DVD, Network: NAS, SAN, long term storage solutions
Image data compression	JPEG 2000 lossless & lossy, ZIP, JPEG lossy for web clients Display as received: JPEG lossless & lossy, RLE, MPEG-2	JPEG 2000 lossless & lossy, ZIP, JPEG lossy for web clients Display as received: JPEG lossless & lossy, RLE, MPEG-2
Web based access	Desktop & mobile devices (not intended for reading)	Desktop & mobile devices (not intended for reading)
Virtualization & Citrix support	Yes, VMware. Java and web clients can be distributed via Citrix.	Yes, VMware

	JiveX 5.0	**SE: JiveX 4.7**
User administr.	Centralized	Centralized
RIS/HIS integration	Image Call Up from RIS, Patient Information Reconciliation, Instance Availability, receive documents via HL7 MDM. Supported Standards: HL7, IHE	Image Call Up from RIS, Patient Information Reconciliation, Instance Availability. Supported Standards: HL7, IHE
IHE XDS	XDS-Consumer	no
Hardware	Windows based, manufacturer independent server, workstations and client hardware, iPAD	Windows based, manufacturer independent server, workstations and client hardware, iPAD
Image Processing Algorithms	- Zoom, Pan, Rotate, Flip, Magnify - Geometrical Measurements - ROI statistics - Mammography auto shutter - 3D Cross Reference - ECG measurements - Interpolation: nearest neighbor, bilinear - Filters: sharpen, CLAHE - Windowing and LUT mapping	- Zoom, Pan, Rotate, Flip, Magnify - Geometrical Measurements - ROI statistics - Mammography auto shutter - 3D Cross Reference - ECG measurements - Interpolation: nearest neighbor, bilinear - Filters: sharpen, CLAHE - Windowing and LUT mapping
Image Processing Algorithms 3D	- MPR - Max. Int. Projection - Min. Int. Projection - Volume Rendering - MIP for tomosynthesis data (not for diagnostic use) - 3D image registration	- MPR - Max. Int. Projection - Min. Int. Projection - Volume Rendering - MIP for tomosynthesis data (not for diagnostic use) - 3D image registration
Hanging protocols	Yes	Yes
Bookmarks	Yes: Captures	Yes: Captures

Discussion of differences and explanation of important differences
JiveX in release 4.7 (K142750) is a predecessor of the device. Functionality has been enhanced and ported to current operating systems and hardware. The most notable enhancements are:

1. The JiveX review client based clients and the web clients can be distributed within the institution via Citrix.
2. New module JiveX Photo Documentation Gateway that provides a proprietary interface to mobile devices. An iPhone App e.g. can query patient demographic information and can send back JPEG images together with meta data including the patient demographic information. JiveX converts these images into DICOM images and imports them.
3. The module JiveX HL7 Gateway has been enhanced with the possibility to receive documents from an information system via HL7 MDM. Also the JiveX HL7 Gateway provides patient demographic information via the IHE PDQm profile. In order to better fit into multi sited institutions and regional healthcare networks the HL7 Gateway supports the issuer of patient ID (assigning authority).

4. New module “JiveX XDS Consumer” that allows to query XDS registries and retrieve documents and images from an XDS repository or XDS source respectively. Plain text, PDF and CDA documents can be displayed.

There are three main lines of development in JiveX 5.0 compared to JiveX 4.7.

- Extend the integration of JiveX into the customers IT environment. The four bullet points mentioned above are accompanied by some smaller enhancements (e.g. improved handling of JPEG and PDF from mass-scanning, automated import of DICOM files from the file system, sending notification to the RIS also for archived or deleted studies)
- The complete user interface has been face lifted. The focus was on unifying the existing interfaces and giving a unique color scheme and graphical language. At the same time the pre-existing user interaction concepts have been maintained.
- Refactorings to improve uptime and data consistency: e.g. allowing services of the communication server to be restarted at runtime, replacing the data base engine, providing automated detection and repair functionality for inconsistent data (which was done manual before)

As a result JiveX 5.0 addresses more customer IT environments than JiveX 4.7 but basically provides the same services. This goes in-line with JiveX 5.0 having the same intended use as JiveX 4.7.

Summary of Non-Clinical Testing

Verification and validation is done through all development phases and includes

- review of requirements, software design, code
- Review and acceptance of newly implemented functionality
- Daily build of the (intermediate) product and performance of automated tests on unit, component, x-component and UI level
- Verification / validation of “off the shelf software”
- Informal test run of newly developed manual test cases and of functionality on risk
- Evaluation of selected software functionality with customers
- Formal test run of all manual test cases
- Additional impact testing for all changes after start of the formal test run

General Safety and Effectiveness Concerns

Using risk analysis potential hazards are identified. Potential hazards are controlled with design measures in the software and with verification and validation testing.
The device labelling contains instructions for use and any necessary cautions and warnings for safe and effective use.

Substantial Equivalence

JiveX is substantially equivalent to the following commercially available devices:

Manufacturer	Trade Name	510(k) number
VISUS Technology Transfer GmbH	JiveX 4.7	K142750

JiveX described in this 510(k) has an equivalent intended use, shares the technological characteristics and provides a similar feature set as the predicate devices.

JiveX does not raise any new issues of safety and efficacy.