Visus Health IT GmbH
Axel Schreiber
Vice President Research and Development
Gesundheitscampus-Sued 15-17
Bochum, 44801
GERMANY

October 23, 2018

Re: K181964
Trade/Device Name: JiveX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 29, 2018
Received: September 4, 2018

Dear Axel 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'hara -S

Digitally signed by Michael D. O'hara -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300226759, cn=Michael D. O'hara -S
Date: 2018.10.23 17:12:27 -04'00'

For

Robert A. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181964

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 of mammographic images are not intended for diagnostic purposes.
For users in the United States of America: Mobile device display is 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K181964

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 Health IT GmbH, Gesundheitscampus 13-15 44801 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	August 23rd, 2018
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.
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including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.
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For users in the United States of America: Mobile device display is 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 in the first place. As far as the limited functionality of the web clients allows for it, the web clients may also be used on personal computers for reading and reporting.

JiveX in release 5.0 (K162008) is a predecessor of the device. Functionality has been enhanced and ported to current operating systems and hardware. The most notable enhancements are:

1. JiveX Web has been qualified for reading. As far as the limited functionality of JiveX Web allows for it, it may now be used for reading and reporting. Nevertheless the main use case of the web clients remains image distribution.
2. Enhancements of the viewing clients include:
   - Optimized display of temporal series of 3D volumes: streamlined navigation to the same location in space at another point in time.
   - Curved MPR: multi planar reconstruction of views along a path curved in 3D
   - Support of presentation states in the web clients.
3. Enhancements of the Healthcare Content Management (HCM) infrastructure include:
   - refinement of the access privileges down to individual documents.
   - Handling of patient IDs from different institutions throughout the system using assigning authority IDs and master patient IDs.
   - Improvements of pre-fetching designed for use cases where image data is stored in 3rd party PACS.
   - The new module JiveX Signature Gateway provides an interface to 3rd party signature servers. It allows to electronically sign documents imported into the HCM system and to validate electronic signatures.
   - The new module JiveX WADO Gateway provides a web interface using the standard DICOM WADO-URI protocol. It allows to retrieve images or documents based on instance UID or the document ID.

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.

Discussion of differences

JiveX in release 5.0 (K162008) is a predecessor of the device. Functionality has been enhanced and ported to current operating systems and hardware. There are two main lines of development in JiveX 5.0.6 compared to JiveX 5.0

- Rounding off viewing functionality for the PACS. The most significant change is to allow JiveX Web for reading. The clinical functions have not changed but risk analysis and testing now also cover reading use cases. The basic reading functionality provided with JiveX Web was available with the JiveX Review based clients before. Therefore the intended use of JiveX remains the same. Only the exemption of the JiveX Web from the reading use case has been removed. The reading of mammographic images is still not allowed using JiveX Web.
- The infrastructure of the Healthcare Content Management System has been broadened. The same use cases are supported. The system now fits into more customer environments and provides some advanced functions like e.g. the support of electronic signatures.

As a result JiveX 5.0.6 is more versatile than JiveX 5.0 but basically provides the same services. This goes in-line with JiveX 5.0.6 having almost the same intended use as JiveX 5.0.

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
- Impact testing for all changes that had been introduced
- Formal test run of all manual test cases pertaining to new or modified functionality
- 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:	VISUS Technology Transfer GmbH
Trade Name:	JiveX 5.0
510(k) number:	K162008

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

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