Visus Health IT GmbH
% Axel Schreiber, M.D., Ph.D.
Vice President, Process & Agile Services
Gesundheitscampus-Sued 15-17
Bochum, 44801
GERMANY

April 14, 2020

Re: K200703
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: March 13, 2020
Received: March 18, 2020

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K200703

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.

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510(k) Summary

K200703

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 Process & Agile Services Telephone +49 234 93693-0 Email: schreiber@visus.com
Date Prepared	March 31st, 2020
Subject Device	**K200703**
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
Predicate Device	**K181964**
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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For users in the United States of America: Mobile device display is not intended for diagnostic purposes.

JiveX is a PACS software, with a Moderate level of concern.
A Communication Server is communicating, storing, and archiving images, documents and signal data via DICOM, HL7 and proprietary interfaces. It also renders images for the web-based image distribution.
The fat clients can be used as workstations for medical reading and reporting. They provide extensive functionality for image display and image processing. The reporting of digital mammography images is also supported.
The web-based clients are mainly intended for image distribution on personal computers and mobile devices. They offer less functionality than the fat clients. As far as the functionality allows for it, the web clients can also be used for reading and reporting on personal computers.

JiveX in release 5.0.6 (K181964) is a predecessor of the device. Functionality has been enhanced and ported to current operating systems and hardware. The most notable enhancements are:

1. Viewing clients:
   - Fused image display
   - Workflow support for manual spine labeling
   - Creation of videos from image series and export into the file system
2. Improvements for the maintenance of the system
   - Interface for external software to retrieve information for status monitoring of the JiveX system
   - Configuration of the web-clients for groups of users
3. Enhancements of the Healthcare Content Management (HCM) include:
   - Quality assurance workflow for documents

- The communication server can act as an integrated XDS source and repository: Incoming data is provided and registered in the document repository and can be registered at an XDS registry. Thus, XDS document consumers can retrieve the data.
- The new Module JiveX Connect allows for connectivity with patients and referring physicians: Patients get temporary access to their studies and can download the data. The access for referring physicians can be integrated into existing portal solutions.
- JiveX supports the IHE profile Imaging Object Change Management as the actor image manager (i.e. it receives and applies rejection notes for withdrawn objects). Withdrawn objects are no longer made available for the reading clients.
- Interface to a 3rd party web viewer for ecg reading. This web viewer (Cordiana DX) is a separate medical device. It can be called up from JiveX within the clinical context. Results are transferred back to JiveX. The correct transfer of the results is ensured by risk control measures.

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 5.0.6 (K181964) 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 5.2 compared to JiveX 5.0.6

- Rounding off viewing functionality for the PACS and streamlining existing workflows. New viewing functionality comprises e.g. image fusion. The preview panel, that gives an overview of loaded studies has been streamlined as well as the dialog to load additional studies. The performance for loading of multi frame data, especially the high resolution tomosynthesis data, has been greatly enhanced.
- The connectivity of the Healthcare Content Management System has been extended to include communication partners outside the institutions. The system now fits into more customer environments, especially hospital networks.

As a result, JiveX 5.2 is more versatile than JiveX 5.0.6 but basically provides the same services. This goes in-line with JiveX 5.2 having the identical intended use as JiveX 5.0.6.

The following table compares JiveX 5.2 with the predicate device JiveX 5.0.6

	JiveX 5.2	**SE: JiveX 5.0.6**
510(k) number	K200703	K181964
Manufacturer	VISUS Health IT GmbH	VISUS Health IT GmbH
Design / Architecture	client / server	client / server
Operating systems	Server: Win. 7/8.1/10 Srv. 2008/ 2012/2016/2019 Client: Win. 7/8.1/10; iOS 12, 13	Server: Win. 7/8.1/10 Srv. 2008/ 2012/2016 Client: Win. 7/8.1/10; iOS 10, 11

	JiveX 5.2	**SE: JiveX 5.0.6**
Image and document communication	TCP/IP, DICOM, HL7, IHE XDS, WADO-URI, proprietary internal image transfer protocol, proprietary interface to accept JPEG from an iPhone via web interface	TCP/IP, DICOM, HL7, IHE XDS, WADO-URI, proprietary internal image transfer protocol, proprietary interface to accept JPEG from an iPhone via web interface
Accepted Image Formats	DICOM data + data accepted as non DICOM and converted to DICOM for storage: PDF, JPG, TIFF, standard and proprietary ECG formats	DICOM data + data accepted as non DICOM and converted to DICOM for storage: PDF, JPG, TIFF, 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, LZ4, 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 (not intended for mammography reading). Mobile devices (not intended for reading)	Desktop (not intended for mammography reading). Mobile devices (not intended for reading)
Virtualization & Citrix support	Yes, VMware. Java and web clients can be distributed via Citrix.	Yes, VMware. Java and web clients can be distributed via Citrix.
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, receive documents via HL7 MDM. Supported Standards: HL7, IHE
IHE XDS	XDS-Consumer, Integrated Source Repository	XDS-Consumer
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 - 4D Navigation - ECG measurements - Interpolation: nearest neighbor, bi-linear, bi-cubic, Lanczos, b-spline - Filters: sharpen, CLAHE - Windowing and LUT mapping	- Zoom, Pan, Rotate, Flip, Magnify - Geometrical Measurements - ROI statistics - Mammography auto shutter - 3D Cross Reference - 4D Navigation - ECG measurements - Interpolation: nearest neighbor, bi-linear - Filters: sharpen, CLAHE - Windowing and LUT mapping

	JiveX 5.2	**SE: JiveX 5.0.6**
Image Processing Algorithms 3D	- MPR, curved MPR - Max. Int. Projection - Min. Int. Projection - Volume Rendering - MIP for tomosynthesis data (not for diagnostic use) - 3D image registration - fused display	- MPR, curved 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

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 pertaining to new or modified functionality
- Impact testing for all changes that had been introduced
- Extensive regression testing

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.

Conclusion
JiveX is substantially equivalent to the following commercially available device:

Manufacturer:	VISUS Health IT GmbH
Trade Name:	JiveX 5.0.6
510(k) number:	K181964

JiveX described in this 510(k) has the identical 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.