Visus Health IT GmbH
℅ Axel Schreiber, M.D., Ph.D.
VP Process & Agile Services
Gesundheitscampus-Süd 15-17
44801 Bochum
GERMANY

September 23, 2021

Re: K212321
Trade/Device Name: JiveX (Model Number / Release: 5.3)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: July 20, 2021
Received: July 26, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212321

Device Name
JiveX (Model Number / Release: 5.3)

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.
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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K212321

Section 5
“510(k) Summary”

of the Traditional 510(k) Premarket Notification Submission
for the medical device JiveX, release 5.3

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

Submitter

Manufacturer (Owner)	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	July 20th, 2021

Device

510(k) Number	K212321
Trade Names	JiveX
Common Name	Picture Archiving and Communication System (PACS)
Classification Panel	Radiology
CFR Section	21 CFR §892.2050
Device Class	Class II
Product Code	LLZ

Predicate Device

Predicate Device	**K200703**
Trade Names	JiveX
Common Name	Picture Archiving and Communication System (PACS)
Classification Panel	Radiology
CFR Section	21 CFR §892.2050
Device Class	Class II
Product Code	LLZ

Device Description

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 functions 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 functions than the fat clients. As far as the functions allow for it, the web clients can also be used for reading and reporting on personal computers.

Indications for 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.
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.

Comment: A note on regulatory requirements for peripherals, that might be used with the device, has been omitted from the Indications for Use. Otherwise the Indications for Use have not changed compared to the predicate device.

Comparison of Technological Characteristics

The subject device and the predicate device have identical technological characteristics: JiveX is a software only medical device (SaMD). The communication server and the fat clients for radiology reading are implemented in Java. The web clients are implemented in java script / type script, HTML and CSS.
The software is run on the customer's own hardware. Clients run on personal computers with MS windows operating systems. Alternatively, clients may be run on a server (-farm) and can be distributed using Citrix. The mobile client runs on iPAD. The server also runs on MS Windows operating systems using server hardware either directly or via virtual machines.

Tabular comparison of subject and predicate device:

	Subject Device	**Predicate Device (K200703)**
Name, Release	**JiveX 5.3**	**JiveX 5.2**
Manufacturer	VISUS Health IT GmbH	Same
Indications for 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. 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.	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.
Prescr./OTC	Prescription	Same
Design / Architecture	client / server	Same
Software only	Yes. Software as a Medical Device (SaMD)	Same
Operating systems	Server: Win. 10 Srv. 2012/2016/ 2019 Client: Win. 8.1/10; iOS 13, 14	Server: Win. 7/8.1/10 Srv. 2008/ 2012/2016/2019 Client: Win. 7/8.1/10; iOS 12, 13

	Subject Device	**Predicate Device (K200703)**
Image and document communication	TCP/IP, DICOM, HL7, IHE XDS, WADO-URI, proprietary internal data transfer protocols, 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	Same
Supported storage solutions	Local storage on HDD/RAID/DVD, Network: NAS, SAN, long term storage solutions	Same
Image data compression	JPEG 2000 lossless & lossy, ZIP, LZ4, JPEG lossy for web clients Display as received: JPEG lossless & lossy, RLE, MPEG-2	Same
Web based access	Desktop (not intended for mammography reading). Mobile devices (not intended for reading)	Same
Virtualization & Citrix support	Yes, VMware. Java and web clients can be distributed via Citrix.	Same
User administr.	Centralized	Same
Workflow support, RIS/HIS integration	Image Call Up from RIS, Patient Information Reconciliation, Instance Availability, receive documents via HL7 MDM. Supported Standards: HL7, IHE. PACS driven reading workflow.	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 Repository	XDS-Consumer, Integrated Source Repository
Hardware	Windows based, manufacturer independent server, workstations and client hardware, iPAD	Same
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	Same

	Subject Device	Predicate Device (K200703)
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, SUV calculation	- MPR, curved MPR - Max. Int. Projection - Min. Int. Projection - Volume Rendering - MIP for tomosynthesis data (not for diagnostic use) - 3D image registration - fused display
Hanging protocols	Yes	Same
Bookmarks	Yes: Captures	Same

Table 1: Tabular comparison of features and specifications

Performance Data

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

Based on the non-clinical performance testing the subject device was found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusions

While there are some differences between JiveX 5.3 and its predicate device, these differences are very minor and do not affect device substantial equivalence. JiveX 5.3 has the same basic operational principles and technical characteristics as its predicate device and it functions in the same manner. Additionally, it has the almost same indications for use. It is as safe, as effective, and performs as well as or better than its predicate device. Therefore, JiveX 3.5 is substantially equivalent to the predicate device cited within this submission