MedicalCommunications GmbH
℅ Mrs. Lena Sattler
Consultant
Orasi Consulting, LLC.
1655 Forest Drive
MEDINA OH 44256

February 18, 2020

Re: K200132
Trade/Device Name: Ashvins
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ, NFJ
Dated: January 17, 2020
Received: January 21, 2020

Dear Mrs. Lena Sattler:

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)*
K200132

Device Name
Ashvins

Indications for Use *(Describe)*

Ashvins is a modular software solution and is used for viewing, reporting, processing, storing, printing, and archiving, as well as for the exchange and distribution or web-based distribution of digital, multimodal medical images, including mammographic images and bio-signals, as well as findings and demographic information. Ashvins also collects, manages, and distributes patient-related and device-related information.

Ashvins offers advanced image processing functions such as multiplanar reconstruction, 3D reconstruction and measurement functions.

For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images and only preprocessed DICOM "For Presentation" images must be used. Existing regulatory or legal requirements regarding hardware, such as diagnostic monitors, that are applicable for diagnosing in respective imaging specialties must be observed.

Ashvins is designed to be used by trained professionals, including but not limited to physicians, radiologists, ophthalmologists, nurses, medical technicians, and assistants.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1. 510(k) Summary as required by section 807.92(c)

510(k)-number K200132

Date Prepared February 7, 2020

1.1 510(k) Owner/ Manufacturer

MedicalCommunicatoins GmbH

Max-Jarecki-Strasse 8

69115 Heidelberg, Germany

Telephone: +49 6221 7531 0

Facsimile: +49 6221 7531 119

Email: FDA@MedicalCommunications.com

Establishment Registration No.: 3003995303

1.2 Official Contact Person

Lena Sattler

President, Orasi Consulting, LLC.

1655 Forest Dr.

Medina, OH 44256

Telephone: (440) 554-3706

Facsimile: (866) 904-4315

E-Mail: lena@orasiconsulting.com

1.3 Common/Usual Name

Picture Archive And Communication System (PACS)

1.4 Proprietary or Trade Names

Proprietary Name:

- Ashvins

Trade Names:

- **Ashvins Diagnostic Workstation**
- **Ashvins Web Extreme**
- **Ashvins Image & Web Management (Data Management)**
- **HEYEX 2 / HEYEX PACS (Product Family: HEIDELBERG EYE EXPLORER)**

1.5 Classification Information

Classification Name:	System, Image Processing, Radiological [LLZ], System, Image Management, Ophthalmic [NFJ],
Medical Specialty:	Radiology
Device Class:	II
Product Code:	LLZ, NFJ

1.6 Product Code: Classification / CFR Title

LLZ, NFJ:	Class II § 21 CFR 892.2050
Regulation Name:	Picture Archiving and Communications System

1.7 Predicate Devices

Table 2: Primary Predicate Device, Secondary Predicate Device

Primary Predicate Device: JiveX 5.0 Radiology	Secondary Predicate Device: FORUM Ophthalmology
VISUS Health IT	Carl Zeiss Meditec AG
Device Class: II Product Code: LLZ 21 CFR 892.2050	Device Class: II Product Code: NFJ 21 CFR 892.2050
K142750	K122938

1.8 General Device Description

Device Description

Ashvins is a modular software solution and is used for viewing, reporting, processing, storing, printing, and archiving, as well as for the exchange and distribution or web-based distribution of digital, multimodal medical images, including mammographic images and bio-signals, as well as findings and demographic information. Ashvins also collects, manages, and distributes patient-related and device-related information.

Ashvins offers advanced image processing functions such as multiplanar reconstruction, 3D reconstruc-tion and measurement functions.

Ashvins does not utilize artificial intelligence or computer-aided diagnosis to identify abnormalities in medical images or to assist in diagnosis.

For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images and only preprocessed DICOM "For Presentation" images must be used. Existing regulatory or legal require-ments regarding hardware, such as diagnostic monitors, that are applicable for diagnosing in respective imaging specialties must be observed.

Ashvins is designed to be used by trained professionals, including but not limited to physicians, radiolo-gists, ophthalmologists, nurses, medical technicians, and assistants.

Ashvins integrates systems including, but not limited to, devices and information systems for medical practices and hospitals (such as radiology and/or ophthalmology information systems, etc.) in accord-ance with international standards. Ashvins also provides manufacturer-specific interfaces for other sys-tems/devices.

Ashvins offers the possibility of capturing and digitizing documents such as PDFs, single images, image sequences and film sequences, as well as converting and archiving them in DICOM format. As such, Ash-vins serves as a manufacturer-independent image management system and archive, a so-called "Vendor Neutral Archive."

Ashvins also provides functions for the collection, processing, and transfer of medical and administrative data in hospitals or medical practices, including billing functions.

Ashvins allows the visualization and statistical evaluation of meta data provided by the devices.

Ashvins is used at a physician's workplace to assist the physician with diagnosis and treatment planning, but the product itself does not generate an automated diagnosis, findings, or a treatment plan. The final decision regarding the diagnosis always remains with the physician or the medical staff within their own decision-making area.

Ashvins is offered in different variants with different ranges of functions for different application areas depending on the configuration (for further information see document "General Description of Product Vari-ants").

- Ashvins variant Ashvins Diagnostic Workstation
- Ashvins variant Ashvins Web Extreme
- Ashvins variant Ashvins Image & Web Management (Data Management)
- Ashvins variant HEYEX 2 / HEYEX PACS

Intended patient groups

There are no specific requirements related to gender, age, or other biological and anatomical characteris-tics of patients for the use of Ashvins.

Ashvins is applicable for all patients. The imaging data is delivered by the imaging devices on which the patients are examined.

Intended usage environment/use environment

Ashvins is used at a medical site such as a medical practice or a hospital, and it has components hosted in the Cloud.

Generally, the diagnostic workstations are used in darkened rooms. These relevant directives and stand-ards must be observed. For other client stations of Ashvins there are no restrictions regarding the place of use.

Service and maintenance

Maintenance and configuration of Ashvins may only be carried out by professionals after appropriate train-ing. It is recommended that a maintenance contract be attained from the manufacturer.

1.9 Indications for Use

Intended Use

Ashvins is a modular software solution and is used for viewing, reporting, processing, storing, printing, and archiving, as well as for the exchange and distribution or web-based distribution of digital, multimodal medical images, including mammographic images and bio-signals, as well as findings and demographic information. Ashvins also collects, manages, and distributes patient-related and device-related information.

Ashvins offers advanced image processing functions such as multiplanar reconstruction, 3D reconstruction and measurement functions.

For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images and only preprocessed DICOM "For Presentation" images must be used. Existing regulatory or legal requirements regarding hardware, such as diagnostic monitors, that are applicable for diagnosing in respective imaging specialties must be observed.

Ashvins is designed to be used by trained professionals, including but not limited to physicians, radiologists, ophthalmologists, nurses, medical technicians, and assistants.

1.10 Substantial Equivalence

The Substantial Equivalence table below illustrate the comparison of Ashvins to the predicate devices.

Table 3: Subjected device Ashvins compared to the Predicate devices K142750 and K12293

Feature	Subject	Primary Predicate Device (K142750)	Secondary Predicate Device (K122938)
	Ashvins	JiveX 5.0	FORUM
Submitter/Manufacturer	MedicalCommunications GmbH	VISUS Health IT	Carl Zeiss Meditec AG
Indications for Use	Ashvins is a modular software solution and is used for viewing, reporting, processing, storing, printing, and archiving, as well as for the exchange and distribution or web-based distribution of digital, multimodal medical images, including mammographic images and bio-signals, as well as findings and demographic information. Ashvins also collects, manages, and distributes patient-related and device-related information.	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	FORUM is a software system intended for use in storage, management, processing, and display of patient, diagnostic, video and image data and measurement from computerized diagnos-tic instruments or documentation systems through networks. It is intended to work with other FO-RUM applications.

Feature	Subject	Primary Predicate Device (K142750)	Secondary Predicate Device (K122938)
	Ashvins	JiveX 5.0	FORUM
	Ashvins offers advanced image processing functions such as multiplanar reconstruction, 3D reconstruction and measurement functions. For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images and only preprocessed DICOM "For Presentation" images must be used. Existing regulatory or legal requirements regarding hardware, such as diagnostic monitors, that are applicable for diagnosing in respective imaging specialties must be observed. Ashvins is designed to be used by trained professionals, including but not limited to physicians, radiolo-gists, ophthalmologists, nurses, medical technicians, and assistants.	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, radiolo-gists, nurses, medical technicians, and assistants. Note: Web-based image distribution and mobile device display are not intended for diagnostic purpos-es.	FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.
Regulation description	Picture archiving and communication system	Picture archiving and communication system	Picture archiving and communication system

Feature	Subject	Primary Predicate Device (K142750)	Secondary Predicate Device (K122938)
	Ashvins	JiveX 5.0	FORUM
Prescription/over-the-counter use	Prescription	Prescription	Prescription
Classification	Device Class: II Product Code: LLZ, NFJ 21 CFR 892.2050	Device Class: II Product Code: LLZ 21 CFR 892.2050	Device Class: II Product Code: NFJ 21 CFR 892.2050
Target Population	Images/System is not patient population specific	Images/System is not patient population specific	Images/System is not patient population specific
Design/ Architecture	Client/server	Client/server	Client/server
Operating systems	Server: Win 2016/19 Client: Win 7/10	Server: Win 7/8.1/10/ Srv. 2008/2012 Client: Win. 7/8.1/10	Windows XP, Windows Server 2003 (Server only) Windows 7, Window Server 2008 R2, Mac Lion (Client only)
Hardware requirements	Windows based, manufacturer independent server, workstations and client hardware, iPAD	Windows based, manufacturer independent server, workstations and client hardware, iPAD	Windows based, manufacturer independent server, workstations and client hardware
Image communication	TCP/IP, DICOM, proprietary internal image transfer protocol	TCP/IP, DICOM, proprietary internal image transfer protocol	TCP/IP, DICOM, proprietary internal image transfer protocol
Accepted Image Formats	DICOM data + data accepted as non DICOM and converted to DICOM for	DICOM data + data accepted as non DICOM and converted to DICOM for	DICOM

Feature	Subject	Primary Predicate Device (K142750)	Secondary Predicate Device (K122938)
	Ashvins	JiveX 5.0	FORUM
	storage: PDF, standard and other proprietary formats	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	Local storage on HDD/RAID/DVD, Network: NAS, SAN, long term storage solutions
Image data compression	JPEG 2000 lossless& lossy, ZIP, JPEG lossless & lossy, MPEG-1, MPEG-2, MPEG-4	JPEG 2000 lossless & lossy, ZIP, JPEG lossy for web clients Display as received: JPEG lossless & lossy, RLE lossless, MPEG-2	JPEG 2000 lossless, JPEG lossless, RLE lossless, MPEG-2, MPEG-4
Web based acces	Yes, Desktop & mobile devices (not intended for reading)	Yes, Desktop & mobile devices (not intended for reading)	No
Virtualization	Yes, VMware. Desktop and web clients can be distributed via Citrix	Yes	Yes
Cebtralized user admininstration	Yes	Yes	Yes
RIS/HIS/EMR integration	Yes, Via standards HL7 and DICOM, aligned to IHE Framework	Yes, Image Call Up from RIS, Patient Information Reconciliation, Instance Availability. Receive documents via HL7 MDM. Supported Standards: HL7, IHE	Yes, Via standards HL7 and DICOM

Feature	Subject	Primary Predicate Device (K142750)	Secondary Predicate Device (K122938)
	Ashvins	JiveX 5.0	FORUM
IHE XDS	no	XDS-Consumer	no
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 - 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	- Pan/Zoom - Image Measurements - Brightness/Contrast
Image Processing Algorithms 3D	- MPR - Max. Int. Projection - Min. Int. Projection -	- MPR - Max. Int. Projection - Min. Int. Projection - Volume Rendering - MIP for tomosynthesis data (not for diagnostic use)	

Feature	Subject	Primary Predicate Device (K142750)	Secondary Predicate Device (K122938)
	Ashvins	JiveX 5.0	FORUM
		- 3D image registration	
Hanging protocols/Clinical Displays	Yes	Yes	Yes
Centrally Schedule Patient Examinations	Yes	No	Yes
Server/Client Technology	Yes	Yes	Yes
Integrate 3rd Party Systems	Yes	Yes	Yes
Multi Site Query	Yes	Yes	Yes
Patient Administration	Yes	Yes	Yes
Patient Directory/Patient Navigator/Study Manager Patient Search	Yes	Yes	Yes
Order Management	Yes	Yes	Yes
Automatic Forwarding (based on DICOM)	Yes	Yes	Yes
Marking of Favorites	Yes	Yes	Yes
User Profiles	Yes	Yes	Yes

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

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

1.11 Design Control

The Design Control procedure of MedicalCommunications complies with the FDA Quality System Regulations CFR Part 820 and ISO 13485:2016. The Design Control procedure also incorporates Risk Management procedures, which comply with ISO 14971:2007.

MedicalCommunications performed software verification and validation, to confirm that Ashvins functions as intended.

1.12 Non-Clinical Performance Summary

Ashvins has been validated for its intended use to determine substantial equivalence to the predicate device.

Our Software documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission.

The performance data demonstrates continued conformance with special controls for medical devices containing software. Non-clinical tests were conducted on the device Ashvins (and variants) during product development.

The Risk Analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all the software specifications have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Medical Communications GmbH conforms to the Cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or the unauthorized use of information that is stored, accessed, or transferred from a medical device to an external recipient.

Summary:

The device is intended for prescription use, identical to the predicate device. The device is not an in vitro diagnostic device, identical to the predicate device.Performance tests were conducted to test the functionality of Ashvins (and variants). These tests have been performed to assess the functionality of the subject device. Results of all conducted testing were found acceptable in supporting the claim of substantial equivalence.

Testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software was considered as a "moderate level of concern", since a failure or latent design flaw could lead

to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

1.13 Conclusion

Ashvins is substantially equivalent to the primary predicate device with regards to intended use and technological characteristics. Results of performance testing demonstrate that the device met the design requirements and as well the user needs.