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

VISARIS d.o.o. Belgrade
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

June 8, 2015

Re: K150725
Trade/Device Name: Visaris Avanse®
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, LLZ
Dated: May 12, 2015
Received: May 14, 2015

Dear Mr. Kamm:

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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K150725

Device Name
Visaris Avanse®

Indications for Use *(Describe)*
The purpose of Visaris Avanse® is to acquire, store, communicate, display and process medical X-ray images. It offers features (e.g. window leveling, zoom, measurements, annotations etc.) routinely used by medical professionals, such as radiologists and radiographers. Visaris Avanse supports printing to DICOM compatible printers. Within a network environment Visaris Avanse may provide other modalities with a DICOM worklist and a DICOM worklist service. Images and worklists can be sent and received using the DICOM protocol. Visaris Avanse has a modular system architecture. It consists of the basic application for image acquisition, processing and viewing as well as a number of other modules for image and worklist management, archiving, search and display. Beside the basic functionality Visaris Avanse also provides a user interface for generator control and image acquisition of medical images DR detectors.

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 VISARIS d.o.o. Belgrade K150725

1. Administrative Information

Reason for Submission:

510(k) Notification for Visaris Avanse®, a new device

Submitter:

Address:	VISARIS d.o.o. Belgrade Batajnički drum 10 deo 1b 11080 Zemun SERBIA
Submission contact person:	Mr. Milan Ratković
Contact telephone:	+381 11 2017 631
Contact e-mail:	mratkovic@visaris.com
Date prepared:	May 12, 2015
Common device name:	Stationary X-Ray System (accessory)
Classification:	Class II
Regulation #s.:	21 CFR 892.1680 and 21 CFR 892.2050
Product codes:	KPR and LLZ

Substantially equivalent device:

Device Name(s):	dicomPACS® 5.2 - dicomPACS DX-R® 1.6
Manufacturer:	Oehm & Rehbein GmbH
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Common Product Name:	Radiological Image Processing System
510(k) Number:	K091364

2. Device description: 21 CFR 807 92 (a) (4)

Visaris Avanse® is a digital radiography imaging, control and management software (for imaging consoles) that works with DR flat panel detectors technology. Visaris Avanse® PACS provides functionality for digital radiography examinations from patient search and entry, generator control, image acquisition and processing to DICOM data archiving and export. Visaris Avanse® PACS can also include a number of Digital Radiology modules such as network DICOM archive (PACS module), DICOM modality worklist module and diagnostic workstation software to turn it into digital radiology department on a PC for small clinics. Visaris Avanse ® is autonomous software and involves no hardware. It runs under the MS Windows XP/7/8 operating system on any hardware platform meeting the minimum system requirements.

3. Indications for Use: 21 CFR 807 92 (a) (5)

The purpose of Visaris Avanse® is to acquire, store, communicate, display and process medical X-ray images. It offers features (e.g. window leveling, zoom, measurements, annotations etc.) routinely used by medical professionals, such as radiologists and radiographers. Visaris Avanse® supports printing to DICOM compatible printers. Within a network environment Visaris Avanse® may provide other modalities with a DICOM worklist and a DICOM worklist service. Images and worklists can be sent and received using the DICOM protocol. Visaris Avanse® has a modular

system architecture. It consists of the basic application for image acquisition, processing and viewing as well as a number of other modules for image and worklist management, archiving, search and display. Beside the basic functionality Visaris Avanse® also provides a user interface for generator control and image acquisition of medical images DR detectors. Not intended for mammography.

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4. Technological characteristics: 21 CFR 807 92 (a) (6)

Visaris Avanse/PACS ® has a modular system architecture. It consists of the basic application for image acquisition, processing and viewing as well as a number of other modules for image and worklist management, archiving, search and display. The software has been validated for compatibility with digital panels previously cleared by FDA and has been validated for control compatibility with the following list of generators:

Manufacturer	Product Name
Sedecal, Spain	All models
Claymount, Switzerland	Clayrad Series
Spellman, Germany	HFe Series
EMD, Canada	All models
CPI, Canada	Indico100, CMP

The image formats used are:
DICOM, TIFF, BMP, PNG, JPEG, RAW (new)

Image Compression:
Visaris Avanse/PACS use the following compression methods within the DICOM standard:

- JPEG Baseline (Process 1): Lossy JPEG 8 Bit Image Compression
- JPEG Extended (Process 2 & 4): Lossy JPEG 12 Bit Image Compression (Process 4 only)
- JPEG Extended (Process 3 & 5)
- JPEG Spectral Selection, Non-Hierarchical (Process 6 & 8)
- JPEG Lossless, Non-Hierarchical (Process 14)
- JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1])
- JPEG-LS Lossless Image Compression
- JPEG-LS Lossy (Near-Lossless) Image Compression
- JPEG 2000 Image Compression (Lossless Only)
- JPEG 2000 Image Compression

These compression methods are defined in the DICOM standard. Support of them is optional.

The modules are:

1. Avanse® DR image acquisition module
2. X-ray Generator Control Module
3. Minet Server internal communication module
4. CDViewer module
5. RIS Interface module
6. Avanse® DR service shell module
7. VisarisPACS database module
8. Worklist Server module
9. Dics Burn server module

10. Worklist generator module
11. Diagon DICOM image viewer module

The interfaces are:

1. DR flat panel
2. X-ray generator
3. HTTP
4. DICOM Store (SCP)
5. DICOM Send (SCU)
6. DCIOM Print (SCU)
7. Worklist Query (SCP)

5. Non clinical testing

The complete Visaris Avanse® PACS system configuration has been assessed and tested at the factory and has passed all in-house criteria. The Verification and Validation plan was design to evaluate all input and output functions, and actions performed by Visaris Avanse® PACS software in each operation mode and followed the process documented in the Validation Test Plan. Validation testing indicate that as required by risk analysis, designated individuals performed all verification and validation activities and that the result demonstrated that the predetermine acceptance criteria were met. If the device is installed by Visaris, installation and integration verification tests are conduct against acceptance criteria prior to release to client.

6. Clinical testing

Clinical images were obtained using each of the declared compatible digital panels. The images were evaluated by a board certified radiologist and were found to be of excellent diagnostic quality.

7. Substantial Equivalence Discussion

The Visaris Avanse® has the same essential indications for use as the predicate and uses the same kind of platform (Windows PC) to perform its functions. The same kind of software validation and panel testing has been performed. It is DICOM compatible like the predicate and handles jpeg images like the predicate.

Substantial Equivalence Table

dicomPACS®5.2 and dicomPACS DX-R K091364, Oehm und Rehbein GmbH (Predicate Device)	**VISARIS AVANSE® (New Device) [Equivalence Level]**	**Equivalence Justification**
Design		
Overal software architecture: A front-end + back-end architecture. Front-end includes user interface realised through „stand-alone“ user applications. Back-end includes image and metadata databases and background services that operate on them. Front and back end are linked through DICOM standard protocol communication. DICOM communication realised trough service provider-client model, back end provides the service and front end is its client.	*Overal software architecture:* A front-end + back-end architecture. Front-end includes user interface realised through „stand-alone“ user applications. Back-end includes image and metadata databases and background services that operate on them. Front and back end are linked through DICOM standard protocol communication. DICOM communication realised trough service provider-client model, back end provides the service and front end is its client. [EQUIVALENT]	*None required. They are EQUIVALENT.*

dicomPACS®5.2 and dicomPACS DX-R K091364, Oehm und Rehbein GmbH (Predicate Device)	VISARIS AVANSE® (New Device) [Equivalence Level]	Equivalence Justification
Software architecture back end: Integrated database of image, examination and patient data linking acquired image files on the file system (local or network storage). Windows services (background processes with no user interface) handle data transfer to and from database and ensure database integrity.	*Software architecture back end* Integrated database of image, examination and patient data linking acquired image files on the file system (local or network storage). Windows services (background processes with no user interface) handle data transfer to and from database and ensure database integrity. [EQUIVALENT]	*None required. They are EQUIVALENT.*
Software architecture front end: Front end is realised throught several static windows (win32) applications implementing main user interface functionality including image acquisition, exam scheduling and image review. Only one application entity active on the user interface at any time. Win32 applications implement DICOM communication clients to communicate with services in the back-end and external DICOM services.	*Software architecture front end:* Front end is realised throught several static windows (win32) applications implementing main user interface functionality including image acquisition, exam scheduling and image review. Only one application entity active on the user interface at any time. Win32 applications implement DICOM communication clients to communicate with services in the back-end and external DICOM services. Exam scheduling user interface is also realised through web based interface. [PRACTICALLY EQUIVALENT]	Web interface architecture is used to collect user input, but not process it. Main processing functionality is still performed in the back end and the web interface is implemented on a win32 process within a browser.
Communication to external components: Realised through each component's proprietary communication protocol using standard interface/data exchange protocols (such as RS232 or TCP-IP). Connections to components managed locally on the main system PC through component proprietary software (SDK) interfaces implemented in dynamicly linked libratries (dlls). Communication from main system software realised through direct calls to exposed functions of the SDK contained within the dlls. Data transfer realised through common memory access.	*Communication to external components*: Realised through each component's proprietary communication protocol using standard interface/data exchange protocols (such as RS232 or TCP-IP). Connections to components managed locally on the main system PC through component proprietary software (SDK) interfaces implemented in dynamicly linked libratries (dlls). Communication from main system software realised through direct calls to exposed functions of the SDK contained within the dlls. Data transfer realised through common memory access. [EQUIVALENT]	*None required. They are EQUIVALENT.*

dicomPACS®5.2 and dicomPACS DX-R K091364, Oehm und Rehbein GmbH (Predicate Device)	VISARIS AVANSE® (New Device) [Equivalence Level]	Equivalence Justification
User Interface design Multiple application enetites with related but separate user interface to cover different workflow aspects (DR/CR acquisition and patient entry, database search, image viewing, examination scheduling). User interface is graphical with clear display of acquired or retreived images and system information on the screen as well as data entry fields. Action commands are input by the user as mouse clicks on command buttons, menus, results lists and data entry fields. Textual data input is handled through keyboard/touchscreen keyboard input.	*User Interface design* Multiple application enetites with related but separate user interface to cover different workflow aspects (DR/CR acquisition and patient entry, database search, image viewing, examination scheduling). User interface is graphical with clear display of acquired or retreived images and system information on the screen as well as data entry fields. Action commands are input by the user as mouse clicks on command buttons, menus, results lists and data entry fields. Textual data input is handled through keyboard/touchscreen keyboard input. [EQUIVALENT]	*None required. They are EQUIVALENT.*
Development Platform: Main development platform Microsoft Windows development platform (.NET Technologies: ADO.NET Entity Framework, LINQ, ADO.NET, XML, ODATA Protocol, Native: ODBC, ADO, MSDASQL, Database: SQL Serever Database Engine, SQL Server Integration Services SSIS, SQL Server Reporting Services SSRS).	*Development Platform:* Main development platform Microsoft Windows development platform (.NET Technologies: ADO.NET Entity Framework, LINQ, ADO.NET, XML, ODATA Protocol, Native: ODBC, ADO, MSDASQL, Database: SQL Serever Database Engine, SQL Server Integration Services SSIS, SQL Server Reporting Services SSRS). Android mobile platform used for UI extension to mobile devices. [PRACTICALLY EQUIVALENT]	Main development platform is equivalent. Android platform is additionally used on Visaris Avanse only to collect user actions from mobile devices. System actions are not processed on this platform, rather on the same main platform as predicate device. Functionality verified.
PC Platform		
Common Personal Computer (PC) platform, static or mobile (laptop, tablet).	Common Personal Computer (PC) platform, static or mobile (laptop, tablet). [EQUIVALENT]	*None required. They are EQUIVALENT.*
Material		
Software only product, no material included.	Software only product, no material included. [EQUIVALENT]	*None required. They are EQUIVALENT.*
Chemical Composition		
Software only product, no chemical composition.	Software only product, no chemical composition. [EQUIVALENT]	*None required. They are EQUIVALENT.*
Energy Source		
Software only product, no energy source included.	Software only product, no energy source included. [EQUIVALENT]	*None required. They are EQUIVALENT.*

8. Substantial Equivalence Conclusion: After analyzing software validation, risk analysis, and clinical images, it is the conclusion of VISARIS d.o.o. Belgrade Inc that the VISARIS AVANSE® is as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.