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

March 30, 2016

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

Re: K160620
Trade/Device Name: Visaris Vision® (Vision C, Vision U, Vision V, Vision X)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: February 29, 2016
Received: March 4, 2016

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,

Michael D. O'Hara For

Robert 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160620

Device Name
Visaris Vision® (Vision C, Vision U. Vision V, Vision X)

Indications for Use *(Describe)*
The purpose of Visaris Vision® is to acquire, store, communicate, display and process medical X-ray images. These radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography, angiography, interventional, or fluoroscopy use.

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

Visaris Vision® (Vision C, Vision U. Vision V, Vision X) K160620

1. Administrative Information

Reason for Submission:

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

Submitter:

VISARIS d.o.o. Belgrade

Address:	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:	January 19, 2016

Trade Names:	Visaris Vision® (Vision C, Vision U. Vision V, Vision X)
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

Substantially equivalent device:

Trade Name:	Multix Fusion
Manufacturer:	Siemens
510(k) #:	K121513
Clearance Date:	August 10, 2012
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR

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

Visaris Vision combines our Visaris Avanse® cleared PACS software (K150725) with all the other components required to make a complete digital diagnostic X-ray system, including tube stands, tube heads, collimators, generators, tables, and (already cleared) digital X-ray panels.

Visaris Avanse®, the software component, is a digital radiography imaging, control and management software (for imaging consoles) that works with DR flat panel detector 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. These models are available:
Vision C: A universal digital system employing an Overhead Tube Crane, a table, and a wall stand.
Vision U: A universal U-Arm system
Vision V: A floor mounted tube system
Vision X: A universal straight Arm system
All of these come with the previously cleared Visaris 360, the integrated digital radiology workflow system. (Visaris Avance, K150725)
Various Brands of generators and Models available: (All HF) (All meet the US Performance Standard):
Claymount, (up to 63 kW)
CPI, (32kW to 100kW)
EMD, (45 kW, to 80 kW)
POSKOM (32 kW to 50 kW)
Sedecal (40, 50, 65, or 80 kW)

Visaris only supplies digital x-ray panels that have previously been cleared by FDA. This device employs our previously cleared software K150725. All of the panels listed below were previously tested with our software:

Detector	Clearance(s)
Careray 1500-1800 Series	K153492 K153058 K141488 K150929
DRTech (Multiple Models)	K132842 K111655 K111583 K111344 K102474 K102284 K091747 K080064
iRay Venu	K123644
Konica AeroDr	K151465 K141271 K130936
Perkin Elmer XRPAD	K140551
Rayence XMARU	K140646, K131114, K130935 K123345 K122928 K122919 K122173 K122182
Toshiba FDX	K130883
Trixell Pixium	K131483
Varian PaxScan	K130318, K024147
Vieworks Vivix	K120020, K122866, K122865

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

The purpose of Visaris Vision® is to acquire, store, communicate, display and process medical X-ray images. These radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography, angiography, interventional, or fluoroscopy use.

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

Comparable Properties	Predicate Device: Siemens Multix Fusion K12113	Vision C, Vision U, Vision V, Vision X Digital Radiography Systems	Comparison Results
Indications for use	The Multix Fusion is a radiographic system used in hospitals, clinics, and medical practices. Multix Fusion enables radiographic exposures of the whole body including: skull, chest, abdomen, and extremities and may be used on pediatric, adult, and bariatric patients. It can also be used for intravenous, small interventions (like biopsy, punctures, etc.) and emergency (trauma, critically ill) applications. Exposures may be taken with the patient sitting, standing, or in the prone position. The Multix Fusion system is not meant for mammography. The Multix Fusion uses a mobile (wired) or portable (wireless) digital detector for generating diagnostic images by converting x-rays into electronic signals. The Multix Fusion is also designed to be used with conventional film/screen or Computed Radiography (CR) cassettes.	The purpose of Visaris Vision® is to acquire, store, communicate, display and process medical X-ray images. These radiographic systems are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography, angiography, interventional, or fluoroscopy use.	Equivalent
Tube crane/Tube stand	Overhead tube crane with manual or automated x-ray tube assembly movement.	Equivalent model: Vision C	Equivalent Functionality
Wall stand	Manual vertical movable wall stand, tiltable tray.	Motorized	Equivalent Functionality
Table	Free-floating and height-adjustable, maximum patient weight 660 lbs., working table height 20-5/16 inch to 37-5/8 inch.	Same.	Equivalent Functionality
X-ray tube	150 kVp, 0.6 mm & 1 mm focal spots.	150 kVp 0.6/1.2mm focal spots	Equivalent Functionality
Collimator	Siemens.	Claymount, X-Alliance, or Ralco (All CFR Certified)	Equivalent Functionality
X-ray Generator	55, 65, or 80 kW Siemens brand	Various Models available: (All HF) Claymount, (up to 63 kW) CPI, (32kW to 100kW) EMD, (45 kW, to 80 kW) POSKOM (32 kW to 50 kW) Sedecal (40, 50, 65, or 80 kW) (All CFR Certified)	Equivalent Functionality

Comparable Properties	Predicate Device: Siemens Multix Fusion K12113	Vision C, Vision U, Vision V, Vision X Digital Radiography Systems	Comparison Results
Wireless detector	14" x 17"	14” x 17” Uses FDA cleared detector and software. Pixium 3543 EZ C (Other previously cleared models available, see table above)	Equivalent Functionality .
Fixed detector	17" x 17"	17”x17”. Uses FDA cleared detector and software. Pixium 4343RC (Other previously cleared models available)	Equivalent Functionality
Conventional film/screen systems or CR cassettes	Film/Screen or CR Cassettes.	Comes with FDA cleared digital x-ray panels. Conventional film and CR cassettes can still be used.	Similar Functionality
Operator console	GUI-based	Same	Similar Functionality
Photos			Similarity is obvious.
Power Source	AC LINE	SAME	Same.
Standards	60601-1:2005; 60601-1-2:2014 60601-2-54 Edition 1.0; PS 3.1 - 3.20 (2011) 21CFR1020	SAME	SAME

5. Non clinical testing

Testing was performed successfully according to the following standards:

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
19-5	IEC	60601-1:2005	Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601 1:2005, MOD)
19-1	IEC	60601-1-2:2014	Medical Electrical Equipment Part 12: General Requirements For Basic Safety And Essential Performance Collateral Standard: Electromagnetic Disturbances Requirements And Tests

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
12-274	**IEC**	60601-2-54 Edition 1.0	Medical Electrical Equipment Part 2-54: Particular Requirements For The Basic Safety And Essential Performance Of X¬ Ray Equipment For Radiography And Radioscopy [Including: Technical Corrigendum 1 (2010), Technical Corrigendum 2 (2011)]
12-238	**NEMA**	PS 3.1 - 3.20 (2011)	NEMA Digital Imaging and Communications in Medicine (DICOM) Set
N/A	**FDA**	21CFR1020	Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components

All of the components subject to the CDRH performance standard are certified to comply with the standard by their respective manufacturers. We do not supply any non-certified components. All X-ray components (generators, tubes, collimators, and applicable accessories) carry an NRTL certification label (UL, ETL, etc.). The software employed was used unmodified from our clearance obtained in K150725. A detailed risk analysis was performed on the entire system, evaluating successful integration of the various components.

6. Clinical testing

Although not required for a determination of substantial equivalence, a clinical evaluation was performed with these objectives:

- verification in the normal working conditions of VISION C digital radiography device performances with respect to those claimed by the producer (Visaris d.o.o.) in their functional specification
- determination of all adverse effects in normal use and an estimate if these pose a risk with respect to the intended performance of the device.
- evaluation of all known hazard sources and estimation of their actual risk to patients, operators or environment of the device in normal working condition

The results were satisfactory. Confirmatory images were acquired with each of the proposed digital panels to assure system compatibility.

7. Substantial Equivalence Discussion.

The Visaris Vision performs the same functions using the same technological methods to produce diagnostic x-ray images. In all material aspects, the Siemens and the Visaris systems are substantially equivalent to each other.

Substantial Equivalence Conclusion:

After analyzing bench test results, risk analysis, and clinical evaluation, it is the conclusion of VISARIS d.o.o. Belgrade Inc that the VISARIS Vision Systems are 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.