



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Cuatro, LLC
% Mr. Matthew Taylor
Director, Quality Assurance/Regulatory
3760 Rocky Mountain Avenue
LOVELAND CO 80538

October 6, 2016

Re: K161937
Trade/Device Name: CuatroDR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, LLZ
Dated: September 14, 2016
Received: September 15, 2016

Dear Mr. Taylor:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style. Behind the signature, there is a faint, light blue watermark of the letters "FDA".

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

4. Indications for Use (Form 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K161937

Device Name

CuatroDR

Indications for Use (Describe)

The CuatroDR, when used with a cleared digital image capture device, provides for the capture of digital images in place of conventional film radiographic examinations.

The device is intended to be available for retrofit on existing or planned x-ray machines with a cleared digital image capture device.

The device is intended for use by trained and qualified personnel in the acquisition and review of radiographic images. The product is not intended for mammography or fluoroscopy applications.

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.

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510(k) summary

510(k) Owner

Cuattro, LLC
3760 Rocky Mountain Avenue
Loveland, CO 80538
Phone: 970-775-2247
Facsimile: 970-775-2247
Registration Number: 3008364043
Date Prepared: August 30, 2016

510(k) Submitter

Cuattro, LLC
3760 Rocky Mountain Avenue
Loveland, CO 80538
Phone: 970-775-2247
Facsimile: 970-775-2247
Contact: Matthew Taylor

Device Trade Name: CuattroDR
Common Name: Stationary X-Ray System
Classification Name: Stationary X-Ray system
Regulation Number: 21 CFR 892.1680
Product Code: KPR, LLZ

Substantial equivalence is claimed to the following Legally Marketed Devices:

Primary predicate K150725:

Manufacturer: VISARIS
Device: Visaris Avanse
510(k) Number: K150725
Classification Name: Stationary X-Ray system
Regulation Number: 21 CFR 892.1680
Product Code: KPR, LLZ

Secondary predicate K093480:

Manufacturer:	Cuattro
Device	UnoMD (CloudDR)
510(k) Number:	K093480
Classification Name:	Picture Archiving and Communications System
Regulation Number:	21 CFR 892.2050
Product Code:	LLZ

Device Description

The CuattroDR device is a software application capable of acquiring x-ray images from commonly commercialized digital flat panels on a Windows based computer workstation. The software can use traditional mouse and keyboard inputs as well as touch screen monitors as an alternative. The use of the CuattroDR software enables the user to use a traditional x-ray generator and capture x-ray images without film. The images are processed and then presented to the user on a touch screen computer monitor, within 12 seconds after the x-ray exposure. The software also has capabilities to send images to hospital medical PACS systems and digital media for archival. In addition to this functionality, the CuattroDR software provides a user interface for generator control in the process of acquiring digital images.

Indications for Use

The CuattroDR, when used with a cleared digital image capture device, provides for the capture of digital images in place of conventional film radiographic examinations. The device is intended to be available for retrofit on existing or planned x-ray machines with a cleared digital image capture device. The device is intended for use by trained and qualified personnel in the acquisition and review of radiographic images. The product is not intended for mammography or fluoroscopy applications.

Technological Characteristics

The technological characteristics are essentially the same as the legally marketed predicate devices:

- All three of the devices (the subject device as well as the predicate devices) provide for features used by personnel in the acquisition and review of radiographic images.
- All three of the devices (the subject device as well as the predicate devices) utilize software on a workstation computer with Ethernet capability, and provide DICOM 3.0 compliant connectivity.
- All three of the devices (the subject device as well as the predicate devices) are a software solution intended for use with already cleared digital image capture devices, utilizing fixed or portable digital image capture devices and wired or wireless digital image capture devices
- All three of the devices (the subject device as well as the predicate devices) provide for image processing of acquired images to enhance images to help clinicians see more detail in the digital X-Ray image

- All three of the devices (the subject device as well as the predicate devices) are stand-alone software products.
- All three of the devices (the subject device as well as the predicate devices) have essentially the same workstation requirements.
- The new CuattroDR device as well as the Visaris Avance® device, in addition to the image acquisition, processing and viewing, provides a user interface for generator control in the acquisition of images. The Cuattro UnoMD (CloudDR) device does not provide an interface for generator control

Technical Characteristic	CuattroDR (this submission)	Cuattro UnoMD – (Name was changed to CloudDR on FDA registration page 6/30/11)	Visaris Visaris Avance®	Equivalence / Rationale
FDA 510(k) #	K161937	K093480	K150725	
Indications for Use	<p>The CuattroDR, when used with a cleared digital image capture device, provides for the capture of digital images in place of conventional film radiographic examinations.</p> <p>The device is intended to be available for retrofit on existing or planned x-ray machines with a cleared digital image capture device.</p> <p>The device is intended for use by trained and qualified personnel in the acquisition and review of radiographic images. The product is not intended for mammography or fluoroscopy applications.</p>	<p>The Cuattro UnoMD, when used with a cleared digital image capture device, provides for the capture of digital images in place of conventional film radiographic examinations.</p> <p>The device is intended to be available for retrofit on existing or planned x-ray machines with a cleared digital image capture device.</p> <p>The device is intended for use by trained and qualified personnel in the acquisition and review of radiographic images. The product is not intended for mammography or fluoroscopy applications.</p>	<p>The purpose of Visaris Avance® 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 Avance supports printing to DICOM compatible printers. Within a network environment Visaris Avance 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 Avance 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 Avance also provides a user interface for generator control and image acquisition of medical images DR detectors.</p>	Equivalent – Both devices are intended to be used to provide for the acquisition of digital X-ray images in place of conventional film for radiographic examinations.
Image acquisition	Cleared digital image capture device (DR), utilizing fixed or portable digital image capture devices and wired or wireless digital image capture devices.	Cleared digital image capture device (DR), utilizing fixed or portable digital image capture devices and wired or wireless digital image capture devices.	Cleared digital image capture device (DR), utilizing fixed or portable digital image capture devices and wired or wireless digital image capture devices.	Equivalent
Features for use by personnel in the acquisition and review of images	Window leveling Zoom Measurements Annotations / Markers Image Stitching Image flip Image rotate Image crop Image shutter Receptor selection Invert (reverses gray scale) Image reject, with reason selection Add/Delete procedure to study Radiology report Patient search and entry	Window leveling Zoom Measurements Annotations / Markers Image Stitching Image flip Image rotate Image crop Image shutter Receptor selection Invert (reverses gray scale) Image reject, with reason selection Add/Delete procedure to study Radiology report Patient search and entry	Window leveling Zoom Measurements Annotations Image Stitching Patient search and entry Etc.	Equivalent

Technical Characteristic	CuattroDR (this submission)	Cuattro UnoMD – (Name was changed to CloudDR on FDA registration page 6/30/11)	Visaris Visaris Avanse®	Equivalence / Rationale
Image Processing	Incorporates Sharp View Image Enhancement System manufactured by Context Vision, AB (K024028) Context Vision is used to enhance images after X-Ray acquisition to help clinicians see more detail in the digital X-Ray image.	Incorporates Sharp View Image Enhancement System manufactured by Context Vision, AB (K024028) Context Vision is used to enhance images after X-Ray acquisition to help clinicians see more detail in the digital X-Ray image.	Advanced anatomy driven image processing (From marketing literature)	Equivalent – Both devices use proprietary image processing
Generator Control	The CuattroDR device does provide, through an RS-232 interface, the ability to provide control for select X-Ray generators, including AEC – Validated with Sedecal Generators	NONE	Control compatibility with select X-Ray generators – Validated with Sedecal and other generators	Equivalent
CPU Workstation Requirements	Microsoft Windows Embedded 8.1 Industry Pro Operating system that meets minimum system requirements.	Microsoft Windows XP/7/8.1/8 Embedded Operating system that meets minimum system requirements.	MS Windows XP/7/8 operating system on any hardware platform meeting the minimum system requirements	Equivalent – All devices run on a Windows platform
Integration	HIS/RIS – import of Modality Worklist information from the institution HIS/RIS	HIS/RIS – import of Modality Worklist information from the institution HIS/RIS	Images and worklists can be sent and received using the DICOM protocol.	Equivalent
External Connectivity	DICOM 3.0 Compatible – Export to external PACS, View Stations, CD, DICOM Print	DICOM 3.0 Compatible – Export to external PACS, View Stations, CD, DICOM Print	Images and worklists can be sent and received using the DICOM protocol.	Equivalent

Determination of Substantial Equivalence

The determination of substantial equivalence is based upon non-clinical performance data. Bench testing has been performed on the device following Cuattro’s design control processes, as well as the applicable FDA guidance documents, in particular the guidance on Content of Premarket Submissions for Software Contained in Medical Devices.

Bench testing has been performed by a member of the team not directly responsible for software development undertook verification testing of the device. The verification test was in accordance with the following documents:

- Cuattro Design Output Document, “Design_Output_SWR_00069_MD”
- Cuattro Design Verification Document, “Design_Verification_SWR_00069_MD”
- Cuattro Design Validation Document, “Design_Validation_SWR_00069_MD”

Validation testing for the new device included a focus on the difference between the Cuattro UnoMD (CloudDR) device and the new CuattroDR device. This testing, utilizing a Sedecal SHFR generator, five different cleared wireless and wired digital image detectors from two manufacturers, and appropriate anatomical phantoms, included:

- Basic Functionality,
 - Establishing/Maintaining Communications,
 - Exposure Feedback
 - kVp Control
 - mAs Control
 - Focal Spot Control
 - mA and Time Controls
 - Unintentional Exposure Prevention
 - Generator Technique Validation Feature

Advanced Functionality,
AEC Control
Workstation Assignment
Patient Size Adjustment

The results of this bench testing have demonstrated that the device is substantially equivalent to the referenced predicate device. The details of this testing and test results are in this submission in section 18, Performance Testing – Bench

Conclusion

Based upon the analysis of the Indications for Use, Technological Characteristics, and the results of the Bench Testing performed on the device, we have determined that the CuattroDR is safe and effective, and substantially equivalent to the Predicate Device.