Konica Minolta Healthcare Americas, Inc.
% Ms. Jan Maniscalco
Director of QA/RA
2217 US Highway 70 East
GARNER NC 27529

January 15, 2020

Re: K193225
Trade/Device Name: KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: November 20, 2019
Received: November 22, 2019

Dear Ms. Maniscalco:

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: 6/30/2020
See PRA Statement below

510(k) Number *(if known)*
K193225

Device Name

KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography.

Indications for Use *(Describe)*

The KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography is indicated for use by qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic static and serial radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position (not for mammography).

Type of Use *(Select one or both, as applicable)*

X 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 - K193225

Manufacturer:	Konica Minolta Healthcare America, Inc 2217 US Highway 70 East Garner, NC 27529
Phone:	800-934-1034 x-1427
Facsimile:	973-523-7408
Contact Person:	Jan Maniscalco, Director of QA/RA
Date Prepared:	January 10, 2020
Establishment Registration Number:	1064396
Proprietary Name:	KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography
Classification Name:	Digital Stationary Diagnostic X-ray System
Regulation Number:	21 CFR 892.1680
Classification:	Class II, Stationary Diagnostic X-ray System, Product Code KPR Solid State X-Ray imager (Flat Panel/Digital Imager) MQB
Predicate Device:	Viztek DR Series Digital Diagnostic Digital X-Ray Systems Viztek, Inc K082604
Reference Devices:	AERODR SYSTEM WITH P-21 (K113248) (Device uses the same HQ /KDR front panel display to capture static images) SKR3000 (K172793) (Device uses the same HD/FNB front panel to capture both static and dynamic images) SKR3000 (K182688) ((Device uses same HQ/KDR and HD/FNB to capture both static and dynamic images) Nexus DR Digital X-ray imaging System

(K190146)
(Device uses the same generator)

Q-Rad Radiographic System with Auto-Tracker Option
(K151924)
(Device uses the same X-ray tubes)

Digital Diagnost C90
(K182973)
(Device uses the same Collimator)

Ultra Vizion
(K133139)
(Device utilizes same software)

Intended Use / Indications for Use

The KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography is indicated for use by qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic static and serial radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position (not for mammography).

Technological Characteristics

The proposed System is a digital radiography diagnostic system that has the capability of obtaining two modes (static mode and dynamic modes) of radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Images may be obtained with the patient sitting, standing, or lying in the prone or supine position. It is not intended for mammographic use. The system is configurable in two options. Both are exactly the same with the exception of the option to select one of two flat panel detectors. One configuration, referred to as KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography contains a HD/FNB flat panel and the other configuration, referred to as KDR™ AU System Advanced U-Arm with Static Digital Radiography a HQ/KDR panel. The technological feature of each flat panel detector is described below.

The proposed system is a compact, floor and wall mounted radiographic system with proprietary ULTRA software and DICOM 3 connectivity.

The system consists of a combination of several components. The System's hardware consists of the 3 key components:

1) A floor and wall-mounted Positioner (also referred to as a stand)

2) A generator
3) An off-the-shelf computer with proprietary software (also referred to as an acquisition workstation)

The positioner has a swivel arm that has several rotating and linear movements, and movement controls including an information screen. Mounted on the positioner are:

a) A collimator,
b) An X-ray tube
c) An Automatic Exposure Control (AEC)
d) A flat panel detector (There are 2 configurations available for the end user to select. The KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography contains a HD/FNB flat panel detector capable of obtaining both static and dynamic images and the KDR™ AU System Advanced U-Arm with Static Digital Radiography, which contains the HQ/KDR flat panel detector capable of obtaining static images only.

Hardware accessories include:

1) A mobile patient table
2) Stitching stand
3) Weight bearing stand

Optional Hardware accessories include:

1) Motorized height adjustable table
2) 3 knob collimator
3) Dose area product meter
4) Advanced weight bearing stand

The proposed system has a proprietary ULTRA software as the central interface of the system. The software for the proposed system enables users to acquire static and dynamic images.

There are two modes within the software package of the proposed system, "static mode," which may be used to generate, a single frame of radiographic images captured at a single time and "dynamic mode" (or "Dynamic Digital Radiography," abbreviated "DDR,") which generates multiple frames in a single series, presenting the physician with a diagnostic view of dynamic density and anatomic motion without using fluoroscopy or cine. The number of images acquired with the proposed system are limited to 300 compared with flouroscopy or cine, which do not limit the number of images (Note: only the configuration with the HD/FNB flat panel detector is capable of obtaining both static and dynamic images. The other configuration may only obtain static images).

The system is also capable of quickly assuming a preprogrammed position when a new exam is selected, saving time when positioning the equipment. This is referred to as “auto positioning,” and made possible by the positioner and image processing software working together.

The KDR AU-DDR system with Dynamic Digital Radiography (DDR) is a system for general radiography and differs from a Fluoroscopy system in the following ways:

-No real-time claim or functionality, no images are shown real-time for diagnostic application, low resolution images are shown during the serial exposure at a lower framerate then the acquisition for rough overview of patient positioning and to give the user feedback on rough exam progress only.

-The complete dataset of acquired images is only available after the exposure run is finished. The images then can be processed, sent to a diagnostic workstation or PACS and presented to the physician. The Ultra workstation is not intended as a diagnostic workstation.

-The exposure time is limited to a maximum time (20 sec or less if the user specifies a shorter maximum time) at 15 frames-per-sec per run, conversely fluoroscopy system are capable of almost unlimited runs, where the maximal dose is monitored during the exam, where the maximal DDR system dose is determined prior to the start of the exam.

- Before exposure the user is informed the maximum allowed/set frames and frame rate, and during the exam a timer shows an indication of how much time is reminding.

-The preparation of the system between exposure sequences is relative long (5-20sec), the standby time after preparation is 5 minutes. After the 5 minutes the system will need to perform a preparation cycle before serial exposures are allowed.

- Due to above operation the DDR mode is not able to perform as a fluoroscopy system. The system is not ready on-demand, what is required for fluoroscopy exams.

- The DDR system uses a static exposure setting for serial imaging, which allows for an exact definition of maximum dose per exam, whereas fluoroscopy in general uses an ABS (Automatic Brightness Control), and total dose is not known before and directly controlled by the user.

- Fluoroscopy imaging is used for diagnosis or guidance during the exam, while a DDR exam provides images for diagnosis only after the exam is completed and images are sent to a diagnostic review stations, not part of the KDR AU -DDR system.

Performance Data

The proposed system was tested in its final configuration.

The System complies with the requirements of IEC 60601-1 version 3.1, regarding General requirements for basic safety and essential performance.

The System complies with the requirements of IEC 60601-1-2, 4th edition, regarding electromagnetic compatibility. Surrounding equipment also follows the standard IEC 60601-1-2. Electrical testing was performed by TUV Rheinland of North America and has been certified as complying with each standard tested.

The Test of Condition had 3 types of conditions: 1) Irradiation (Serial X-Ray Exposure) and Positioner Movement, 2) Positioner Movement and 3) Standby mode.

The System complies with the requirements of IEC 60601-1-3 rev 2.1 General requirements for basic safety and essential performance – Collateral Standard:Radiation protection in diagnostic X-ray equipment.

The system was tested against Standards No.21 CFR Part 1020:30 and standards No.21 CFR Part 1020:31

The System complies with the requirements of IEC 60601-2-54, 1.2 edition, regarding Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.

The system was also tested and complies with the DICOM standard In addition to the standards testing noted above, the system successfully passed all verification and validation testing covering user requirement software specifications, device requirements for performance, packaging, design requirements, human /ergonomic factors, interfacing with other devices and compatibility with the environment of the intended use..

In all instances, the proposed system functioned as intended and as expected.

Substantial Equivalence

The proposed System is as safe and effective as the Viztek DR Series Digital Diagnostic Digital X-Ray Systems (multiple models) K082604 and reference devices: SKR3000 (K172793); Nexus DR Digital X-ray imaging System (K190146); Q-Rad Radiographic System with Auto-Tracker Option (K151924) and Digital Diagnost C90 (K182973) and Ultra software (K133139).

Therefore, the proposed system is also equivalent to those reference devices noted below.

	Proposed KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography	Predicate/Reference Viztek DR Series Digital Diagnostic Digital X-Ray Systems (multiple models) K082604
Intended Use	The KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography is indicated for use by qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic static and serial radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position (not for mammography).	Same as predicate
Images produced	Series of static or serial digital images that may be viewed individually or as a cine loop	Individual static digital images viewed individually
Communication	DICOM 3.0 compliant communication	Same as predicate
Configuration	U arm mount	Same as predicate
Performance Standard	21 CFR 1020.30	Same as predicate
Generator	High Frequency Power ratings (32-80 kW) Exposure voltage (40-150K)	High Frequency Power ratings (50-80 kW) Exposure voltage (40-150K) Note: the generator in the proposed device is the same as that used in reference device K190146
Flat Panel Detector	See below	Provided with system
	AeroDR FPD	

	HD/FNB	KDR/HQ
Reference K	K172793	K113248
Static imaging	Yes	Yes
Dynamic imaging	Yes	No
Pixel size (um)	100	175
Spatial resolution (Lp/mm)	~5.0	~2.8
Dynamic frame rate (fps)	15	N/A
Ultra	Software	the software in the proposed device is the same as that used in reference device K133139 with modifications for serial/dynamic imaging
X-Ray table	Provided with system	Provided with system Note: The 2 X-ray tubes are the same as that used in Reference device: K151924;
Collimator	Provided with system	Provided with system Note:The collimator is the same as that used in Reference device: K182973;
Automatic Exposure Control, (AEC)	Provided with system	Provided with system note The AEC is the same as that used in Reference device K190146;
Electrical Safety	IEC-60601	Same as predicate

The KDR™ AU-DDR System Advanced U-Arm with Dynamic Digital Radiography and KDR™ AU System Advanced U-Arm with Static Digital Radiography system has the same intended uses and indications, and principles of operation as its predicate device. The minor technological differences between the proposed System and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the proposed System is as safe and effective as the predicate device. Thus, the proposed System is substantially equivalent.

Conclusions

Data from Verification and validation data as well as external laboratory testing to applicable standards demonstrate that the proposed System is as safe and effective as the Viztek DR Series Digital Diagnostic Digital X-Ray Systems (multiple models) (K082604) and reference devices: K190146; K182973:K151924; K190146; K172793 and K113248