July 27, 2022

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

Re: K221853
Trade/Device Name: OTC DDR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: June 24, 2022
Received: June 27, 2022

Dear Jan 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221853

Device Name
OTC DDR

Indications for Use *(Describe)*

The OTC DDR 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)*

☒ 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 K221853

Konica Minolta Healthcare Americas, Inc.
2217 US Highway 70 East
Garner, NC 27529
1-800-366-5343

1. **Administrative Information**

Reason for Submission: 510(k) Notification for **OTC DDR, a modified device.**

Submitter:

Submission contact person:	Jan Maniscalco, Executive Vice President of QA/RA
Contact telephone:	973.633.1500
Contact e-mail:	jan.maniscalco@konicaminolta.com
Date prepared:	July 19, 2022

Identification:	OTC DDR
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, MQB

Substantially equivalent device:

Trade Name:	Straight Arm DDR System
Manufacturer:	Konica Minolta Healthcare Americas, Inc
510(k) #:	K214012
Classification Name:	Stationary x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, MQB

Reference device: The Overhead Tube Crane, Table, and Wall Stand components were previously cleared in:

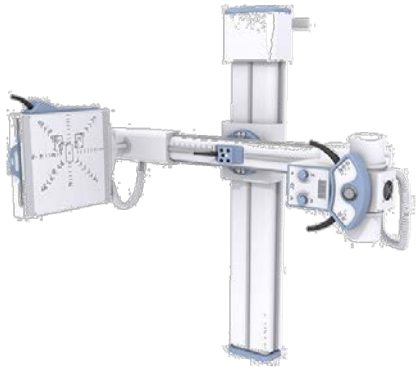
Trade Name:	Radiographic System Challenge X
Manufacturer:	Sedecal SA
510(k) #:	K202293
Classification Name:	Stationary x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	KPR, MQB

2. **Device description:** This submission is for a MODIFICATION to our predicate device. Instead of supplying a straight arm tube stand we be supplying an overhead tube crane. The imaging components of the system remain unchanged. This is a is a versatile digital radiography system that facilitates workflow and provides exceptional dose efficiency. The OTC DDR features the latest developments in high-technology construction and design, including the potential for Dynamic Digital Radiography (DDR), making it possible to rapidly capture sequential radiographs in a single exam. It consists of the following subassemblies: X-ray tube, positioner, automatic exposure control, collimator, X-ray generator, patient mobile table, and digital x-ray acquisition station with ULTRA software. The ULTRA software was most recently cleared in K214012 and has not been changed from the cleared version

3. **Indications for Use:** The OTC DDR 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).

4. **Technological characteristics**: Comparison Table presented below.

Comparable Properties	Predicate Straight Arm DDR K214012	OTC DDR	Comparison Results
Indications for use	The Straight Arm DDR 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).	The OTC DDR 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 Only the name has changed.
Tube stand/Digital Panel Receptor Configuration	Straight Arm	Overhead tube crane, receptor panel in table and/or wall stand.	Equivalent performance, difference is in user preference.

Comparable Properties	Predicate Straight Arm DDR K214012	OTC DDR	Comparison Results
Photo			These are functionally equivalent. The OTC offers more flexibility in patient positioning.
Digital X-Ray Detectors	ULTRA and AeroDR FPD	ULTRA and AeroDR FPD	No change
Operator console	Windows PC using Windows 10	SAME	No change.
Acquisition Software	ULTRA SOFTWARE DICOM OUTPUT	ULTRA SOFTWARE DICOM OUTPUT	No change.
Generator	Sedecal	Sedecal	No change
Collimator	Ralco R225/R225 DHHS	Ralco R225/R225 DHHS	No change
Power Source	AC Line	AC Line	No change
Standards	Same as below	See below	No change

5. Non clinical testing: Testing was performed according to the following standards:

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
19-4	IEC	ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Medical Electrical Equipment Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601 1:2005, MOD)
19-8	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
12-269	IEC	60601-1-3 rev 2.1	Collateral Standard: Radiation protection in diagnostic X-ray equipment.
12-317	IEC	IEC 60601-2-54, 1.2 2018-06 CONSOLIDATED VERSION	Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
12-300	NEMA	PS 3.1 - 3.20 (2011)	NEMA Digital Imaging and Communications in Medicine (DICOM) Set

The digital panel software employed was used unmodified from the predicate. The software has been previously validated as a control for Sedecal diagnostic x-ray generators.
The following testing was performed:
Image Quality Testing and Product Validation.
Product validation consisted of assembling and fully functionally testing the entire system.
The proposed compatible generator carries NRTL (UL) listing labels, having been tested for safety.
Validation of proper generator technique control had been previously performed. Each system is tested for proper integration prior to shipment to the customer. Since multiple configurations are available (generator and panel models), our service engineers fully test each new system upon installation at the customer site.

We performed IEC60601-1 Safety and IEC60601-1-2 EMC testing with satisfactory results.

6. Clinical testing. Not required for a determination of substantial equivalence.

7. Substantial Equivalence Discussion.

The OTC DDR performs the same functions as the predicate using the same technological methods to produce diagnostic x-ray images. In all material aspects, the Straight Arm DDR and OTC DDR systems are substantially equivalent to each other.

8. Substantial Equivalence Conclusion:

After analyzing bench test results, risk analysis, and clinical evaluation, it is the conclusion of Konica Minolta that the OTC DDR is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.