January 21, 2022

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

Re: K214030
Trade/Device Name: Universal DR 1748
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MQB, LLZ
Dated: December 22, 2021
Received: December 23, 2021

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
Assistant Director
Diagnostic X-ray Systems Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K214030

Device Name
Universal DR 1748

Indications for Use *(Describe)*

This device is indicated for use in generating radiographic images of human anatomy. It is intended to a replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary K214030

Konica Minolta Healthcare Americas, Inc.
2217 US Highway 70 East
Garner, NC 27529
973.633.1500

1. **Administrative Information**

Reason for Submission: 510(k) Notification for **Universal DR 1748**

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:	December 22, 2021

Identification:	**Universal DR 1748**
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	MQB, LLZ

Substantially equivalent device:

Trade Name:	SKR 3000
Manufacturer:	Konica Minolta Healthcare Americas, Inc
510(k) #:	K210919
Classification Name:	Stationary x-ray system
Classification Panel:	Radiology
Classification Regulation:	21 CFR §892.1680
Device Class:	Class II
Product Code:	MQB, LLZ

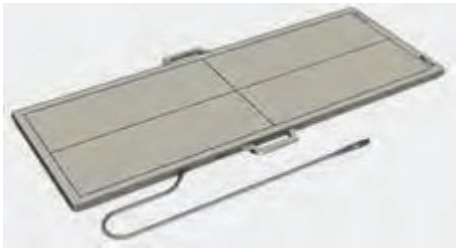
Reference Device: The device software "Ultra" was most recently cleared in K212291
Trade/Device Name: PHOENIX
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL, MQB

2. **Device description:** Konica Minolta **Universal DR 1748** combines components into a complete digital x-ray system upgrade kit, including software and digital radiography panel.
The indications for use remains unchanged: This device is indicated for use in generating radiographic images of human anatomy. It is intended to a replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and

angiography applications. So the only difference between this submission and the predicate submission is the manufacturer of the digital panel and the supplied software is different
Each system consists of the following items:
Customer supplies: Diagnostic x-ray generator (HF) Class I Code IZO. + Tubehead: Class I Code ITY + Tube Mount: Class I Code IYB + Attached Collimator, Manual (IZX) Class II 510(k) Exempt
We supply:
Digital X-Ray Receptor Panel 892.1680 Class II Code MQB. Digital X-ray Software 892.2050 Class II Code LLZ. The software offered for sale with this system has received previous 510(k) clearance in K212291.

3. **Indications for Use:** This device is indicated for use in generating radiographic images of human anatomy. It is intended to a replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography applications.

4. **Technological characteristics**: Comparison Table

Comparable Properties	Konica Minolta SKR 3000 K210619	Universal DR 1748	Comparison Results
Indications for use	This device is indicated for use in generating radiographic images of human anatomy. It is intended to a replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography applications.	This device is indicated for use in generating radiographic images of human anatomy. It is intended to a replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography applications.	SAME
Digital X-Ray Detectors	P-65 and P-75	Venu1748V	Different Detector, same indications
Photo			Rectangular and larger.
Panel Performance	MTF (1 cycle/mm) 0.62 DQE (1.0 cycle/mm) 0.56 DQE (0 cycle/mm) 0.65	MTF@1.0lp/mm 0.563 MTF@2.0lp/mm 0.244 MTF@3.0lp/mm 0.121 DQE@1.0lp/mm 0.205 DQE@2.0lp/mm 0.104 DQE@3.0lp/mm 0.052	The difference is explained by the difference in scintillator. Diagnostic quality images are nevertheless produced by the new panel.

Comparable Properties	Konica Minolta SKR 3000 K210619	Universal DR 1748	Comparison Results
Number of Pixels	3,488 × 4,256 pixels or 4,248 × 4,248 pixels	8704 x 3072 pixels	Larger image can be obtained with one exposure instead of two.
Pixel Pitch	100 µm / 200 µm / 400 µm	139um	SIMILAR
Scintillator	CsI (Cesium Iodide)	GOS	GOS offers lower cost per unit area.
A/D Conversion	16 bits	16 bits	SAME
Panel Sizes	14" X 17" 17" X 17"	17" x 48"	Proposed device is a larger panel. Allows for a much larger image to be captured with one exposure
Data Interface	Ethernet or Wireless	Ethernet	Since this large panel is not moved very often tethering is not a serious disadvantage
Operator console	Windows PC using Windows 10	SAME	SAME.
Acquisition Software	Console CS-7 DICOM OUTPUT	ULTRA SOFTWARE DICOM OUTPUT	Similar performance characteristics, both previously cleared
Power Source	AC Line or rechargeable batteries (wireless models)	AC Line or rechargeable battery	SAME
Standards	Same as below	See below	SAME

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	60601-1:2005/(R)2012 And A1:2012	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

FDA Recognition Number	Standard Developing Organization	Standard Designation Number And Date	Title Of Standard
12-238	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 clearance obtained from FDA. The software has been validated as a control for CPI and Sedecal diagnostic x-ray generators.
Compatible CPI generators: CMP 200 Series. Compatible Sedecal generators: SFHR and SHF Series.

In recognition of possible cybersecurity threats to the software, we consulted this guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff.* As a result, we updated our own internal standard operating procedures and added cybersecurity precautions to the software users' manuals.

Since the three new digital receptor panels have not had previous FDA clearance, testing was performed according to the FDA guidance document: *Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, Guidance for Industry and Food and Drug Administration Staff*. Clinical image evaluation was performed on the proposed new panels by a Board-Certified Radiologist. The images were found to be of excellent quality. The User Manuals contain pediatric and cybersecurity supplements. All proposed compatible generators carry NRTL 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

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

7. Substantial Equivalence Discussion.

When combined with a compatible generator/Tubestand combination the Accuvue+ performs the same functions as the predicate using the same technological methods to produce diagnostic x-ray images. In all material aspects, the Visaris and the Konica Minolta 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 LLC that the Konica Minolta Universal DR 1748 series of upgrade kits are 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.