November 17, 2022

Konica Minolta, Inc.
% Jan Maniscalco
Executive Vice President QA/RA
Konica Minolta Healthcare Americas, Inc.
411 Newark Pompton Turnpike
WAYNE NJ 07470

Re: K223267
Trade/Device Name: SKR 3000
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB, LLZ
Dated: October 24, 2022
Received: October 24, 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)*
K223267

Device Name
SKR 3000

Indications for Use *(Describe)*
The SKR 3000 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen system in general-purpose diagnostic procedures.

The SKR 3000 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.

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KONICA MINOLTA

510(k) Summary

K223267

Company:	KONICA MINOLTA, INC. 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan
Contact:	Tsutomu Fukui Senior Manager of Regulatory & QMS Division Quality Assurance Operations Healthcare Business Headquarters Telephone: +81 42 589 8429 Email: tsutomu.fukui1@konicaminolta.com
Date Prepared:	November 04, 2022
Device Name:	SKR 3000
Common Name:	Digital Radiography
Regulation Number:	21 CFR 892.1680
Regulation Name:	Stationary x-ray system
Regulatory Class:	Class II
Product Code(s):	MQB, LLZ
Predicate Device:	K213908 - SKR 3000 (KONICA MINOLTA, INC.) Regulation Number: 21 CFR 892.1680 Regulation Name: Stationary x-ray system Regulatory Class: Class II Product Codes: MQB, LLZ
Reference Device:	K221803 - PHOENIX/AeroDR TX m01 and PHOENIX/mKDR Xpress (SEDECAL SA) Regulation Number: 21 CFR 892.1720 Regulation Name: Mobile x-ray system Regulatory Class: Class II Product Codes: IZL, MQB

Device Description

The digital radiography SKR 3000 performs X-ray imaging of the human body using an X-ray planar detector that outputs a digital signal, which is then input into an image processing device, and the acquired image is then transmitted to a filing system, printer, and image display device as diagnostic image data.

• This device is not intended for use in mammography

• This device is also used for carrying out exposures on children.

The Console CS-7, which controls the receiving, processing, and output of image data, is required for operation. The CS-7 is a software with Moderate level of concern. CS-7 implements the following image processing; gradation processing, frequency processing, dynamic range compression, smoothing, rotation, reversing, zooming, and grid removal process/scattered radiation correction (Intelligent-Grid). The Intelligent-Grid is cleared in K151465. The CS-7 modifications have been made for a wireless serial radiography.

The SKR 3000 is distributed under a commercial name AeroDR 3.

This submission is to introduce a wireless serial radiography into the SKR 3000 system. The wireless serial radiography function of P-65 / P-75 used with Phoenix was cleared under K221803. These detectors are wireless and their serial radiography functions are not being controlled by the x-ray generator. Hence no detector integration testing is necessary.

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.

Comparison Table

The comparison to the predicate device was summarized in the table blow.

	Subject Device	Predicate Device
Device Name	**SKR 3000**	**SKR 3000**
510(K) Number	**K223267**	**K213908**
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.
DR Detector	P-61 (14" x 17") P-71 (17" x 17") P-81 (10" x 12") P-65 (14" x 17") P-75 (17" x 17") P-82 (14" x 17") P-85 (14" x 17") P-95 (17" x 17")	P-61 (14" x 17") P-71 (17" x 17") P-81 (10" x 12") P-65 (14" x 17") P-75 (17" x 17") P-82 (14" x 17") P-85 (14" x 17") P-95 (17" x 17")
Serial Radiography	Wired (P-61, P-71, P-65, P-75) Wireless (P-65, P-75)	Wired (P-61, P-71, P-65, P-75)
Components or Accessories	AeroDR Interface Units, Detector Interface Units, Power Supply Unit, Generator Interface Units, GIU SZ, Battery Charger, etc.	AeroDR Interface Units, Detector Interface Units, Power Supply Unit, Generator Interface Units, Battery Charger, etc.
Operator Console	CS-7	CS-7
Image Processing	Auto-gradation process Frequency processing (F process) Equalization processing (E process) Hybrid processing (HF, HE, HS) REALISM processing (RF, RE, RS) Intelligent-Grid Automatic exposure field recognition process	Auto-gradation process Frequency processing (F process) Equalization processing (E process) Hybrid processing (HF, HE, HS) REALISM processing (RF, RE, RS) Intelligent-Grid Automatic exposure field recognition process

Performance Data

The SKR 3000 is designed to comply with the following standard; AAMI/ANSI ES 60601-1 (Ed.3.1) and IEC 60601-1-2 (Ed.4.0). The verification and validation including the items required by the risk analysis for the SKR 3000 were performed and the results demonstrated that the predetermined acceptance criteria were met. The results of risk

management did not require clinical studies to demonstrate the substantial equivalency of the subject device modifications.

Conclusion

The SKR 3000 has the same intended use and indications for use, technological characteristics, and principal operations. The technological differences raised no new issues of safety or effectiveness as compared to its predicate device (K213908). Performance tests demonstrate that the SKR 3000 performs according to specifications and functions as intended. It is concluded that the subject device is to be as safe and effective as the predicate and substantially equivalent to the predicate device.