November 21, 2024

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

Re: K241319
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: May 10, 2024
Received: May 10, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241319

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.
The P-53 is for adult use only.

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

K241319

Company: KONICA MINOLTA, INC.
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Date Prepared: November 21, 2024

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: K151465 – AeroDR System2 (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: K210619 – 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

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 basic documentation level. 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.

This submission is to add the new flat-panel x-ray detector (FPD) P-53 to the SKR 3000. The new P-53 panel shows improved performance compared to the predicate device. The P-53 employs the same surface material infused with Silver ions (antibacterial properties) as the reference device.

The FPDs used in SKR 3000 can communicate with the image processing device through the wired Ethernet and/or the Wireless LAN (IEEE802.11a/n and FCC compliant). The WPA2-PSK (AES) encryption is adopted for a security of wireless connection.

The SKR 3000 is distributed under a commercial name AeroDR 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.

The P-53 is for adult use only.

KONICA MINOLTA

Comparison Table

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

	Subject Device	Predicate Device
Device Name	**SKR 3000**	**AeroDR System2**
510(K) Number	**K241319**	**K151465**
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. The P-53 is for adult use only.	The AeroDR SYSTEM 2 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 AeroDR SYSTEM 2 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.
Specification Detection method Scintillator TFT sensor substrate Image area size Pixel size A/D conversion Max. Resolution MTF(1.0 lp/mm) DQE (1.0 lp/mm)	**P-53** Indirect conversion method CsI (Cesium Iodide) Glass-based TFT substrate 345.6×420.0mm (2,304×2,800 pixels) 150 µm 16 bit (65,536 gradients) 2.5 lp/mm 0.62 40% @ 1mR	**P-52** Indirect conversion method CsI (Cesium Iodide) Glass-based TFT substrate 348.95 ×425.25mm (1,994×2,430 pixels) 175 µm 16 bit (65,536 gradients) 2.0 lp/mm 0.62 35% @ 1mR
Mechanical External dimensions IP Code (IEC 60529)	 384(W)×460(D)×15(H)mm IP56	 383.7(W)×460.2(D)×15.9(H)mm IPX5
Battery Type Number of batteries Battery duration in standby status	 Lithium-ion capacitor One Approx. 6.2 hours	 Lithium-ion capacitor One Approx. 10 hours
Surface Material	Carbon Surface infused with Silver ions (antibacterial properties)	Carbon Surface

	Subject Device	Predicate Device
Communication I/F	Wired and Wireless	Wired and Wireless
Peripherals, Cables/minor components	AeroDR Interface Units, Detector Interface Units, Power Supply Unit, Generator Interface Units, Battery Charger, Cables etc.	AeroDR Interface Units, Generator Interface Units, Battery Charger, Cables etc.
Operator console (Software)	CS-7 - SKR 3000/AeroDR3 interface for P-53 (CTDS)	CS-7 - SKR 3000/AeroDR3 interface for P-52 (CTDS)
Image Processing	Auto-gradation process Frequency processing (F process) Equalization processing (E process) Hybrid processing (HF process - HE process) Hybrid smoothing process (HS process) REALISM processing (RE process - RF process) REALISM smoothing process (RS process) Grid removal process/Scattered Radiation Correction (Intelligent-Grid) Automatic exposure field recognition process	Auto-gradation process Frequency processing (F process) Equalization processing (E process) Hybrid processing (HF process - HE process) Hybrid smoothing process (HS process) Grid removal process/Scattered Radiation Correction (Intelligent-Grid) Automatic exposure field recognition process
Serial radiography	Not applicable	Not applicable

The Indications for Use statement has been modified to exclude the P-53 from use in pediatric imaging. The software functionality remains unchanged from the recently cleared device (K223267).

Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility (EMC)

The system complies with the IEC 60601-1 for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Content of Premarket Submissions for Device Software Functions"*. The software for this device was considered as a "Basic" documentation level, since a failure or latent flaw in the software could not directly result in serious injury or death to the patient or operator.

Cybersecurity Testing

Security testings were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *"Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions"*.

Performance Testing

The performance testing was conducted according to the "*Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*". The comparative image testing was conducted to demonstrate substantially equivalent image performance for the subject device. The other verification and validation including the items required by the risk analysis for the SKR 3000 were performed and the results showed that the predetermined acceptance criteria were met. The results of risk management did not require clinical studies to demonstrate the substantial equivalence of the proposed device.

Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the SKR 3000 should perform for its intended purpose of general imaging. The comparative image data demonstrate that the SKR 3000 shows improved image performance compared to the predicate device.

Therefore, as for our conclusion, the SKR 3000 is substantially equivalent to the predicate devices and presents no new questions of safety or effectiveness.