



June 17, 2025

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

Re: K250665  
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 13, 2025  
Received: May 13, 2025

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A large, light blue 'FDA' watermark is visible in the background. Overlaid on it is a handwritten signature in black ink that reads 'Lu Jiang'.

Lu Jiang, 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

**Indications for Use**

510(k) Number (if known)

K250665

Device Name

SKR 3000

Indications for Use (Describe)

This device 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.

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

### K250665

Complying with 21 CFR R §807.92

#### I. SUBMITTER

KONICA MINOLTA, INC.  
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Mailing Address: 411 Newark Pompton Turnpike, Wayne, New Jersey 07470  
Date Prepared: June 13, 2025

#### II. DEVICE

Name of Device: SKR 3000  
Common Name: Digital Radiography  
Classification Name: Stationary x-ray system (21 CFR 892.1680)  
Regulatory Class: Class II  
Product Code: MQB, LLZ

#### III. PREDICATE DEVICES

**Primary Predicate Device:** K241319 - 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



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**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

#### **IV. 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.

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.

The purpose of the current premarket submission is to add pediatric use indications for the SKR 3000 imaging system.



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## **V. INDICATIONS FOR USE**

This device 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.

This device is not indicated for use in mammography, fluoroscopy, and angiography applications.

The subject device has the same Indications for Use statement as the primary predicate device except for the explicit inclusion of pediatric applications for the detector P-53 of the SKR 3000. This difference does not alter the intended use of the device. The subject device has the identical technological characteristics as the primary predicate device.

## **VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE**

The technological characteristics are identical in the proposed subject device and the primary predicate device. The sole purpose of this submission is to support the conditions of use for a pediatric population for the detector P-53 of the SKR 3000.

## **VII. PERFORMANCE DATA**

Since this submission is to support the conditions of use for a pediatric population for the detector P-53 of the SKR 3000, image quality evaluation was conducted in accordance with the *“Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices”*. Pediatric image evaluation using small-size phantoms was performed on the P-53.

The comparative image evaluation demonstrated that the SKR 3000 with P-53 provides substantially equivalent image performance to the comparative device, AeroDR System 2 with P-52, for pediatric use.



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## **VIII. CONCLUSIONS**

It is concluded that the subject device is as safe and effective as the predicates and is substantially equivalent to the predicate devices to support the indication for pediatric imaging for the detector P-53 of the SKR 3000.