August 24, 2021

Konica Minolta, Inc.
% Mr. Jan Maniscalco
QA Manager
Konica Minolta Healthcare Americas, Inc.
2217 US Highway 70 E
GARNER NC 27529

Re: K210619
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: July 16, 2021
Received: July 20, 2021

Dear Mr. 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,

, for

Thalia T. Mills, Ph.D.
Director
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)*
K210619

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 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.

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KONICA MINOLTA

510(k) Summary

K210619

Company: KONICA MINOLTA, INC.
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Date Prepared: August 23, 2021

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: K182688 - 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.

- The subject device SKR3000 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. 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 proposed SKR 3000 is modified to consist of new FPD P-65 and P-75 in addition to previously cleared P-61, P-71, and P-81, Console CS-7 and other peripherals. The DR Detector uses the exposure signal or exposure from the X-ray device to generate X-ray digital image data for diagnosis, including serial exposure images, and send to the image processing controller.

The operator console software, Console CS-7, is a software program for installation on a OTC PC. Software module modifications have been made to use new FPDs (P-65 and P-75) (Cassette Type Detection Software (CTDS)) and to support 40 seconds serial radiography (SIC).

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 new DR panels, P-65 and P-75, employ the surface material containing antibacterial agent in both radiation and irradiation sides. In the serial radiography settings, acquisition time has been changed from up to 20 seconds to 40 seconds to observe a variety of dynamic objects. Other control parameters of serial radiography are not changed from the predicate device.

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.

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	**K210619**	**K182688**
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 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.
Specification Detection method Scintillator Image area size Pixel size A/D conversion MTF(1.0 cycle/mm) DQE (1.0 cycle/mm) DQE (0 cycle/mm)	 Indirect conversion method CsI (Cesium Iodide) P-65: 348.8×425.6mm (3,488×4,256 pixels) P-75: 424.8×424.8mm (4,248×4,248 pixels) 100 µm / 200 µm / 400 µm 16 bit (65,536 gradients) (Non-binning) 0.62 (2x2 binning) 0.58 56% @ 1mR 65% @ 0.02mR	 Indirect conversion method CsI (Cesium Iodide) P-61: 348.8×425.6mm (3,488×4,256 pixels) P-71: 424.8×424.8mm (4,248×4,248 pixels) P-81: 245.6×296.8mm (2,456×2,968 pixels) 100 µm / 200 µm / 400 µm 16 bit (65,536 gradients) (Non-binning) 0.62 (2x2 binning) 0.58 56% @ 1mR 65% @ 0.02mR
Mechanical External dimensions IPX	 P-65: 384(W)×460(D)×15(H)mm P-75: 460(W)×460(D)×15(H)mm IPX6	 P-61: 384(W)×460(D)×15(H)mm P-71: 460(W)×460(D)×15(H)mm P-81: 282(W)×333(D)×15(H)mm IPX6
Battery (Lithium-ion capacitor) Battery duration in standby status	 P-65: Approx. 13.2 hours P-75: Approx. 12.2 hours	 P-61: Approx. 13.2 hours P-71: Approx. 12.2 hours P-81: Approx. 6.3 hours
Surface Material	Surface infused with Silver ions (antibacterial properties)	No antibacterial agent

	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, etc.	AeroDR Interface Units, Detector Interface Units, Power Supply Unit, Generator Interface Units, Battery Charger, etc.
Operator console (Software)	CS-7 - Software module modification to use new FPDs (Cassette Type Detection Software (CTDS)) - Software module modification to support 40 seconds serial radiography (SIC)	CS-7
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) REALISM processing (RE process - RF process) Realism smoothing process (RS process) Grid removal process/Scattered Radiation Correction (Intelligent-Grid) Automatic exposure field recognition process
Serial radiography	Max. acquisition time: 40 seconds	Max. acquisition time: 20 seconds

Performance Data

The SKR 3000 is designed to comply with the following standards; AAMI/ANSI ES 60601-1 (Ed.3.1), IEC 60601-1-2 (Ed.4.0), and ISO 10993-1 (2018). The performance tests according to the "*Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices*" and the other verification and validation including the items required by the risk analysis for the SKR3000 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 proposed device.

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 (K182688). Performance tests demonstrate that the SKR 3000 performs according to specifications and functions as intended. All the information to demonstrate assurance of our evaluation is attached to relevant sections of this submission.

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