Konica Minolta, Inc.
% Mr. Russell D. Munves
Official Correspondent
Storch Amini PC
140 East 45th Street
25th Floor
NEW YORK NY 10017

August 16, 2019

Re: K191645
Trade/Device Name: SKR 4000
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: June 17, 2019
Received: June 19, 2019

Dear Mr. Munves:

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K191645

Device Name
SKR 4000

Indications for Use *(Describe)*

The SKR 4000 is indicated for use in generating radiographic images of human anatomy. It is intended to replace a radiographic film/screen system in general purpose diagnostic procedures.

The SKR 4000 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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K191645

# 510(k) Summary

| | |
|---|---|
| Submitter's Name: | KONICA MINOLTA, INC. |
| Address: | 1 Sakura-machi,<br>Hino-shi, 191-8511 Japan |
| Contact: | Tsutomu Fukui |
| Telephone: | +81 42 589 8429 |
| Date: | July 26, 2019 |
| Trade Name: | SKR 4000 |
| Model No: | P-41 |
| Common Name: | Digital Radiography |
| Regulation Name / Number: | Stationary x-ray system / 21 CFR 892.1680 |
| Regulatory Class: | Class II |
| Product Code(s): | 90-MQB |

Predicate Device(s):

K160810 - ViZionDR + Wireless (Viztek LLC)
Regulation Name: Stationary x-ray system
Regulation Number: 21CFR 892.1680
Product Codes: 90-MQB

K182688 - SKR 3000 (KONICA MINOLTA, INC.)
Regulation Name: Stationary x-ray system
Regulation Name: 21CFR 892.1680
Product Codes: 90-MQB, 90-LLZ

Device Description:

The SKR 4000 consists of the DR Detector (P-41), Battery, Battery Charger, AC Adapter, AC Power Cable and DC Power Cable. It is intended for use replacing a radiographic film/screen system in general-purpose diagnostic procedures of human anatomy.

The SKR 4000 performs radiography imaging of the human body using an X-ray FPD that outputs a digital signal, which is then input into an image processing device.

The SKR 4000 can communicate with the image processing device through the Wireless LAN (IEEE802.11a/b/g/n/ac and FCC compliant). The WPA2-PSK (AES) encryption is adopted for a security of wireless connection.

The SKR 4000 is designed to comply with the following standards; AAMI/ANSI ES 60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance", IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests", and ISO 10993-1 "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Indications for Use:

The SKR 4000 is indicated for use in generating radiographic images of human anatomy. It is intended to replace a radiographic film/screen system in general-purpose diagnostic procedures.

The SKR 4000 is not indicated for use in mammography, fluoroscopy and angiography applications.

Comparison Table:

| | Subject Device | Predicate Device 1 (PD1) | Predicate Device 2 (PD2) |
|---|---|---|---|
| | SKR 4000 | ViZionDR + Wireless | SKR 3000 |
| **510(K) Number** | This Submission | K160810 | K182688 |
| **Indications for Use** | The SKR 4000 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 4000 is not indicated for use in | Intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion DR + Wireless allows imaging of skull, chest, | 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 30000 is not indicated for use in |

| | Subject Device | Predicate Device 1 (PD1) | Predicate Device 2 (PD2) |
|---|---|---|---|
| | SKR 4000 | ViZionDR + Wireless | SKR 3000 |
| **510(K) Number** | This Submission | K160810 | K182688 |
| | mammography, fluoroscopy, and angiography applications. | shoulders, spine, abdomen, pelvis, and extremities. | mammography, fluoroscopy and angiography applications. |
| **Specification** | | | |
| Detection method | Same as PDs | Indirect conversion method | Indirect conversion method |
| Scintillator | Same as PDs | CsI (Cesium Iodide) | CsI (Cesium Iodide) |
| Image area size | 345.6×420.0mm (2,304 x 2,800 pixels) | 343.2mm x 420mm (2,288 x 2,784 pixels) | 348.95×425.25mm (3,488 × 4,256pixels) |
| Pixel size | Same as PD1 | 150 µm | 100 µm / 200 µm / 400 µm |
| A/D conversion | Same as PD2 | 14 bit | 16 bit |
| MTF (1.0 cycle/mm) | More than 0.60 | 0.83 at 0.5 (1/mm) (Better) | More than 0.53 |
| DQE (1.0 cycle/mm) | More than 30%@0.3mR | 0.55 at 0.5 (1/mm) (Better) | More than 49% @ 1mR<br>More than 39% @ 0.1mR |
| **Electrical** | | | |
| Power source | Same as PD1 | AC Line and/or Removable Battery | AC Line and/or Built-in Battery |
| Battery type | Same as PD1 | Lithium Ion Battery | Lithium Ion Capacitor |
| **Mechanical** | | | |
| External dimensions | 384(W)×460(D)×15(H)mm | 384(W)×460(D)×15.2(H)mm | 384(W)×460(D)×15(H)mm |
| Weight | 3.6kg (with battery) | 3.82 kg (with battery) | 2.6 kg |
| IPX | IPX1 | IPX0 | IPX6 |
| **Communication** | Wireless | Wireless/Wired | Wireless/Wired |

Summary of Technological Characteristics

Compared to Predicate Devices:

The SKR 4000 employs the same fundamental scientific technologies as the PDs (K160810 and K182688). The indications for use is identical to the PD1 (K182688), and the other summary of comparisons of technological characteristics for both systems is provided below;

<u>Operational principles and designing:</u>

The SKR 4000 has same scientific technologies and operational principal as the predicate devices (K160810 and K182688). All the verification activities required by the specification and the risk analysis for the SKR 4000 were performed and the results demonstrated that the predetermined acceptance criteria were met.

Performance test:

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 SKR 4000 were performed and the results demonstrated that the predetermined acceptance criteria were met.

The concurrence study is not necessary because the proposed modifications are categorized as the type of unnecessary to provide additional clinical data in accordance with the SSXI guidance. Besides, the results of risk management did not require clinical studies to demonstrate the substantial equivalency of the proposed device.

Safety:

The system is in conformance with the standards described above, which are same standards to those of predicate device.
The risk analysis for the SKR 4000 has been conducted in accordance with ISO 14971 "Medical devices -- Application of risk management to medical devices". The risks associated with all the identified hazards were reduced to acceptable level by the risk control measures as shown in risk assessment record.

Biocompatibility:

The all patient contact materials for human body surface are evaluated under ISO 10993 "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process" and determined as acceptable for this usage. The proposed P-41 and the predicate devices achieve the same acceptance level for biocompatibility.

Relevant FDA Guidance

The SKR 4000 was developed in accordance with the following FDA guidance:

- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices (September 2016)
- Radio Frequency Wireless Technology in Medical Devices (August 2013)
- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices (September 2018)
- Refused to Accept Policy for 510(k)s (February 2019)
- Format for Traditional and Abbreviated 510(k)s (August 2005)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)

Conclusion:

The SKR 4000 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 devices. Performance tests demonstrate that the SKR 4000 performs according to specifications and functions as intended. Therefore, the SKR 4000 is substantially equivalent to its predicate devices (K160810 and K182688).