DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

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

October 3, 2016

Re: K162504
Trade/Device Name: SKR 3000
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB, LLZ
Dated: September 5, 2016
Received: September 7, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162504

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 a radiographic film/screen system in general purpose diagnostic procedures.

The SKR 3000 is not indicated for use in mammography, fluoroscopy, tomography 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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510(k) Summary

Submitter's Name:	KONICA MINOLTA, INC.
Address:	1 Sakura-machi, Hino-shi, 191-8511 Japan
Contact:	Tsutomu Fukui
Telephone:	+81 42 589 8429
Date:	September 28, 2016
Trade Name:	SKR 3000
Model No:	P-61
Common Name:	Digital Radiography
Regulation Name / Number:	Stationary x-ray system / 21 CFR 892.1680
Regulatory Class:	Class II
Product Code(s):	90-MQB, 90-LLZ
Predicate Device(s):	K141271 - AeroDR SYSTEM 2 (KONICA MINOLTA, INC.) Regulation Name: Stationary x-ray system (21CFR 892.1680), Product Codes: 90-MQB, 90-LLZ

Device Description:

The SKR 3000 consisting of new FPD P-61, Console CS-7 and other peripherals is intended for use replacing a radiographic film/screen system in general-purpose diagnostic procedures of human anatomy. The system can be used in conjunction with current cleared AeroDR FPDs. The P-61 and the other compatible FPDs availably used in SKR 3000 are lightweight, mobile FPD and they are formed in compatible size with the cassette of ISO standard size.

The SKR 3000 performs radiography imaging of the human body using an X-ray planar detector (FPD) that outputs a digital signal, which is then input into an image processing device. The acquired image is transmitted to a filing system, printer, and image display device as diagnostic image after applying image processing to the raw data of image by the image processing device, Console CS-7.

The acquisition of the X-ray image in the FPD begins being synchronized with a trigger timing of X-ray irradiation in SRM / S-SRM connection between the SKR 3000 and X-ray generator. The AeroSync allows to use a FPD without a wired connection of SRM / S-SRM, the FPD itself begins to acquire an image when it detects X-ray irradiation in this mode.

The SKR 3000 can be connected with X-ray devices being compatible with XIF, XGIF or UEC Board along with certain electronic requirement such as specific signal controls for hardware and software, that information is separately provided pursuant to needs of a user and/or an assembler.

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 designed to comply with the following standards; AAMI/ANSI ES 60601-1 (Ed.3.1), IEC 60601-1-2, and ISO 10993-1.

Indications for Use:

The SKR 3000 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 3000 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

Predicate Comparison Table:

	KONICA MINOLTA SKR 3000	KONICA MINOLTA AeroDR SYSTEM 2
510(K) Control Number	Proposed device	K141271
Indications for Use	Same as Predicate device	
Specification		
Detection method	Same as Predicate device	Indirect conversion method
Scintillator	Same as Predicate device	CsI (Cesium Iodide)
Image area size	348.8×425.6mm (3,488×4,256 pixels@100 µm)	348.95×425.25mm (1,994×2,430 pixels)
Pixel size	100 µm / 200 µm	175 µm
A/D conversion	Same as Predicate device	16 bit (65,536 gradients)

	KONICA MINOLTA SKR 3000	KONICA MINOLTA AeroDR SYSTEM 2
510(K) Control Number	Proposed device	K141271
Mechanical		
External dimensions	384(W)×460(D)×15(H)mm	383.7(W)×460.2(D)×15.9(H)mm
Weight	Same as Predicate device	2.6 kg
IPX	Same as Predicate device	IPX6
Communication I/F	Same as Predicate device	
Operator console	Same as Predicate device	
Compatible X-ray system Spec.	Same as Predicate device	

Summary of Technological Characteristics
Compared to Predicate Device:

The SKR 3000 employs the same fundamental scientific technologies as the predicate device (K141271). The indications for use are same as the predicate device, and the other summary of comparisons of technological characteristics for both systems is provided below;

Operational principles and designing:

Nothing was changed in the operational principles of the SKR 3000 from the predicate device. The proposed P-61 provides smaller pixel size and higher DQE than those of the predicate AerDR P-51, however it employs the same structure and principles as the predicate AeroDR P-51. The newly designed peripheral components provides same function of the component of the predicate device, and complies with same EMC and electrical safety standards. The proposed device is essentially the same as previously cleared predicate device from technology view point.

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 3000 were performed and the results demonstrated that the predetermined acceptance criteria were met.

The concurrence study in a way of comparing images between the proposed device and the predicate device was conducted, and the qualified persons have affirmed and have concluded that both images of proposed P-61 and predicate AeroDR P-51 are equivalent and have

sufficient capabilities for the intended purpose of the device. 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.

Biocompatibility:
The all patient contact materials for human body surface are evaluated under ISO 10993 and determined as acceptable for this usage. The proposed P-61 and the predicate AeroDR P-51 achieve same acceptance level for biocompatibility.

Conclusion:

The clinical study as a performance testing is not required to support substantial equivalence for the proposed device. In addition, as discussed in the above technological comparison, the technological characteristics of the SKR 3000 are deemed to be substantially equivalent to the predicate device that have already been cleared for USA distribution with 510(k) premarket notification number K141271.