DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

June 29, 2015

Re: K151465
Trade/Device Name: AeroDR System 2
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB, LLZ
Dated: May 28, 2015
Received: June 1, 2015

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 A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K151465

Device Name
AeroDR System 2

Indications for Use *(Describe)*
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-purpse diagnostic procedures.

The AeroDR SYSTEM 2 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter's Name:	KONICA MINOLTA, INC.
Address:	1 Sakura-machi, Hino-shi, 191-8511 Japan
Contact:	Shigeyuki Kojima
Telephone:	+81 42 589 8429
Date:	May 28, 2015
Trade Name:	AeroDR System 2
Model No:	AeroDR P-51, AeroDR P-52
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 AeroDR SYSTEM 2 including AeroDR P-51 and AeroDR P-52 is intended for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures. The AeroDR SYSTEM 2 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

The AeroDR P-51 and AeroDR P-52 (hereinafter AeroDR detector) are lightweight, mobile FPD those are that is compatible with the size of ISO standard.

The AeroDR SYSTEM 2 performs X-ray 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, and the acquired image is then transmitted to a filing system, printer, and image display device as diagnostic image data. The image processing device displays the image on the screen after applying image processing to the raw data of image provided by FPD. The AeroDR detector 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 operator console software, Console CS-7, is a software program for installation on a PC. It performs image processing of X-ray images received from an AeroDR FPDs. The modified post processing function named 'Intelligent Grid' (IG Processing) is introduced as a part of the Image post processing function of console CS-7 software. The IG processing are fundamentally the same as those functions of other post processing of the Image Processing module of Console CS-7. The IG Processing is NOT a function for substitution of Grid's effects. It's a post processing of image adjustment to reduce the effects of scatter radiation. The user can adjusts to improve contrast by reducing effects of scatter radiation, and then the user MUST confirm the effects of the processing prior to determining the final images as well.

The AeroDR System 2 is designed to comply with the following standards: AAMI/ANSI ES 60601-1 (Ed.3), IEC 60601-1-2, and ISO 10993-1.

Indications for Use:

The AeroDR SYSTEM2 is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen systems in general-purpose diagnostic procedures. The AeroDR SYSTEM 2 is not indicated for use in mammography, fluoroscopy, tomography and angiography applications.

Summary of Technological Characteristics
Compared to Predicate Device:

The modified AeroDR SYSTEM 2 employs the same fundamental scientific technologies as the predicate device (K141271). The indications for use are identical to the predicate device, and the operating principles are not changed from K141271.

The summary of comparisons of technological characteristics for both systems is provided as follows;

Operational principles and designing:
Nothing to be changed from the operational principles of the predicate device. The changes in operation and weight by means of different size of battery are NOT essential for the intended use of this device.
The specification for the image performance of proposed device is same as AeroDR P-12, which is a component of AeroDR SYSTEM 2(K141271) and originally cleared as K102349.

Non-clinical test:
The qualified persons have affirmed and have concluded that both non-clinical images of proposed AeroDR P-52 and predicate AeroDR P-12 are equivalent and have sufficient capabilities for the intended purpose of the device. Besides, the results of risk management, the proposed modification does NOT require clinical evaluation to demonstrate the substantial equivalency of the modified device.

Safety:
The system is in conformance with the standards described above, which are same standards to those of predicate device.

Biocompatibility:
The patient contact materials of human body surface are evaluated under ISO 10993 and determined as acceptable for these usages. The both systems achieve same acceptance level for biocompatibility.

Modification under the Design Control as per 21CFR 820.30:
The risk analysis was performed on the proposed device including two major differences from the predicate device, that differences are the addition of AeroDR P-52 and the modification of the post processing function named 'Intelligent Grid' of console CS-7 software, and the conclusion of risk analysis is that two above-mentioned changes don't pose any significant risk to device safety or effectiveness. The modified device has been verified and validated according to the same procedure as the predicate device. All of the verification activities, as required by the risk analysis, for the modification to AeroDR SYSTEM 2 were performed and the results demonstrated that the predetermined acceptance criteria were met.

Conclusion:

The clinical studies as a performance testing are not required to support substantial equivalence for the proposed device. In addition to that, as discussed in the above technological comparison, the technological characteristics of the modified AeroDR SYSTEM 2 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.