September 13, 2021

Konica Minolta, Inc.
% Jan Maniscalco
Director of QA/RA
Konica Minolta Healthcare Americas, Inc.
411 Newark-Pompton Turnpike
WAYNE NJ 07470

Re: K212685
Trade/Device Name: KONICAMINOLTA DI-X1
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: August 16, 2021
Received: August 24, 2021

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 (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)*
K212685

Device Name
KONICAMINOLTA DI-X1

Indications for Use *(Describe)*
KONICAMINOLTA DI-X1 is a software device that receives digital x-ray images and data from various sources (i.e. R/F Units, digital radiographic devices or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and/or across computer networks at distributed locations. It is not intended for use in diagnostic review for mammography.

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

K212685

Company: KONICA MINOLTA, INC.
1 Sakura-machi, Hino-shi, Tokyo, 191-8511 Japan

Contact: Tsutomu Fukui
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Date Prepared: September 08, 2021

Device Name:

Trade Name:	KONICAMINOLTA DI-X1
Common Name:	Medical Image Management and Processing System
Regulation Number:	21 CFR 892.2050
Regulatory Class:	Class II
Product Code(s):	LLZ

Predicate Device: K182431 - KONICAMINOLTA DI-X1
KONICA MINOLTA, INC.
Regulation Number: 21 CFR 892.2050
Regulatory Class: Class II
Product Codes: LLZ

Device Description

KONICAMINOLTA DI-X1 is a software device that performs image processing and display using X-ray digital images (single-frame images, multi-frame images) generated by various diagnostic imaging modality consoles. It is a standalone software device intended to install onto off-the -shelf Servers and PCs.

KONICAMINOLTA DI-X1 receives X-ray digital images, including serial images, processes the received images, as well as displays and sends the resulting images to PACS and other devices. In addition, KONICAMINOLTA DI-X1 can display images through the browser connection with the client that displays and process images, and instruct transmission of images.

The personal computer used in KONICAMINOLTA DI-X1 stores the same data in two hard disks in real time using RAID1 mirroring function. Thus, even if one hard disk is defective, operations can be continued with the other hard disk which has the same data.

The modifications are made on software to the identified predicate device to add the PC client to connect to the server using the browser on a personal computer to display images for a WEB reference. In addition, additional imaging processing MODES are implemented into the subject device. The subject device also modifies the graphical display to compare the past exam. graphs based on the measurement values in a chronological order.

Indications for Use

KONICAMINOLTA DI-X1 is a software device that receives digital x-ray images and data from various sources (i.e. R/F Units, digital radiographic devices or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and/or across computer networks at distributed locations. It is not intended for use in diagnostic review for mammography.

Comparison Table

The comparison to the predicate decides was summarized in the Table below.

	Subject Device	Predicate Device
	KONICAMINOLTA DI-X1	**KONICAMINOLTA DI-X1**
510(K) Number	**This Submission**	**K182431**
Indications for Use	KONICAMINOLTA DI-X1 is a software device that receives digital x-ray images and data from various sources (i.e. R/F Units, digital radiographic devices or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and/or across computer networks at distributed locations. It is not intended for use in diagnostic review for mammography.	KONICAMINOLTA DI-X1 is a software device that receives digital x-ray images and data from various sources (i.e. R/F Units, digital radiographic devices or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and/or across computer networks at distributed locations. It is not intended for use in diagnostic review for mammography.
Input image	• DICOM 3.0 • DICOM Modality (RF, DX, CR)	• DICOM 3.0 • DICOM Modality (RF, DX, CR)
I/O Data	• DICOM Storage	• DICOM Storage
Image Processing	• REGIUS • FE-MODE • DM-MODE • BS-MODE • PL-MODE • Pk to Pk • PH-MODE • PH2-MODE • LM-MODE	• REGIUS • FE-MODE • DM-MODE • BS-MODE • PL-MODE • Pk to Pk
Display Functions	• Adjustment of density and gradation, Rotation and reversal, Scaling, Panning • Screen display (listing, viewer) • Image display (Cine, Comparison, Annotation, Overlay) • Graph display (Time-series comparison)	• Adjustment of density and gradation, Rotation and reversal, Scaling, Panning • Screen display (listing, viewer) • Image display (Cine, Comparison, Annotation, Overlay) • Graph display
Measurement	• Distance • Angle • Area • CTR (Only the image of the front of the chest)	• Distance • Angle • Area • CTR
Client	• DI-X1 client • DI-X1 Server client • PC client (WEB reference)	• DI-X1 client • DI-X1 Server client

Performance Data

All the verification activities required by the specification and the risk analysis for the KONICAMINOLTA DI-X1 were performed and the results demonstrated that the predetermined acceptance criteria were met. No clinical studies were required to support the substantial equivalence.

Conclusion

KONICAMINOLTA DI-X1 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 (K182431). Performance tests demonstrate that the KONICAMINOLTA DI-X1 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 KONICAMINOLTA DI-X1 is substantially equivalent to the predicate device and presents no new questions of safety or effectiveness.