Konica Minolta, Inc.
% Jan Maniscalco
Executive Vice President QA/RA
Konica Minolta Healthcare Americas, Inc.
411 Newark Pompton Turnpike
Wayne, New Jersey 07470

April 25, 2023

Re: K230906
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: March 31, 2023
Received: March 31, 2023

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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)*
K230906

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

K23xxxx (will be assigned)

Company: KONICA MINOLTA, INC.
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Date Prepared: March 31, 2023

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: K212685 - KONICAMINOLTA DI-X1
KONICA MINOLTA, INC.
Regulation Number: 21 CFR 892.2050
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.

Modifications are made to add the TD-MODE, Position Tracking and Signal Value Change. The TD-MODE is designed to extract the initial contour of the tracheal wall. The TD-MODE also displays the minimum and maximum tracheal diameter in the frame. The subject device also incorporates Position Tracking and Signal Value Change. Position Tracking is used to track the reference point specified in a frame and display a graph of the position change data. Signal Value Change graphically displays the signal value change within the ROI specified in a frame.

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**
Device name	**KONICAMINOLTA DI-X1**	**KONICAMINOLTA DI-X1**
Version	**1.30**	**1.20**
510(K) Number	**This Submission**	**K212685**
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	• REGIUS	• REGIUS

	Subject Device	Predicate Device
Device name	**KONICAMINOLTA DI-X1**	**KONICAMINOLTA DI-X1**
Version	**1.30**	**1.20**
510(K) Number	**This Submission**	**K212685**
Processing	• FE-MODE • DM-MODE • BS-MODE • PL-MODE • PH-MODE • PH2-MODE • LM-MODE • TD-MODE	• FE-MODE • DM-MODE • BS-MODE • PL-MODE • Pk to Pk • PH-MODE • PH2-MODE • LM-MODE
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) • Graph display the max/min of the tracheal diameter including past images	• 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)
Measurement	• Distance • Angle • Area • CTR (Only the image of the front of the chest) • Position Tracking, Signal Value Change	• Distance • Angle • Area • CTR (Only the image of the front of the chest)
Client	• DI-X1 client • DI-X1 Server client • PC client (WEB reference)	• DI-X1 client • DI-X1 Server client • PC client (WEB reference)

Performance Data

All the verification activities required by the specification and the risk analysis for the KONICAMINOLTA DI-X1 were performed and the results showed 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 principle operations. The technological differences do not raise new issues of safety or effectiveness as compared to its predicate device (K212685). Performance tests demonstrate that the KONICAMINOLTA DI-X1 performs according to specifications and functions

as intended. All information supporting our assessment is included in the relevant sections of this submission.
Therefore, it is our conclusion that the KONICAMINOLTA DI-X1 is substantially equivalent to the predicate device and does not raise new issues of safety or effectiveness.