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

May 6, 2021

Re: K210066
Trade/Device Name: ImagePilot
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: April 7, 2021
Received: April 8, 2021

Dear Ms. 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)*
K210066

Device Name
ImagePilot

Indications for Use *(Describe)*
The ImagePilot software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications. The ImagePilot software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The ImagePilot software can process and display medical images from the following modality types: Plain X-ray Radiography, X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities. The ImagePilot must not be used for primary image diagnosis in 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.

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510(k) Summary

K210066

Company: KONICA MINOLTA, INC.
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Date Prepared: May 06, 2021

Device Name:

Trade Name:	ImagePilot
Version:	Version 1.92
Common Name:	Medical Image Management and Processing System
Regulation Number:	21 CFR 892.2050
Regulatory Class:	Class II
Product Code(s):	LLZ

Primary Predicate Device:	K071436 -	REGIUS Unitea KONICA MINOLTA MEDICAL & GRAPHIC, INC. Regulation Number: 21 CFR 892.2050 Product Codes: LLZ
Secondary Predicate Device:	K133730 -	CO Pilot/REGIUS Unitea KONICA MINOLTA, INC. Regulation Name: 21 CFR 892.2050 Product Codes: LLZ

Device Description

The ImagePilot software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications. The ImagePilot software primarily facilitates

processing and presentation of medical images on display monitors suitable for the medical diagnostics task being performed. The ImagePilot software can process and display medical images from the following modality types: Plain X-ray Radiography, X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities including mammography. When used for mammography the ImagePilot should never be used as a diagnostic tool.

Indications for Use

The ImagePilot software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications. The ImagePilot software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The ImagePilot software can process and display medical images from the following modality types: Plain X-ray Radiography, X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities. The ImagePilot must not be used for primary image diagnosis in mammography.

Comparison Table

The comparison to the predicate decides was summarized in the table blow.

	Subject Device	**Predicate Device 1 (PD1)**	**Predicate Device 2 (PD2)**
	ImagePilot	**REGIUS Unitea**	**CO Pilot/REGIUS Unitea**
510(K) Number	**K210066**	**K071436**	**K133730**
Indications for Use	The ImagePilot software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications. The ImagePilot software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The ImagePilot software can process and display medical images from the following modality types: Plain X-ray Radiography,	The REGIUS Unitea software is intended for installation on an off-the-shelf PC meeting or exceeding minimum specifications. The REGIUS Unitea software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The REGIUS Unitea software can process and display medical images from the following modality types:	The CO pilot is intended for installation on an off-the-shelf PC (REGIUS Unitea /510(K) number: K071436) meeting or exceeding minimum specifications. The CO pilot software primarily facilitates processing and presentation of medical images on display monitors suitable for the medical task being performed. The CO pilot software can process and display images from the following modality types: Plain X-ray Radiography,

	Subject Device	Predicate Device 1 (PD1)	Predicate Device 2 (PD2)
	ImagePilot	**REGIUS Unitea**	**CO Pilot/REGIUS Unitea**
510(K) Number	**K210066**	**K071436**	**K133730**
	X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities. The ImagePilot must not be used for primary image diagnosis in mammography.	Plain X-ray Radiography, X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities. The REGIUS Unitea must not be used for primary image diagnosis in mammography.	X-ray Computed Tomography, Magnetic Resonance imaging, Ultrasound, Nuclear Medicine and other DICOM compliant modalities. The CO pilot must not be used for primary image diagnosis in mammography.
Operating System	Microsoft Windows 10	Microsoft Windows XP	Microsoft Windows 7
Importable images	• CR images (REGIUS110/190/Σ1/Σ2/210/110HQ) • DR Images (AeroDR System, AeroDR System2, SKR3000, SKR4000) • DICOM Images (CT, MRI, US, etc.) • Generic format images	• CR images (REGIUS110/190/110HQ) • DICOM (CT, MRI, US, etc.) • Generic format images	• CR images (REGIUS110/190/Σ1/Σ2/210/110HQ) • DR Images (AeroDR System) • DICOM Images (CT, MRI, US, etc.) • Generic format images
Image Processing	• Automatic tone adjustment • Sharpness processing • Equalization processing • Noise suppression function • Automatic customize function • Initial display optimization processing (DR only) • Grid Suppression • Masking • Re-sampling and Resizing • Stitching • Bone suppression function	• Automatic tone adjustment • Sharpness processing • Equalization processing • Noise suppression function • Automatic customize function • Grid Suppression • Masking • Re-sampling and Resizing • Stitching	• Automatic tone adjustment • Sharpness processing • Equalization processing • Noise suppression function • Automatic customize function • Initial display optimization processing (DR only) • Grid Suppression • Masking • Re-sampling and Resizing • Stitching

Technological Characteristics

The subject and predicate devices use the same fundamental scientific technology to perform their intended use. Those modifications are for software modifications to the identified predicate device to update the Windows 10. In addition, the Bone Suppression

function cleared by via the KONICAMINOLTA Di-X1 (K182431) is incorporated into the subject device. The subject device also adds the cleared Konica Minolta Digital Radiography Systems (AeroDR System2, SKR 3000, and SKR 4000).
These differences were found to not affect safety or effectiveness via design verification activities.

Performance Data

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

Conclusion

The modifications raised no new issues of safety or effectiveness as compared to its legally marketed predicate devices. Performance tests demonstrate that the ImagePilot performs according to specifications and functions as intended. Therefore, the ImagePilot is substantially equivalent to its predicate devices (K071436 and K133730).