Merge Healthcare Incorporated
% Ms. Carol Nakagawa
Sr. Manager of Regulatory Affairs
900 Walnut Ridge Drive
HARTLAND WI 53029

January 26, 2021

Re: K203104
Trade/Device Name: IBM iConnect Access
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: December 17, 2020
Received: December 17, 2020

Dear Ms. Nakagawa:

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)*
K203104

Device Name

IBM iConnect Access

Indications for Use *(Describe)*

The IBM iConnect Access application provides internet access to multi-modality softcopy medical images, reports, and other patient-related information to conduct diagnostic review, planning and reporting through the interactive display and manipulation of medical data. IBM iConnect Access provides healthcare professional tools to aid in interpreting medical images including:

- Displaying DICOM compliant medical images and non-DICOM content using XDS
- Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images
- Manipulating displayed images via control of slice thickness, slice interval, obliquity, perspective, rotation, window/level, crop, zoom, color/monochrome transformations, segmentation, sculpting, straightening the display of curved structures, and creating images perpendicular to a curvilinear path.
- Creating individually captured DICOM images that can be displayed and stored in a PACS
- Measuring coronary calcium, which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms.
- Creating and outputting digital files suitable for the fabrication of physical replicas, such as 3D printing, using DICOM files as inputs. Physical/3D printed models generated from the digital output files are not for diagnostic use.

The IBM iConnect Access application can be configured to provide either lossless or lossy compressed images for display. The medical professional user must determine the appropriate level of image data compression that is suitable for their purpose.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. Use of IBM iConnect Access application on mobile devices such as iPhones and iPads is not intended for diagnostic use.

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

K203104

In accordance with 21 CFR 807.92 the following summary of information is provided:

Submitter Information

Submitter:	Merge Healthcare Incorporated 900 Walnut Ridge Drive Hartland, Wisconsin 53209 USA
510(k) Number:	K203104
Date Prepared:	October 9, 2020
Contact Person:	Carol Nakagawa Sr. Manager of Regulatory Affairs Phone: (905) 316-2579 Email: carol.nakagawa@ca.ibm.com or med.reg.contact@ca.ibm.com
Secondary Contact:	Tracey Fox RAQA Executive, Regulatory Affairs Phone: (262) 369-3156 Email: tracey.fox@ibm.com

Identification of the Device

Trade Name:	IBM iConnect Access
Common Name:	Picture Archiving and Communication System (PACS)
Classification Name:	Radiological Image Processing System 21 CFR 892.2050
Product Code:	LLZ
Device Class:	Class II

Predicate Device

Predicate Device:	IBM iConnect Access 7.0 (K182290)

Device Description

IBM iConnect Access provides healthcare professionals with access to diagnostic quality images, reports, and various types of patient data over conventional TCP/IP networks.

With no download or application-specific installation required on the user's computer, healthcare professionals can use IBM iConnect Access with a standard internet browser to view exams and

patient information including but not limited to the following content: Diagnostic Reports, Key Images, Presentation Series, Modality Imaging, Scope/ Surgery Videos, Visible Light, and File Attachments.

IBM iConnect Access was designed with an easy and convenient workflow providing image viewing and manipulation capabilities including but not limited to zoom, pan, window/ level, scroll, CINE, link series, line/ angle/ ROI measurements, and MPR.

The software displays patient studies and other patient data but does not interpret or provide a diagnosis. Medical diagnosis is the responsibility of the user.

When configured by an Administrator, patients can view their radiological information via portals that launch IBM iConnect Access and provide the ability to view clinical results, modality imaging, key images, scope/surgery videos, and associated clinical documentation. The role for patient access is limited to zooming the image, panning the image, and scrolling through a series of images.

The IBM iConnect Access 3D advanced imaging solution supports MIP (maximum intensity project), MPR (multiplanar reconstruction), 3D volume rendering, and cardiac calcium scoring. Reading physicians, referring physicians, and other appropriate healthcare personnel and can employ advanced image processing and display from local or remote locations.

IBM iConnect Access provides advanced image segmentation and editing tools for the purpose of creating digital 3D anatomical models. These models can be exported as STL files for the purpose of fabricating physical replicas, such as 3D printing. Physical/3D printed models generated from the digital output files are not for diagnostic use.

IBM iConnect Access can be used to query and retrieve content from the IBM iConnect Enterprise Archive. IBM iConnect Enterprise Archive is a software system that supports storage and communications of medical images and data. Qualified system administrators monitor and maintain the software in their healthcare enterprise environment.

IBM iConnect Suite is an offering that combines the image storage capability of IBM iConnect Enterprise Archive with the diagnostic viewer capability of IBM iConnect Access.

Intended Use / Indications for Use

The IBM iConnect Access application provides internet access to multi-modality softcopy medical images, reports, and other patient-related information to conduct diagnostic review, planning and reporting through the interactive display and manipulation of medical data. IBM iConnect Access provides healthcare professional tools to aid in interpreting medical images including:

- Displaying DICOM compliant medical images and non-DICOM content using XDS
- Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images
- Manipulating displayed images via control of slice thickness, slice interval, obliquity, perspective, rotation, window/ level, crop, zoom, color/monochrome transformations, segmentation, sculpting, straightening the display of curved structures, and creating images perpendicular to a curvilinear path.
- Creating individually captured DICOM images that can be displayed and stored in a PACS

- Measuring coronary calcium, which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms.
- Creating and outputting digital files suitable for the fabrication of physical replicas, such as 3D printing, using DICOM files as inputs. Physical/3D printed models generated from the digital output files are not for diagnostic use.

The IBM iConnect Access application can be configured to provide either lossless or lossy compressed images for display. The medical professional user must determine the appropriate level of image data compression that is suitable for their purpose.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.

Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. Use of IBM iConnect Access application on mobile devices such as iPhones and iPads is not intended for diagnostic use.

Technological Characteristics

IBM iConnect Access is a zero-client universal viewer and image sharing/exchange platform that has multiple modules and scalable architectures.

Determination of Substantial Equivalence

The modification to IBM iConnect Access includes updates to the software and labeling. A summary of the key changes in the subject device compared to the predicate device IBM iConnect Access that was cleared in 510(k) K182290 is provided below. Additional non-significant changes to non-clinical workflow and performance speed were made, and software bugs were fixed.

	Proposed Device: **IBM iConnect Access (v8.0)**	**Predicate Device:** **IBM iConnect Access (v7.0)** **K182290**	**Rationale**
510(k) Number	TBD	K182290	Information Only
510(k) Applicant	Merge Healthcare Incorporated	Merge Healthcare Incorporated	Information Only
Common Name of Device/ Classification/ Product Code	Picture Archiving and Communications System (PACS) 21 CFR 892.2050 LLZ – Radiological Image Processing System	Picture Archiving and Communications System (PACS) 21 CFR 892.2050 LLZ – Radiological Image Processing System	Information Only
Intended Use/Indications for Use	The IBM iConnect Access application provides internet access to multi-modality softcopy medical images,	The IBM iConnect Access application provides internet access to multi-modality softcopy medical images,	Substantially Equivalent:

	Proposed Device: IBM iConnect Access (v8.0)	Predicate Device: IBM iConnect Access (v7.0) K182290	Rationale
	reports, and other patient-related information to conduct diagnostic review, planning and reporting through the interactive display and manipulation of medical data. IBM iConnect Access provides healthcare professional tools to aid in interpreting medical images including: • Displaying DICOM compliant medical images and non-DICOM content using XDS • Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images • Manipulating displayed images via control of slice thickness, slice interval, obliquity, perspective, rotation, window/ level, crop, zoom, color/monochrome transformations, segmentation, sculpting, straightening the display of curved structures, and creating images perpendicular to a curvilinear path. • Creating individually captured DICOM images that can be displayed and stored in a PACS • Measuring coronary calcium, which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms. • Creating and outputting digital files suitable for the fabrication of physical replicas, such as 3D printing, using DICOM files as inputs. Physical/3D printed models generated from the digital output files are not for diagnostic use. The IBM iConnect Access application can be configured to provide either lossless or lossy compressed images for display. The medical professional user must determine the appropriate level of image data compression that is suitable for their purpose. Lossy compressed mammographic images and digitized film screen images must not be reviewed for	reports, and other patient-related information to conduct diagnostic review, planning and reporting through the interactive display and manipulation of medical data. IBM iConnect Access provides healthcare professional tools to aid in interpreting medical images including: • Displaying DICOM compliant medical images and non-DICOM content using XDS • Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images • Manipulating displayed images via control of slice thickness, slice interval, obliquity, perspective, rotation, window/ level, crop, zoom, color/monochrome transformations, segmentation, sculpting, straightening the display of curved structures, and creating images perpendicular to a curvilinear path. • Creating individually captured DICOM images that can be displayed and stored in a PACS • Measuring coronary calcium, which is intended for non-invasive identification and quantification of calcified atherosclerotic plaques in the coronary arteries using tomographic medical image data and clinically accepted calcium scoring algorithms. The IBM iConnect Access application can be configured to provide either lossless or lossy compressed images for display. The medical professional user must determine the appropriate level of image data compression that is suitable for their purpose. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA.	Addition of "Creating and outputting digital files suitable for the fabrication of physical replicas, such as 3D printing, using DICOM files as inputs". Added the ability for the user to perform 3D segmentation interactively using the same image processing algorithms as the cleared device There is no impact to safety and effectiveness.

	Proposed Device: **IBM iConnect Access (v8.0)**	**Predicate Device:** **IBM iConnect Access (v7.0)** **K182290**	**Rationale**
	primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 MP resolution and meets other technical specifications reviewed and accepted by FDA. Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. Use of IBM iConnect Access application on mobile devices such as iPhones and iPads is not intended for diagnostic use.	Display monitors used for reading medical images for diagnostic purposes must comply with applicable regulatory approvals and with quality control requirements for their use and maintenance. Use of IBM iConnect Access application on mobile devices such as iPhones and iPads is not intended for diagnostic use.	

Image Manipulation	• Cine
	• Filters:
	  • Edge Enhancement for X-ray images
	  • RGB channel filter
	  • color/ monochrome transformations
	• Image Rotate
	• Image Flip
	• Magnify
	• Invert Image
	• Mirror
	• Tools for Segmentation
	• Auto Draw Centerline
	• Path Definition and Boundary detection
	• Rotate - Click Center
	• Rotate – Image Center
	• Sculpting – polygon
	• Sculpting – freehand
	• Straightening the display of curved structures
	• Cross-sections perpendicular to and rotation around curved anatomy
	• Crop
	• Control of slice thickness
	• Freehand scalpel to remove unwanted tissue from 3D model
	• Interactive cylindrical eraser tool
	• Circular eraser tool for 3D model refinement
	• Circular paint tool to augment 3D segmentation in MPR viewports
		• Cine
		• Filters:
		  • Edge Enhancement for X-ray images
		  • RGB channel filter
		  • color/ monochrome transformations
		• Image Rotate
		• Image Flip
		• Magnify
		• Invert Image
		• Mirror
		• Tools for Segmentation
		• Auto Draw Centerline
		• Path Definition and Boundary detection
		• Rotate - Click Center
		• Rotate – Image Center
		• Sculpting – polygon
		• Sculpting – freehand
		• Straightening the display of curved structures
		• Cross-sections perpendicular to and rotation around curved anatomy
		• Crop
		• Control of slice thickness
			Substantially equivalent:
			
			Added tools for users to interactively modify and refine the digital 3D model:
			- Freehand scalpel
			- Cylindrical eraser
			- Circular eraser
			- Circular paint tool
			- Adjustable cut plane
			- Hold filling and noise reduction
			- Freehand and polygon scalpel
			- Freehand and polygon brush tool
			
			There is no impact to safety and effectiveness.

	Proposed Device: **IBM iConnect Access (v8.0)**	**Predicate Device:** **IBM iConnect Access (v7.0)** **K182290**	**Rationale**
	• Adjustable cut plane extending through entire data volume • Hole filling and noise reduction • Freehand and polygon scalpel tool on MPR views for 3D model refinement • Freehand and polygon brush tool on MPR views for 3D model refinement		
User Access	Internet Browser • via desktop and mobile (iPad and iPhone) • Browsers supported: Microsoft Internet Explorer 11, Microsoft Edge, Mozilla Firefox, Google Chrome, and Apple Safari • HTML4 Enterprise viewer support • HTML5 Universal viewer support Administrators can configure a user role for patient access to limited image viewing and report viewing features.	Internet Browser • via desktop and mobile (iPad and iPhone) • Browsers supported: Microsoft Internet Explorer 11, Microsoft Edge, Mozilla Firefox, Google Chrome, and Apple Safari • HTML4 Enterprise viewer support • HTML5 Universal viewer support	Substantially equivalent Added the ability to enable a patient viewing role. There is no impact on safety or effectiveness.
Image Rendering	HTML4 Enterprise Viewer: Server side rendering via web browser as JPEG for lossy data and PNG for lossless data HTML5 Universal Viewer: Client side rendering via web browser as JPEG for lossy data and PNG for lossless data	HTML4 Enterprise Viewer: Server side rendering via web browser as JPEG for lossy data and PNG for lossless data HTML5 Universal Viewer: Client side rendering via web browser as JPEG for lossy data and PNG for lossless data	Identical
Measurement and Analysis	• Plumb lines • Joint lines (angles for metatarsal osteotomies) • Transischial measurement • Calibration lines • Pixel Value • OCT cross reference line • Line measurement • Rectangle • Ellipse • ROI • Angle • Cobb Angle • Cardiac Calcium Scoring • PET imagery analysis • Undo-Segmentation • Redo- Segmentation • Reset • Tissue selection tool	• Plumb lines • Joint lines (angles for metatarsal osteotomies) • Transischial measurement • Calibration lines • Pixel Value • OCT cross reference line • Line measurement • Rectangle • Ellipse • ROI • Angle • Cobb Angle • Cardiac Calcium Scoring • PET imagery analysis • Undo-Segmentation • Redo- Segmentation • Reset • Tissue selection tool	Identical

	Proposed Device: **IBM iConnect Access (v8.0)**	**Predicate Device:** **IBM iConnect Access (v7.0)** **K182290**	**Rationale**
Storage & Image Transfer (Import/Export)	Interfaces with DICOM or XDS compliant archives Image import: HTML5 web uploader, Exam Importer (Windows MSI), Java web uploader Image export: transfer feature to route DICOM, download image to local, de-identified DICOM tags. Generate and export STL files to 3D printing service. Physical/3D printed models generated from the digital output files are not for diagnostic use.	Interfaces with DICOM or XDS compliant archives Image import: HTML5 web uploader, Exam Importer (Windows MSI), Java web uploader Image export: transfer feature to route DICOM, download image to local, de-identified DICOM tags.	Substantially equivalent: Added the ability to export STL files. There is no impact on safety or effectiveness.
3D Image Reformatting	3D Reconstructions of 2D multi-slice DICOM exams: • Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images • Planar Reconstructions (MPRs): orthogonal, oblique, curved/cross-curved, slab • Color Slab • 3D volume review • Tomographic colonography • Endoscopic Review • Extract and display surface mesh for 3D model • Enable user to control the level of smoothing applied to the surface mesh • Output the surface mesh to an STL file	3D Reconstructions of 2D multi-slice DICOM exams: • Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images • Planar Reconstructions (MPRs): orthogonal, oblique, curved/cross-curved, slab • Color Slab • 3D volume review • Tomographic colonography • Endoscopic Review	Substantially equivalent: Added the ability to create a digital surface mesh from a segmented digital 3D model to output as STL files. There is no impact to safety or effectiveness.
Image View and Notation	• Navigation: zoom, pan • Window Level • Auto Window Level • Reset • Scout/localizer Lines • Annotate • Oblique • Scrolling Tool • Available volumes • Perspective • Slice interval	• Navigation: zoom, pan • Window Level • Auto Window Level • Reset • Scout/localizer Lines • Annotate • Oblique • Scrolling Tool • Available volumes • Perspective • Slice interval	Identical

Summary of Non-Clinical Tests

IBM iConnect Access complies with voluntary standards as detailed in this premarket notification.

In-house testing of de-identified CT and MRI DICOM images confirmed that interactive segmentation of digital 3D models and mesh generation for STL file creation was acceptable.

Verification and validation testing of qualified datasets was performed to ensure that the software design outputs meet its design inputs.

The subject of this submission, IBM iConnect Access, is a software device and does not require animal testing, biological testing, sterility testing, electrical safety testing or electromagnetic compatibility testing.

Summary of Clinical Tests

Clinical studies are not required to demonstrate the safety and effectiveness of IBM iConnect Access.

Conclusion

Comparison of the Intended Uses/Indications for Use, the technological characteristics, and performance specifications demonstrate the equivalence of the subject device to the predicate device. Verification and validation test results established that the device meets its design requirements and intended uses and that no new issues relative to safety and effectiveness were raised. Watson Health Imaging considers the IBM iConnect Access device to be as safe and as effective as the predicate device.