September 25, 2018

Merge Healthcare Incorporated
Tracey Fox
Global Regulatory Affairs Program Manager
900 Walnut Ridge Drive
HARTLAND, WI 53209

Re: K182290
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: August 22, 2018
Received: August 23, 2018

Dear Tracey Fox:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. Ochs, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182290

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:

o Displaying DICOM compliant medical images and non-DICOM content using XDS
o Reformatting images, including creation of MPRs, MIPS, MinIPs, color/monochrome 3D volume rendered images
o 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.
o Creating individually captured DICOM images that can be displayed and stored in a PACS
o 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.

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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Submitter: Merge Healthcare Incorporated
900 Walnut Ridge Drive
Hartland, Wisconsin 53209 USA

Date Prepared: August 22, 2018

Contact Person: Tracey Fox
Global Regulatory Affairs Program Manager
Phone: (262) 369-3156
Email: tracey.fox@ibm.com or med.reg.contact@ca.ibm.com

Secondary Contact: Meg Mucha
Sr. RA/QA Leader
Phone: (262) 912-3514
Email: meg.mucha@ibm.com

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 Devices: Cedara Web Access 2.4 (K092915)
Zero-Download 3D Solution (K143318)

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 application-specific installation required on the user's computer, healthcare professionals can use IBM iConnect Access with a standard internet browser to view studies 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.

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 can employ advanced image processing and display from local or remote locations.

IBM iConnect Access can be used to query 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 Access along with IBM iConnect Enterprise Archive comprise a cloud based solution marketed as iConnect Cloud Archive. The IBM iConnect Access 3D advanced imaging solution option is not available on iConnect Cloud Archive.

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.

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.

Comparison with Predicate

The primary predicate, Cedara Web Access 2.4 cleared under K092915, was rebranded iConnect Access after the full transition of Cedara into Merge Healthcare. The reference predicate, Zero Download 3D Viewer cleared under K143318 by DR Systems, will now be offered as an option branded, IBM iConnect Access 3D advanced imaging solution. DR Systems was acquired by Merge Healthcare in February 2015. The indications for use of IBM iConnect Access have been expanded to include the indications for use of the IBM iConnect Access 3D advanced imaging solution. Feature enhancements include an RGB channel filter, a real-time collaboration feature, an additional user interface option and other non-significant changes.

Category	Proposed Device IBM iConnect Access	Primary Predicate Cedara Web Access 2.4	Reference Predicate Zero Download 3D Viewer	Rationale
510(K) Number	TBD	K092915	K143318	Information Only
510(K) Applicant	Merge Healthcare Incorporated	Cedara Software Company	DR Systems, Inc.	Information Only
Common Name of Device/ Classification/ Product Code	Picture Archiving and Communications System (PACS) 21 CRF 892.2050 LLZ – Radiological Image Processing System	Picture Archiving and Communications System (PACS) 21 CRF 892.2050 LLZ – Radiological Image Processing System	Digital Image Processing 21 CRF 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, reports, and other patient-related information to conduct diagnostic review, planning and reporting through the interactive display and	Cedara WebAccess 2.4 is a software application that provides internet access to multi-modality softcopy medical images, reports and other patient related	DR Systems Z3D is intended to provide reading physicians, referring physicians, and other appropriate healthcare professionals' tools to aid in interpreting medical images, including:	Substantially Equivalent – Proposed device combines both predicate indications for use with minor

Category	Proposed Device IBM iConnect Access	Primary Predicate Cedara Web Access 2.4	Reference Predicate Zero Download 3D Viewer	Rationale
	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	information for conducting diagnostic review, planning, and reporting through the interactive display and manipulation of medical data. Cedara WebAccess 2.4 is capable of being configured to	• Displaying DICOM compliant medical image volumes, such as CT, MRI, and PET • 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 series of DICOM images and individually captured 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	modifications for clarification. Addition of statement that mobile use is not for diagnostic viewing.

Category	Proposed Device IBM iConnect Access	Primary Predicate Cedara Web Access 2.4	Reference Predicate Zero Download 3D Viewer	Rationale
	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.	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. 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. 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.	scoring algorithms.	

Image Manipulation	• Cine
	• Filters:
	  • Edge Enhancement for X-ray images
	  • RGB channel filter
		• Image Rotate
		• Image Flip
		• Magnify
		• Invert Image
		• Mirror
			• Color/Monochrome transformations
			• Tools for Segmentation
			• Auto Draw Centerline
			• Path Definition and Boundary detection
			• Rotate - Click Center
				Substantially Equivalent – RGB channel filter added with this release. Edge Enhance-

Category	Proposed Device IBM iConnect Access	Primary Predicate Cedara Web Access 2.4	Reference Predicate Zero Download 3D Viewer	Rationale
	• 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		• 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	ment and Cine evaluated in previous release as non-significant change.
Server	• Windows Server 2012 R2 • Windows Server 2016 • SQL Server 2012 • SQL Server 2014 • SQL Server 2016 • Hyper-V Windows Server 2012 R2 and 2016 • VMware ESX and Vsphere 5.x and 6.x	Windows Server 2008 R2 Windows Server 2003 R2 SQL Server 2003 SQL Server 2005	Windows Server 2008 R2	Substantially Equivalent – compatible with more recent versions.
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	Internet Browser • via desktop and mobile (iPad, IPhone, iPod Touch, Blackberry) • Browsers supported: Microsoft Internet Explorer, Mozilla Firefox, Google	• Desktop Windows PC & Apple MacIntosh with Microsoft Silverlight 4 or above • Browsers supported: Microsoft Internet Explorer, Mozilla Firefox, Google Chrome, and Apple Safari • HTML4 viewer support	Substantially Equivalent – compatible with more recent versions.

Category	Proposed Device IBM iConnect Access	Primary Predicate Cedara Web Access 2.4	Reference Predicate Zero Download 3D Viewer	Rationale
		Chrome, and Apple Safari • HTML4 viewer support		
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	Server side rendering via web browser as JPEG for lossy data and PNG for lossless data	Server side rendering via web browser as JPEG for lossy data and PNG for lossless data	Substantially Equivalent – provides client side rendering for HTML5
Images Displayed	DICOM compliant medical image volumes (DICOM conformance statement available on-line) Non-DICOM images (JPG, GIF)	DICOM compliant medical image volumes (DICOM conformance statement available on-line)	DICOM compliant medical image volumes (DICOM conformance statement available on-line)	Substantially Equivalent – IBM iConnect Access includes the ability to display non-DICOM images.
Collaboration	Real-time collaboration screen viewing	Image Sharing via email	None	Substantially Equivalent – real time collaboration builds upon the current email connection and image rendering engine to allow simultaneous viewing
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	• Line measurement • Rectangle • Ellipse • ROI • Angle • Cobb Angle	• Line measurement • Cardiac Calcium Scoring • PET imagery analysis • Undo-Segmentation • Redo- Segmentation • Reset • Tissue selection tool	Substantially Equivalent – Additional lines and Pixel Value evaluated in previous releases as non-significant change.

Category	Proposed Device IBM iConnect Access	Primary Predicate Cedara Web Access 2.4	Reference Predicate Zero Download 3D Viewer	Rationale
	• Cardiac Calcium Scoring • PET imagery analysis • Undo-Segmentation • Redo- Segmentation • Reset Tissue selection tool			
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	Interfaces with DICOM archives	Interfaces with DICOM archives Download Image	Substantially equivalent – Addition of de-identified DICOM tags/Data Masking. XDS compliance and image transfer evaluated in previous release as non-significant change.
Printing	• Print to PDF or printer at local or networked printer	Print to local or networked printer	None	Substantially equivalent – IBM iConnect Access includes the ability to print to pdf
Workflow and Navigation Functions	• User Preference of UI • Briefcase / teaching worklist (TWL) • Patient History Tab • Viewing Order Requisitions • Viewing Attachments • Sharing Studies to Recipients and Conference Folders • Consultation Notes • Archiving / suggesting archiving • Comparing Related Studies • Viewing Study Reports • Navigating Studies by Thumbnails • Viewing/searching Patient Records	• Comparing Related Studies • Viewing Study Reports • Navigating Studies by Thumbnails • Viewing/ searching Patient Records	• Navigating Studies by Thumbnails	Substantially Equivalent – user able to choose between old and new UI navigation; additional workflow features evaluated in previous releases as non-significant change.

Category	Proposed Device IBM iConnect Access	Primary Predicate Cedara Web Access 2.4	Reference Predicate Zero Download 3D Viewer	Rationale
Reports & Document Viewing	DICOM structured reports Document viewing available: • Adobe Portable Document Format (PDF) documents • Microsoft Office documents (such as Microsoft Word, Microsoft PowerPoint, Microsoft Excel) • HTML reports • Clinical Document Architecture (CDA) files • Videos (such as AVI and MPG files) • Audio (such as WAV and MP3 files) • Visible Light (such as JPEG, PNG, and TIFF)	DICOM structured reports	None	Substantially Equivalent – additional document viewing evaluated in previous releases as non-significant change

IBM iConnect Access employs the same fundamental scientific technology as its predicate devices and does not pose any new issues of safety and effectiveness.

Performance Data

The software documentation was provided at a moderate level of concern following the FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". IBM iConnect Access complies with voluntary standards as detailed in this premarket notification submission.

Results from internal verification and validation testing performed in accordance with Watson Health Imaging design control processes confirm that IBM iConnect Access product specifications have been met. Supporting documentation is included in this 510(k) Premarket Notification and supports the claims of substantial equivalence to the predicate device.

The subject of this submission, IBM iConnect Access, did not require animal testing, biological testing, sterility testing, electrical safety testing or electromagnetic compatibility testing.

Clinical studies were 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 functional equivalence of the subject device to the predicate devices.

Verification and validation test results established that the device meets its design requirements and intended use, and that it is as safe, as effective, and performs as well as the predicate devices and that no new issues of safety and effectiveness were raised.