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

December 8, 2017

Re: K173475
Trade/Device Name: Merge PACS™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 2, 2017
Received: November 9, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Michael D. O'Hara For

Robert 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)*

K173475

Device Name

Merge PACS(TM)

Indications for Use *(Describe)*

Merge PACS™ is a Picture Archiving and Communication System (PACS) for multi-modality (CT, MR, PT, US, MG, BTO, CR, DR/DX, NM, XA, RF, secondary capture (SC), and other DICOM-compliant modalities) image processing and display, diagnostic reading and reporting, communication, printing, and storage of medical imaging studies and other patient data. Intended clinical users include radiologists, orthopedic and other surgeons, referring physicians, technologists, and other qualified medical professionals.

Data can be received directly from acquisition modalities, CAD systems, and other image processing systems, or indirectly via importing. Data that is not DICOM-compliant, such as photos, can be converted to DICOM format by Merge PACS.

Merge PACS provides image manipulation tools to enable users to view and compare images such as: linking, MPR, MIP, 3D image fusion/ registration of CT, MR, and PET; as well as CVR (Color Volume Rendering), measurements (linear distances, angles, areas, SUV, etc.), and annotations (for example, outline and label regions of interest, label spinal vertebrae).

The Real Time Worklist (RTWL) displays the real-time status of radiology activity and provides customizable workflow management capabilities. Communication of critical results is facilitated and documented through optional, configurable components.

The Patient Dashboard provides a composite view of patient data, both imaging and non-imaging. The optional Reach component provides clinicians with secure, proactive communication and access to clinical reports and images. Multi-tier patient identity matching provides a comprehensive view even when dealing with multiple disparate patient identities.

Order and report information generated by the HIS/RIS and report creation systems are received and displayed via the transmission of HL7 messaging.

Lossless (reversible) and lossy (irreversible) image compression are supported for viewing, storage and communication.
Merge PACS displays full fidelity DICOM images for use in the diagnostic interpretation of mammography using MG or BTO images. Thick slab MIP presentation can be applied to BTO images.

Lossy compressed images and digitized screen film images must not be used for primary diagnosis of mammography studies, and only display monitors that have regulatory clearance for mammography interpretation should be used for the interpretation of mammography studies.

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

I. SUBMITTER

Merge Healthcare Incorporated
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Merge Healthcare, an IBM Company
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Date Prepared: November 3, 2017

II. DEVICE

Proprietary Name of Device:	Merge PACS™
Common or Usual Name:	Picture Archiving and Communications System (PACS)
Classification Name:	Radiological Image Processing System (21 CFR 892.2050)
Regulatory Class:	Class II
Product Code:	LLZ

III. PREDICATE DEVICES

Trade Name	510(k) Submitter	510(k) Number
Primary Predicate Device: AMICAS PACS 6.0	AMICAS, Inc.	K082144 Class II Product Code LLZ
Synapse PACS	Fujifilm Medical Systems U.S.A., Inc.	K160108 Class II Product Code LLZ

IV. DEVICE DESCRIPTION

Merge PACS™, a software medical device, is a standards-based medical imaging diagnostic workstation that serves as an adjunct to assist the clinician to view, read, and report their findings. Merge PACS processes and displays medical images from DICOM-compliant modalities. The device is designed to enable efficient workflows by maintaining clinicians' worklists and retrieving and managing studies for reading, reporting, communication, and storage.

Merge PACS software runs on off-the-shelf computer hardware and can be configured to operate standalone or to integrate with vendor-neutral imaging archives (VNAs) such as iConnect Enterprise Archive (iCEA) for image storage, and with radiological and hospital information systems (RIS and HIS) and medical record systems (EMR, EHR, etc.).

Merge PACS can be accessed from within the hospital or enterprise, or from remote locations via web-based access. Images viewed on mobile devices must not be used for diagnostic review.

The focus of this premarket notification is on the addition of the ability to "fuse" images for viewing (image fusion) and on the ability to measure Standardized Uptake Values (SUV) on PET (Positron Emission Tomography) images.

Image Fusion

The primary use for image fusion is to view PET and CT images overlaid on top of each other in addition to the previously available ability to view them side-by side in different viewports, or sequentially one after the other.

The ability to view images overlaid on top of each other in one viewport does not change the intended use of Merge PACS, which is intended to be used for multi-modality image viewing in 2D and 3D. The fusion of the display of two images does not change the fundamental image processing that is used. The original images are always available and each can be faded completely in or out in the fused display. The unfused image is the default display.

PET and CT images from modern scanners are acquired with a common DICOM frame of reference. The spatial processing of the PET and CT image objects uses the same algorithms (i.e., having a common DICOM frame of reference provides the basis from which the images can either be cross-referenced with localizer lines or registered with each other). The DICOM frame of reference, pixel spacing, slice spacing, orientation vector and other data already provide the technological basis for the display of localizer or cross reference lines and the 3D cursor tool. These are core functions of most PACS viewers including those that support 3D operations (such as Merge PACS under its previous 510(k) clearance) and are applied now to image registration for image fusion.

Alignment is done as a simple rigid transformation allowing for translation and rotation about each of the axes of the 3D image volumes. This is similar to the existing technology used to provide manual linking of studies (e.g., to enable side-by-side simultaneous scrolling of two studies in different viewports) or to allow re-linking with an offset for common-frame-of-reference series or studies, as was previously cleared for Merge PACS.

Merge PACS does not enable warping or non-rigid transformation of the images, nor automation of the realignment or registration adjustment process.

The original images are always available and the most common viewing paradigm is to view the fused (corrected PET and CT) images alongside the unfused corrected PET images.

Standardized Uptake Values (SUV)

SUVs (Standardized Uptake Values) are calculated for FDG PET studies to judge the biological activity of a tumor and its response to therapy.

The SUV calculation can be performed for individual pixels or on a Region Of Interest (ROI) as an adjunct to viewing the relative intensities of different areas of the PET images.

SUV measurements can be made in Merge PACS discretely via a point / pixel measurement tool, or via SUVmean measurements via a planar elliptical ROI measurement tool. These raw measurements can be normalized according to any of the four common normalizations:

- Body Weight (BW)
- Lean Body Mass (LBM)
- Body Surface Area (BSA)
- Ideal Body Weight (IBW)

Merge PACS does not provide automated or semi-automated segmentation of PET lesion volumes. Merge PACS provides manual single point SUV values and SUVs for manually defined ROI. The user determines where they want to measure SUV on the image and decides how to interpret the information, for example whether activity is related to tumor activity or to other processes such as infection or inflammation. Merge PACS does not provide a diagnosis or treatment recommendation.

Merge PACS SUV measurements and image registration meet the RSNA (Radiological Society of North America)/ QIBA (Quantitative Imaging Biomarkers Alliance) guidelines using the DRO (Digital Reference Object) that they developed in conjunction with their guideline document.

The SUV measurements in Merge PACS are based on the existing pixel value and ROI tools of AMICAS PACS 6.0. The RSNA/ QIBA testing and qualification process for SUV measurements is being implemented to have an independent means of assessing the measurement and registration accuracy.

V. INTENDED USE / INDICATIONS FOR USE

Merge PACS™ is a Picture Archiving and Communication System (PACS) for multi-modality (CT, MR, PT, US, MG, BTO, CR, DR/DX, NM, XA, RF, secondary capture (SC), and other DICOM-compliant modalities) image processing and display, diagnostic reading and reporting, communication, printing, and storage of medical imaging studies and other patient data.

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VI. COMPARISON WITH PREDICATES

Merge PACS and the predicate devices are software products and physical technological characteristics do not apply. The comparison of Merge PACS to the predicate devices is based primarily on the functionality and technological design of their software features.

Merge PACS, AMICAS PACS 6.0, and Synapse PACS devices have the same intended use. Each is a multi-modality diagnostic workstation for viewing, reading, and reporting on medical images from various imaging modalities. They are all “tool type” devices that have the same general indications for use that do not specify a disease, condition, or population.

Each device has essentially the same basic image processing, display, storage, and communication features, based on the same or similar technology as the primary predicate device. The availability of additional specific features may vary between devices. Bundling of subsets of features or toolsets makes the workflow more suitable for clinicians with different specializations, such as mammography or orthopedics, however the image processing technology behind each feature is essentially the same regardless of how the features are bundled.

It is our opinion that Merge PACS is substantially equivalent to AMICAS PACS 6.0, a multi-modality diagnostic workstation that represents an earlier version of Merge PACS and shares the same basic technology and intended uses as Merge PACS.

It is also our opinion that Merge PACS is substantially equivalent to Synapse PACS, which is a multi-modality diagnostic workstation. Synapse PACS has

essentially the same basic image processing, display, storage, and communication features as Merge PACS. Synapse PACS supports 3D image fusion and is capable of performing SUV measurements.

VII. The following table compares features/technologies of changes

Category	Feature	Subject 510(k): Merge PACS	Primary Predicate: AMICAS PACS 6.0 510(k) K082144 Cleared Sept. 5, 2008	Predicate: Fuji Synapse PACS K160108 Cleared Feb. 3, 2016
New Features:				
Image Display	PET/CT/MR Image Fusion	Yes Rigid fusion of 3D PET, CT, MR	No	Yes Rigid 3D fusion (MIP/MPR) of CT, MR, PET, SPECT Non-Rigid 3D fusion (MIP/MPR) of CT, MR, PET, SPECT 2D Multi-modality fusion
Image Display	PET/CT Fusion enhancements: Rotation of MIP images, manual entry of missing SUV attributes (height, weight, BSA)	Yes	No	Has PET/CT fusion and SUV No significant difference
Measurement	SUV Calculation (PET)	Yes	No	Yes
Non-Significant Changes:				

Category	Feature	Subject 510(k): Merge PACS	Primary Predicate: AMICAS PACS 6.0 510(k) K082144 Cleared Sept. 5, 2008	Predicate: Fuji Synapse PACS K160108 Cleared Feb. 3, 2016
Image Display	Enhanced mammography tools: Stacked scrolling, Dual magnifier, Binocular, Hotlight	Yes	No	Supports mammography reading No significant difference
Image Display	BTO – Breast Tomosynthesis Objects (MG Tomosynthesis)	Yes	No	Yes
Study Management	Real Time Study List with Saved Searches	Yes	No	Not known Not a clinically significant feature
NA	Access to Teaching Worklists from iConnect Access	Yes	No	Similar, sends images and notes to teaching archives Not a clinically significant feature
Compliance	Credentialing, Licensure, ME filtering	Yes	No	Not known Not a clinically significant feature
Study Management	Real-Time Study List (RTSL) Enhancements: Quick filter and worklist folders fly-out, Reading pools, Saved searches, Custom fields, Configurable	Yes	No	Similar, e.g. has custom work folders and other configurable study

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	columns, Due in time display, Column filters and sorting			management features Not a clinically significant feature
Storage	Use iConnect VNA as the Long Term Archive (iConnect VNA is now known as iConnect Enterprise Archive	Yes	No	Similar, uses own VNA No significant difference
Storage	PACS EA (Enterprise Archive) interoperation	Yes	No	Yes
Interoperability	Improved DICOM alignment between PACS and EA	Yes	No	Not known Not a clinically significant feature
Study Management	Automatic archive retrieval	Yes	No	Yes
Interoperability, Security	Tight integration between PACS and EA: common security model, viewer loads directly from EA, seamless integration between PACS and EA storage, image ingestion from PACS or from EA	Yes	No	Similar No significant difference
Workflow	Composite worklists deliver efficient high volume reading	Yes	No	Not known

Category	Feature	Subject 510(k): Merge PACS	Primary Predicate: AMICAS PACS 6.0 510(k) K082144 Cleared Sept. 5, 2008	Predicate: Fuji Synapse PACS K160108 Cleared Feb. 3, 2016
				Not a clinically significant feature
Storage	Instant access to archive with iConnect Enterprise Archive	Yes	No	Similar, access to an archive (VNA) No significant difference
Compliance	Maintain compliance and manage control with physician credentialing and licensure	Yes	No	Not known Not a clinically significant feature
Technology	64-Bit Viewer: effectively removes study size limits and improves performance	Yes	No	Yes
Collaboration	Instant Messaging	Yes	No	Not known Not a clinically significant feature
Image Manipulation	Enhanced skin line detection for mammography	Yes	No	Similar, breast bounds image alignment No significant difference
Annotation	Enhancements to DICOM overlays	Yes	No	Similar, has modality specific overlays

Category	Feature	Subject 510(k): Merge PACS	Primary Predicate: AMICAS PACS 6.0 510(k) K082144 Cleared Sept. 5, 2008	Predicate: Fuji Synapse PACS K160108 Cleared Feb. 3, 2016
				No significant difference
Image Manipulation	Enhanced Window/Level for NM / PT	Yes	No	Similar, supports NM and PT No significant difference
Measurement	Orthopedic specific tools	Yes	Yes (Cobb Angle)	Yes
Print	DICOM Printing, including True Size	Yes	No	Yes
Export	Key image collage: save key image layout as SC for export to non KO aware PACS	Yes	No	Not known Not a clinically significant feature
Technology	Infrastructural enhancements: worklist over port 80 - simplifies deployments, full 64-bit support on server, replace IIS with Apache, Jboss7, Java 7 (functionality, security and performance)	Yes	No	Similar, 64-bit server support No significant difference
Image Display	Mammo tomosynthesis position indicator	Yes	No	Similar, displays MG Tomosynthesis images

Category	Feature	Subject 510(k): Merge PACS	Primary Predicate: AMICAS PACS 6.0 510(k) K082144 Cleared Sept. 5, 2008	Predicate: Fuji Synapse PACS K160108 Cleared Feb. 3, 2016
				No significant difference
Image Display	Tomosynthesis improvements: creation of nominal Axial, Sagittal, and Coronal views oriented to the slice stack	Yes	No	Similar, displays MG Tomosynthesis images No significant difference

VIII. PERFORMANCE DATA

Mandatory performance specifications or special controls applicable to diagnostic workstation devices or to image fusion or SUV features specifically, have not been established by the FDA.

Merge PACS and the primary predicate device AMICAS PACS 6.0 comply with the following voluntary standards and guidelines:

- DICOM – Digital Imaging and Communications in Medicine, for the format of medical images and data
- JPEG – Joint Photographic Experts Group, for image compression standards
- FDA Guidance, "Guidance for the Submission of Premarket Notifications for Medical Image Management Devices", July 27, 2000

The determination of substantial equivalence is based on a comparison of features and software technology and on tests to confirm the correct behavior or result for each feature or measurement.

Non-Clinical Tests

In-house non-clinical testing of the features of Merge PACS, a software device, was performed in compliance with design control processes.

The results of software testing confirmed that the Merge PACS device with image fusion and SUV measurement features performs as expected, and documented evidence was provided in this submission.

Clinical Tests

Clinical studies were not required to demonstrate the safety and effectiveness of Merge PACS.

Conclusion

The intended uses and indications for use of Merge PACS are, in our opinion, substantially equivalent to the primary predicate device AMICAS PACS 6.0 as well as to the predicate device Synapse PACS.

The majority of features and functionalities, including image fusion and SUV measurements, were compared and found to be similar or the same as each other. We believe that any differences in features and their underlying technologies between the subject and predicate devices are minor and not significant since all comply with the same fundamental standards such as DICOM, and the resulting displayed images and measurements would be essentially equivalent.

The results of non-clinical testing and compliance with design controls demonstrate that the subject device, Merge PACS, is safe and effective, and performs as intended.