Merge Healthcare Incorporated
% Ms. Amy Tannenbaum
Regulatory Affairs Specialist
900 Walnut Ridge Drive
HARTLAND WA 53209

October 17, 2019

Re: K192455
Trade/Device Name: Merge PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: September 16, 2019
Received: September 17, 2019

Dear Ms. Tannenbaum:

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

Section 4

Indications for Use Statement (Form 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: 0MB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192455

Device Name
Merge PACS

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. 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 – Merge PACS K192455

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:	K192455
Date Prepared:	September 6, 2019
Contact Person:	Amy Tannenbaum Regulatory Affairs Specialist Phone: 617-528-3087 Email: amy.tannenbaum@ibm.com
Secondary Contact:	Tracey Fox Global Regulatory Affairs, Manager Phone: 1-262-369-3156 Email: tracey.fox@ibm.com

Identification of the Device

Trade Name:	Merge PACS
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(s)

Primary Predicate:	Merge PACS (K173475)
Reference Predicate:	Xelis Fusion (K111613)

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) via DICOM protocol, for image storage, and with radiological and hospital information systems (RIS and HIS) and medical record systems (EMR, EHR, etc.) via HL7.

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

The focus of this premarket notification is on the addition of the Region Analysis Area and Region Analysis Volume tools, which allows for additional clinical analysis of images, including volumetric Standard Uptake Value (SUV) calculation. There has been a minor change in the indications for use statement from the previous Merge PACS device, with the removal of the optional Reach component which is no longer offered. Additional non-significant changes since the previous submission will be discussed.

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. 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. 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.

Technological Characteristics

Merge PACS and its predicate device(s) have the same fundamental scientific technology. The primary predicate is the previous Merge PACS (K173475) for which the subject device is a modification of, with reference predicate Xelis Fusion (K111613).

The subject device has the same basic intended use as the predicates and near identical indications for use as Merge PACS (K173475). The devices have essentially the same basic image processing, display, storage, and communication features, based on the same or similar technology. Availability and bundling and naming of additional features and toolsets may vary between the devices, but the technology behind each feature is essentially the same regardless of how it is catered to a specific user.

It is our opinion that the subject Merge PACS device is substantially equivalent to the previous Merge PACS (K173475) as it is an earlier version of the device that contains the same technology and functionality. The subject device is also substantially equivalent to the reference predicate, Xelis Fusion (K111613), sharing essentially the same basic image processing, display, storage and communication features as well as the new capability of volumetric SUV measurements.

Determination of Substantial Equivalence

The modifications to Merge PACS include updates to the software and labeling from the previous Merge PACS K173475. A summary of the key changes in the subject Merge PACS

device are summarized below with comparison to its predicates. Additional non-significant changes and bug fixes have been made to improve workflow and security, and do not have an impact on clinical functionality of the device.

Table 1: Comparison to predicates

Category	Feature/ Information	Subject Merge PACS (K192455)	Primary Predicate: Merge PACS (K173475)	Reference Predicate: Xelis Fusion (K111613)	Clinically Significant Change?
General	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	Picture Archiving and Communications System (PACS) 21 CFR 892.2050 LLZ- Radiological Image Processing System	No changes
	Operating System	Windows 10	Windows 7/8.1/10	Unknown	Not a clinically significant difference – support for latest Windows OS.
	Browser Support	Internet Explorer 11, Edge, Chrome	Internet Explorer 7, 8, 9, 10, 11	Unknown	Not a clinically significant difference – support for new browser only
	Server OS Support	Windows 2016 64-bit, Windows 2012 R2	Windows 2012 R2	Windows 32 and 64-bit	Not a clinically significant difference – support for latest server OS
	Indication for Use Statement	Merge PACS™ is a Picture Archiving and Communication System (PACS) for multi-modality (CT, MR, PT, US, MG, BTO, CR, DR/DX, NM, XA,	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,	The Xelis Fusion is a software device that receives digital images and data from various sources (e.g. CT	There is only a minor change in the indications for use statement from the previous Merge PACS device, with the removal of the optional Reach

Category	Feature/ Information	Subject Merge PACS (K192455)	Primary Predicate: Merge PACS (K173475)	Reference Predicate: Xelis Fusion (K111613)	Clinically Significant Change?
		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	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	scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other image sources). Diagnosis or computer aided diagnosis is not performed by the software but by Radiologists. Images (including mammographic) and data can be stored, communicated, processed and displayed within the system and or across computer networks at	component which is no longer offered. Similar indications to reference predicate. There is no clinically significant difference as Reach was not used by radiologists for diagnosis.

Category	Feature/ Information	Subject Merge PACS (K192455)	Primary Predicate: Merge PACS (K173475)	Reference Predicate: Xelis Fusion (K111613)	Clinically Significant Change?
		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.	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	distributed locations. In addition, Xelis Fusion can be integrated with an institution's HIS or RIS for an integrated and electronic patient record. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretation. Mammographic images may only be interpreted using and FDA approved monitor that offers at least 5 Mega-pixel resolution and meets other technical specifications	

Category	Feature/ Information	Subject Merge PACS (K192455)	Primary Predicate: Merge PACS (K173475)	Reference Predicate: Xelis Fusion (K111613)	Clinically Significant Change?
		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. 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.	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	reviewed and accepted by FDA.	

Category	Feature/ Information	Subject Merge PACS (K192455)	Primary Predicate: Merge PACS (K173475)	Reference Predicate: Xelis Fusion (K111613)	Clinically Significant Change?
		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	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		

Category	Feature/ Information	Subject Merge PACS (K192455)	Primary Predicate: Merge PACS (K173475)	Reference Predicate: Xelis Fusion (K111613)	Clinically Significant Change?
		interpretation of mammography studies.	interpretation should be used for the interpretation of mammography studies.		
Significant change(s) introduced in subject device Merge PACS:					
Measurement	SUV Calculation (PET)	Probe Tool, ROI Tool Regional Area Analysis and Regional Volume Analysis 2D and 3D SUV calculations	Probe Tool and ROI Tool 2D SUV calculations only	Supports 3D region of interest (ROI) SUV analysis	Addition of Region Area and Volume Analysis tools allows for additional clinical analysis of PET images for patient treatment, including 3D SUV calculations. The reference predicate device shares this new feature with the subject Merge PACS. Applicable verification and validation testing has been performed to justify the safety and efficacy of this difference from the primary predicate.

Category	Feature/ Information	Subject Merge PACS (K192455)	Primary Predicate: Merge PACS (K173475)	Reference Predicate: Xelis Fusion (K111613)	Clinically Significant Change?
Non-significant changes(s) introduced in subject device Merge PACS:					
Viewer	Terarecon Integration	Yes - Terarecon embedded in Merge PACS, opens in same window	Yes – Terarecon opens in separate window	Unknown	Not a clinically significant difference. End functionality owned by Terarecon. Smoother integration with Merge PACS for user convenience, but no clinical impact to the patient.
	Automatic Registration for series that do not share a common frame of reference	Yes	No – Automatic linking of series with same frame of reference UID and manually linking of series that do not share a common frame of reference only	Yes	Not a clinically significant difference for Merge PACS. Automatic registration is through the functionality of Blackford to deliver DICOM objects to Merge PACS for automatic registration of series that do not share a common frame of reference. No impact to safety or effectiveness.
	Patient Synopsis information within Patient Record	Yes	No	Similar functionality – can Integrate with patient record	Not a clinically significant different, Watson Imaging Patient Synopsis provides a new option for clinicians to view patient information.

Category	Feature/ Information	Subject Merge PACS (K192455)	Primary Predicate: Merge PACS (K173475)	Reference Predicate: Xelis Fusion (K111613)	Clinically Significant Change?
					No clinical impact to the patient.
Viewer – Mammo Support	2D/3D Mammo toggle tool	Yes	No – user must perform additional key clicks to go between 2D and 3D images	Unknown	Not a clinically significant difference. Provides a user convenience only to more quickly toggle between views. No clinical impact to the patient.
DICOM user accounts	Allow flexibility in choosing the desired local, network (e.g LDAP), or Merge PACS accounts of various user services	Yes	No	Unknown	Security enhancements only and allows for more customizable controls. No impact to safety or effectiveness.
Other changes	Security enhancements, and updates to graphics in About Screen	Yes	No	Unknown	Not a clinically significant difference. About Screen provides information only and security enhancements have no impact to safety or effectiveness.

Summary of Non-Clinical Tests

The following quality assurance measures were applied to the Merge PACS product:

- Risk Analysis
- Requirements Review
- Design Reviews
- Testing on unit level
- Integration testing
- Performance testing

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".*

No performance standards for PACS system or components have been issued under the authority of Section 514. Non-clinical testing has been performed on Merge PACS and demonstrates compliance with international and FDA-recognized consensus standards and FDA guidance documents. This Traditional 510(k) has been written in accordance with the applicable *FDA Guidance Document for the Submission of Premarket Notifications for Medical Image Management Devices (July 2000),* and meets the following voluntary standard(s):

- DICOM – Digital Imaging and Communications in Medicine, for the format of medical images and data, NEMA PS 3.1 – 3.20 Set (2016)

Results from internal verification and validation testing performed in accordance with Watson Health Imaging design control processes confirm that Merge PACS 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. Cybersecurity is also addressed in this submission.

The subject of this submission, Merge PACS, did not require animal testing, biological testing, sterility testing, electrical safety testing or electromagnetic compatibility testing.

Summary of Clinical Tests

The subject of this premarket submission, Merge PACS, did not require clinical studies to support substantial equivalence.

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 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 Merge PACS to be as safe and as effective as its predicate devices.