Merge Healthcare Incorporated
Sara Pesian
Senior Manager, Regulatory Affairs
900 Walnut Ridge Drive
HARTLAND, WI 53029

April 14, 2025

Re: K250301
Trade/Device Name: Merge Universal Viewer (MUV)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 31, 2025
Received: January 31, 2025

Dear Sara Pesian:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jessica Lamb
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices AND Electronic Products
OHT8: Office of 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250301

Device Name

Merge Universal Viewer (MUV)

Indications for Use *(Describe)*

Merge Universal Viewer (MUV) is intended to provide internet access to multi-modality softcopy medical images, medical data, reports, and other patient- related information to conduct diagnostic review, processing, analyzing, reporting and sharing of DICOM-compliant medical images and relevant digital data.
MUV provides functionality that allows for 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.
MUV is intended to be used by trained healthcare professionals.
MUV 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 MUV 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.

510(k) #: K250301

510(k) Summary

Prepared on: 2025-04-13

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Merge Healthcare Incorporated
Applicant Address	900 Walnut Ridge Drive Hartland WI 53029 United States
Applicant Contact Telephone	(262)367-0700
Applicant Contact	Mrs. Sara Pesian
Applicant Contact Email	spesian@merative.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Merge Universal Viewer (MUV)
Common Name	Picture Archiving and Communication System (PACS)
Classification Name	Medical image management and processing system
Regulation Number	892.2050
Product Code(s)	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K203104	Merge Universal Viewer V8.0 (Formerly known as IBM iConnect Access V8.0)	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

Merge Universal Viewer (formerly known as IBM iConnect Access) is a software application that is intended to provide internet access to multi-modality softcopy medical images, medical data, reports, and other patient- related information to conduct diagnostic review, processing, analyzing, reporting and sharing of DICOM-compliant medical images and relevant digital data. Merge Universal Viewer provides healthcare professionals with access to diagnostic quality images, reports, and various types of patient data over conventional TCP/IP networks.

Merge Universal Viewer 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, and MPR. Additionally, the existing Merge Universal Viewer offers measurement and analysis tools such as line measurement, cross reference lines, rectangle, ellipse, perfect circle, freehand ROI, angle, Cobb angle, calibration, pixel value, plumb lines and cardiac calcium scoring.

A high-level overview of the modifications to the subject device being introduced as part of this 510(k) are as follows:

- Ability to display Mammography CAD SR
- Addition of the Volumetric SUV (Standard Uptake Value) to the measurement tools
- Addition of a DICOM Structured Report (SR) ingestion panel: The “Findings Panel”:
  - o Display of lung nodule detection and characteristics
  - o Generalized lesion tracking (for CT and MR studies)
- Addition of cardiology measurement tools (for cardiac ultrasound studies)
- Miscellaneous updates such as:
  - o Cybersecurity improvements to ensure full compliance with FDA’s Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions Guidance issued September 27, 2023.
  - o The ability to display mammography images in full resolution using a keyboard shortcut
  - o Bug fixes

• Labeling update, i.e., revised Indications for Use statement to reflect the new branding as well as to align with the current industry standards to consolidate the information

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Merge Universal Viewer (MUV) is intended to provide internet access to multi-modality softcopy medical images, medical data, reports, and other patient- related information to conduct diagnostic review, processing, analyzing, reporting and sharing of DICOM-compliant medical images and relevant digital data.
MUV provides functionality that allows for 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.
MUV is intended to be used by trained healthcare professionals.
MUV 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 MUV on mobile devices such as iPhones and iPads is not intended for diagnostic use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Indication for Use (IFU) statement of the subject device is similar to that of the predicate device (K203104), with the following updates:
1- Branding Update: The IFU statement has been revised to reflect the new branding of the device. This change is purely a rebranding and does not affect the device's intended use or functionality.
2- Consolidation of Information: The IFU has been streamlined to remove references to specific image manipulation tools that were previously included. These tools are not essential to the core functionality of the device and are now described elsewhere as part of the device's overall description.
There are no changes to the device's intended use or primary clinical function. The device continues to be intended for viewing and interpreting DICOM images. These revisions to the IFU statement do not introduce new indications for use or alter the functionality of the device. The updates are administrative in nature, with the goal of simplifying and clarifying the information presented to the user.

Technological Comparison

21 CFR 807.92(a)(6)

Merge Universal Viewer V9.0 and the legally marketed Merge Universal Viewer V8.0 (K203104) have the same intended use of medical image management and processing, providing capabilities related to the review and interpreting of medical images. Merge Universal Viewer V8.0 represents an earlier version of Merge Universal Viewer and shares the same fundamental scientific technology of the subject Merge Universal Viewer V9.0. The subject Merge Universal Viewer has been updated to include additional capabilities for display and review of the medical images. Any variation in features or technical specifications compared to Merge Universal Viewer V8.0 have been identified and addressed through testing to support a substantial equivalence determination. The performed testing confirmed that no new concerns of safety and effectiveness were raised due to the modifications made to the software. Additionally, a reference predicate, Image Management V15 (K240822) has been used to compare MUV's newly added features against to support the substantial equivalence discussion. All new features added to the modified Merge Universal Viewer are already present in this predicate. Both devices have the same intended use and technological characteristics, noting that the reference predicate contains additional intended use beyond what Merge Universal Viewer provides. However, this 510(k) focuses specifically on the primary clinical applications that both devices share such as the newly added features to the modified Merge Universal Viewer. The additional clinical applications of the reference predicate (i.e. ECG Application, CT Perfusion Application, MR diffusion Application) do not affect the fundamental performance or the core technology for its primary intended use. These differences do not raise any new concerns of safety or effectiveness for the subject Merge Universal Viewer V9.0, as the subject does not provide those clinical applications.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing activities including software verification and validation, cybersecurity testing, and usability testing, were performed to support a substantial equivalence determination for the modifications included in the Merge Universal Viewer version 9.0 and to ensure the safety and effectiveness of the subject device. All tests passed.

Software Verification Testing:
Incremental software verification was performed for software units at the individual level as well as for the integrated software at the integration / system level. The scope of software verification testing included an analysis of each change introduced in Merge Universal Viewer software version 9.0. Each change was thoroughly evaluated to ensure that it was appropriately verified, and that proper

regression testing was performed to detect any unintended side-effects. All planned verification tests were performed and met their acceptance criteria.

Cybersecurity Testing:
Cybersecurity risk assessment and testing against all software components of Merge Universal Viewer 9.0 was performed according to FDA's guidance document "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued September 27, 2023)". All planned tests were performed and met their acceptance criteria.

Usability Testing:
Formative and early evaluation usability testing was conducted to provide input to human factors-related design aspects for the new features. Risk-based summative usability testing was performed to validate the acceptability of user interactions with the subject device. The results of the usability testing demonstrated that Merge Universal Viewer 9.0 met the acceptance criteria and that no new use errors or use-related risks were identified that could lead to patient or user harm.

Design Validation Testing:
Design validation testing was performed in a simulated use environment using a fully configured system. The scope of design validation testing covered clinical workflow scenarios and user needs including those applicable to new device features and functionality and to the software user interface. All planned tests were performed and met their acceptance criteria.

No clinical testing was performed as part of performance testing for MUV 9.0.

The conclusions of all non-clinical testing activities confirmed that the differences in the features and design compared to the predicate device(s) did not adversely affect the safety and effectiveness of the subject device and demonstrated that the subject device meets its predetermined acceptance criteria and functions according to its intended use. Software, cybersecurity, and usability test results demonstrated that Merge Universal Viewer 9.0 is substantially equivalent to the legally marketed predicates.