January 5, 2026

maihub Corp.
Gyungeun Park
RA Manager
4F, 58, Baumoe-ro 37-gil, Seocho-gu
Seoul, 06744
Republic Of Korea

Re: K253008
Trade/Device Name: maiLink
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 8, 2025
Received: December 8, 2025

Dear Gyungeun Park:

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, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253008

Please provide the device trade name(s).

maiLink

Please provide your Indications for Use below.

maiLink, a PACS and radiology workflow management software available as both a desktop/laptop application and a web viewer, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D mammography. It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, secondary capture tools, imaging gateways. maiLink enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations. Only pre-processed DICOM images specifically intended for presentation are suitable for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretation on the maiLink. To ensure accurate interpretation, mammographic images should only be evaluated on a monitor that adheres to the technical specifications outlined by the FDA. This system is designed exclusively for use by proficient and certified medical experts, including physicians, radiologists, and medical technicians.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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Tel: 82-2-6949-1867, Fax: 82-2-6949-1868

K253008

510(k) Summary

[As required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

December 03, 2025

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: maihub Corp.
- Address: 4F, 58 Baumoe-ro 37-gil, Seocho-gu, Seoul, Republic of Korea, 06744
- Correspondent: Gyungeun Park / Manager
- Telephone No.: +82-2-6949-1867
- Fax No.: +82-2-6949-1868
- Email Address: gyungeun.park@maihub.ai
- Registration No.: K253008

3. Identification of Proposed Device [21 CFR 807.92(a)(2)]

Trade/Device Name	maiLink
Classification Device	system, image processing, radiological
Regulation Number	892.2050
Regulation Name	Medical image management and processing system
Regulation Class	2
Product Code	LLZ

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

Primary Predicate device

- 510(k) Number: K232891
- Applicant: CARPL.AI Inc.
- Trade/Device Name CARPL
- Regulation Number 892.2050
- Regulation Name: Medical image management and processing system
- Regulation Class: 2
- Product Code: LLZ

The predicate device has not been subject to a design-related recall.

5. Indications for use [21 CFR 807.92(a)(5)]

maiLink, a PACS and radiology workflow management software available as both a desktop/laptop application and a web viewer, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D mammography.
It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, secondary capture tools, imaging gateways. maiLink enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations.
Only pre-processed DICOM images specifically intended for presentation are suitable for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretation on the maiLink. To ensure accurate interpretation, mammographic images should only be evaluated on a monitor that adheres to the technical specifications outlined by the FDA. This system is designed exclusively for use by proficient and certified medical experts, including physicians, radiologists, and medical technicians.

6. Description of the Device [21 CFR 807.92(a)(4)]

maiLink is software designed to receive and transmit medical images from various medical imaging devices through SDK, DICOM communication, or user image uploads. It sends these images to an AI medical imaging reading solution software, receives the interpretation results, and allows for storage or transmission to the hospital's PACS system. maiLink acts as an intermediary service between medical imaging modalities and AI-assisted reading solutions.

The medical imaging devices and AI medical imaging reading solution software are not included in this product and require separate authorization. This product complies with the DICOM standard protocol, a standard for medical imaging, to facilitate integration with PACS for the storage and communication of medical images.

maiLink's integrated FDA-cleared algorithm list is exclusively managed by maiLink. AI Customers do not have the ability technically or administratively to add or modify which FDA-cleared AI algorithms are integrated with maiLink. Only FDA-cleared algorithms which have passed rigorous regulatory and quality standards review by maihub Corp. to guarantee functionality, safety and security are made available in maiLink.

maiLink simply presents the simple AI response output, and the initial anonymized image remains consistently available. The duty of evaluating the AI output, validating the results, and conducting the diagnosis lies with competent medical professionals.

maiLink current list of integrated FDA cleared AI Models:

Device Name	FDA K Number	Company Name
Lunit Insight CXR	K211733	Lunit Inc
Lunit Insight MMG	K211678	Lunit Inc
VUNO Med - Chest X-ray	K241439	VUNO Inc.
AView CAC	K243696	Coreline Soft Co., Ltd
AVIEW LCS	K201710	Coreline Soft Co., Ltd
BoneView	K212365	Gleamer

7. Determination of Substantial Equivalence

The maiLink is substantially equivalent to legally marketed predicate device with respect to indications for use and technology characteristics.

Comparison of Proposed Device to Predicate Device K232891

	Proposed Device	Predicate Device
Device Name	maiLink	CARPL
510(k) Number	K253008	K232891
Manufacturer	maihub Corp.	CARPL.AI Inc.
Product Code	LLZ	LLZ

	Proposed Device	Predicate Device
Device Class	2	2
Common specification		
Indications for Use	maiLink, a PACS and radiology workflow management software available as both a desktop/laptop application and a web viewer, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D mammography. It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, secondary capture tools, imaging gateways. maiLink enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations. Only pre-processed DICOM images specifically intended for presentation are suitable for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretation on the maiLink. To ensure accurate interpretation, mammographic images should only be evaluated on a monitor that adheres to the technical specifications outlined by the FDA. This system is designed exclusively for use by proficient and certified medical experts, including physicians, radiologists, and medical technicians.	CARPL, a web-based PACS and radiology workflow management device, used for viewing and assessing DICOM images Ex: DX, DR, CR, CT, MR, US, RF and 2D/3D mammography. It gathers digital images and information from a variety of sources that adhere to the DICOM standard. These sources encompass a range of devices, including digital and computed radiographic equipment, CT and MR scanners, ultrasound and RF machines, PET units, secondary capture tools, imaging gateways. CARPL enables the storage, transmission, processing, and visualization of images and data within the system itself or over computer networks spanning different locations. Only pre-processed DICOM images specifically intended for presentation are suitable for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretation on the CARPL. To ensure accurate interpretation, mammographic images should only be evaluated on a monitor that adheres to the technical specifications outlined by the FDA. This system is designed exclusively for use by proficient and certified medical experts, including physicians, radiologists, and medical technicians.
Modalities	Various Image sources	Various Image sources

	Proposed Device	Predicate Device
Web Browser software	Google Chrome, Mozilla, Safari, and Edge	Google Chrome, Mozilla, and Edge
Resolution	32 bit Color Display & 1920x1080	32 bit Color Display & 1920x1080
Image Storage	YES	YES
Software environment	OS: Windows 10 or higher	OS: Windows 10 or higher
Functions		
Main Functions	• Log In • Studylist – Search Filter • Studylist – Open image • Studylist – study List • Studylist – Report • Studylist – Series • Viewer – View exam • Viewer – Control View window • Viewer – Changing the layout • Viewer – Comparative study • Viewer - Zoom • Viewer – Panning • Viewer - Invert Image • Viewer – Viewing mode (Image/ Stack) • Viewer – Rotation • Viewer – Reference line • Viewer – Measure • Viewer – Inverting image color • Viewer – Cine	• Log In • Worklist – Search Filter • Worklist – Open image • Work list – study List • Worklist – Report • Worklist – Series • Viewer – View exam • Viewer – Control View window • Viewer – view mode (real resolution) • Viewer – View mode (Highlight) • Viewer – Stacking • Viewer – Changing the layout • Viewer – Comparative study • Viewer – Preset filter • Viewer - Zoom • Viewer – Panning • Viewer - Invert Image • Viewer – Viewing mode (Normal/ Image/ Stack/ Custom/ Annotation) • Viewer – Rotation • MIP/MPR Reconstruction • Viewer – Reference line

	Proposed Device	Predicate Device
		• Viewer – Sharpening • Viewer – Measure • Viewer – Inverting image color • Viewer – Cine • Viewer- Overlaying.
Optional Integration of FDA - cleared 3rd party AI models	YES	YES
Operation feature	• Desktop application and Web PACS/Viewer. • Viewing and handling DICOM medical images. • Review and report study located on a server • View multiple AI model output	• Web environment-based PACS. • Viewing and handling DICOM medical images. • Review and report study located on a server • View multiple AI model output

The technological principle for both the proposed and predicate devices is the same in terms of prescription use, support of various modalities, resolution, image storage, use of the DICOM Standard, and Operation features. Most of the features, specifications, and functions of both the proposed and predicate devices, like indications for use, software web browser, software intended environment, study viewer, and study worklist are similar.

maiLink provides the feature of optional integration with external FDA-cleared 3rd party AI models like the predicate device CARPL does. The integration with the FDA cleared 3rd party AI models is optional based on the user's discretion, and always in accordance with the 3rd party manufacturer's regulatory clearance.

8. Non-Clinical Test Summary

Non-clinical tests were conducted for the device maiLink during product development.

- NEMA PS 3.1 - 3.15, 3.18 (2016), Digital Imaging and Communication in Medicine (DICOM)
- IEC 62304:2015, Medical devices software – Software life-cycle processes
- ISO 14971:2019 Medical devices - Application of risk management to medical devices
- IEC TR 80002-1:2009, Medical device software — Part 1: Guidance on the application of ISO 14971 to medical device software
- AAMI TIR57:2016, Principles for medical device security-Risk management

The risk analysis was completed, verification and validation tests were performed to support the claim of substantial equivalence, and the test results support that all software specifications

meet the acceptance criteria. It complies with cybersecurity requirements by implementing processes to prevent unauthorized access, modification, misuse, or refusal to use information stored, accessed, or transmitted by medical devices.

Timing of Notification Test

A timing of notification test was performed to verify that, after receiving the AI analysis result, maiLink does not introduce any additional delay or data distortion that would degrade the performance of the triage AI.

- Notification Time

Condition	Number of tests	Max. time	Min. Time	Average	Acceptance Criteria	Pass/Fail
Cloud	20	0.417 sec	0.235 sec	0.3141 sec	≤ 7.86 sec	Pass

- Result Integrity

Total case	Data loss (case)	Modification (case)	Distortion (case)	Pass/Fail
20	0	0	0	Pass

Measurement Test

This test was conducted to verify the accuracy of maiLink measurement functions (length, angle, ROI Rectangle).

Item		Length (mm)	Angle(°)	Area (mm^2)	Worst Condition		
					Length (mm)	Angle(°)	Area (mm^2)
Actual value		120	90	14400	120	90	14400
Measure-ment	Max.	120.24	90.47	14438	120.24	90.14	14492
	Min.	119.76	89.78	14370	119.86	89.86	14474
Average error range		0.115	0.148	0.118	0.095	0.101	0.203
Result		Pass	Pass	Pass	Pass	Pass	Pass

9. Substantial Equivalence Conclusion

The new device maiLink and predicate device are substantially equivalent in the areas of technical characteristics, general functions, application, and intended use. The new device does

not introduce a fundamentally new scientific technology, and the nonclinical tests demonstrate that the device is as safe and effective as the predicate devices currently on the market.