October 3, 2025

HealthHub
Sanglok Lee
Official Correspondent
14F, 20, Mapo-daero, Mapo-gu
Seoul, 04175
Korea, South

Re: K250039
Trade/Device Name: HPACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 18, 2025
Received: August 18, 2025

Dear Sanglok Lee:

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.

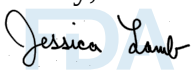
All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (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, PhD
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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)*

K250039

Device Name

HPACS

Indications for Use *(Describe)*

HPACS is a web-based software solution intended for storing, retrieving, transmitting, viewing, and processing medical images for non-diagnostic purposes. It operates in conjunction with a PACS server to enable access to imaging data.
HPACS supports the display and comparison of images from CR, CT, DX, MR, US, XA, and SC modalities that are compliant with the DICOM standard.
The system is designed for use by radiologists, technologists, and clinicians for reference and review purposes only. It is not intended for primary diagnostic interpretation.
HPACS supports operation on Windows 10 or higher and macOS 12 or higher platforms, exclusively via Google Chrome browser. Compatibility with other browsers or operating systems is not claimed.

HPACS is not intended for diagnostic image reading and should be used under standard indoor lighting conditions for optimal viewing; use in direct sunlight or high-glare environments is not recommended, and mobile or tablet devices are not supported. HPACS is not supported on any OS that is no longer officially supported by its manufacturer (e.g., Windows 7).

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) Summary – Traditional 510(K)

The assigned 510(k) Number: K250039

01. Date of Submission: January 3, 2025

02. Applicant / Submitter

HealthHub Co., Ltd.
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03. Submission Correspondent

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04. Proposed Device Identification

Device Identification and Regulatory information

Proprietary Name: HPACS
Classification Device: system, image processing, radiological
Device Class: Class II
Regulation Number: 21 CFR 892.2050
Product Code: LLZ

Indication for use:

HPACS is a web-based software solution intended for storing, retrieving, transmitting, viewing, and processing medical images for non-diagnostic purposes. It operates in conjunction with a PACS server to enable access to imaging data.
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05. Predicate Device Identification

- Predicate device
510(k) Number: K231662
Device Name: Aid-U
Manufacturer: iAID

06. Device Description

HPACS is a software system that allows healthcare professionals to access and manipulate medical images in real time using any web browser without device/location restrictions, without installing client software. The PACS application program runs on the AWS Cloud server. It stores, searches, and retrieves medical images and meta information using an initialization database based on secure communication, logging, DICOM tags stored in the DB, and file storage information stored in the AWS Cloud. AWS Cloud provides storage, query, and retrieval functions only to authorized users, and blocks unauthorized access. It also provides a web browser-based PACS/Web Viewer UI that can interact with the PACS application program to store and retrieve medical images and meta information.

07. Summary of Technological Characteristics Comparison

HPACS has the same intended uses, principle of operation and similar technical characteristics and functionality as predicate devices.

	Subject Device	Predicate Device	Substantial Equivalence
Device Name	HPACS	Aid-U	-
510K number	K250039	K231662	-
Classification	System, Image Processing, Radiological	System, Image Processing, Radiological	Equivalent
Intended use	HPACS is a web-based software solution intended for storing, retrieving, transmitting, viewing, and processing medical images for non-diagnostic purposes. It operates in conjunction with a PACS server to enable access to imaging data. HPACS supports the display and comparison of images from CR, CT, DX, MR, US, XA, and SC modalities that are compliant with the DICOM standard. The system is designed for use by radiologists, technologists, and clinicians for reference and review purposes only. It is not intended for primary diagnostic interpretation. HPACS supports operation on Windows 10 or higher and macOS 12 or higher platforms, exclusively via Google Chrome browser. Compatibility with other browsers or operating systems is	Aid-U is a software solution intended to be used for storing, zoom-in, zoom-out, retrieving, transmitting, and processing medical images, or outputting them. Aid-U is intended for use as a web- based application and is networked with a PACS server. It enables the display, comparison of CT, MR, PT, US, XA, NM, DX, and SC from other DICOM compliant modalities. Typical users are radiologists, technologists, and clinicians.	Equivalent

	not claimed. HPACS is not intended for diagnostic image reading and should be used under standard indoor lighting conditions for optimal viewing; use in direct sunlight or high-glare environments is not recommended, and mobile or tablet devices are not supported. HPACS is not supported on any OS that is no longer officially supported by its manufacturer (e.g., Windows 7).		
Modalities	CR, CT, DX, MR, SC, US, XA	CT, MR, PT, US, XA, NM, DX, SC	Equivalents
Window Level	Yes	Yes	Equivalent
User Authentication	Yes	Yes	Equivalent
Network Access	Web browser connects to existing PACS	Web browser connects to existing PACS	Equivalent
Transfer/Storage/Display of Medical Images	Yes	Yes	Equivalent
Pan/Zoom	Yes	Yes	Equivalent
Measurement	Yes	Yes	Equivalent
Annotation	Yes	Yes	Equivalent

08. Nonclinical Testing Data

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

- NEMA PS 3.1 - 3.20 (2022d), Digital Imaging and Communication in Medicine (DICOM) Set
- IEC 62304:2015 Medical devices software – Software life-cycle processes
- ISO 14971:2019 Medical devices - Application of risk management to medical devices

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.

09. Substantial Equivalence Conclusion

The new device HPACS and predicate device are substantially equivalent in the areas of technical characteristics, general functions, application, and intended use. The new device does not introduce fundamentally new scientific technology, and the nonclinical tests demonstrate that the device is substantially equivalent to the predicate devices.