iAID
Jooyoung Park
Quality Development Manager
#1307 6, Wiryeseong-daero, Songpa-gu
Seoul, 05544
Korea, South

February 8, 2024

Re: K231662
Trade/Device Name: Aid-U
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management and Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 10, 2024
Received: January 10, 2024

Dear Jooyoung 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.

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 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.

510(k) Number *(if known)*
K231662

Device Name
Aid-U

Indications for Use *(Describe)*
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.

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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K231662 **510(k) Summary**

1. Applicant / Submitter

Submitter: iAID
#1307 6, Wiryeseong-daero,
Songpa-gu, Seoul, Republic of Korea [05544]

Contact person (application correspondent):

- Name : Jooyoung Park

- Title : Quality Manager

- Phone number : +82-10-9033-4422

- E-mail address : chacha4422@gmail.com

Date Prepared: Feb 07, 2024

2. Proposed Device

Device	System, Image Processing, Radiological
Trade/Device Name	Aid-U
Regulation Number	21 CFR 892.2050
Device Classification Name	Medical Image Management and Processing System
Regulatory Class	Class II
Product Code	LLZ
Classification Panel	Radiology Devices

3. Device Description

Aid-U is a medical image transmission device software, of SaaS type (Software as a Service, provided as a service, not as a software installation) or an On-Premise Software type web application (Companies install software in data centers managed by their own facilities) that allows patient medical image data generated by medical imaging devices to be transmitted, stored, managed, and retrieved using standard internet protocols (HTML5).

4. Indication for use

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.

5. Technology

Aid-U is a software system that enables health care professionals to access, manipulate in real-time, medical images using any web-browser without installing client software without restrictions of device/location. PACS application program is executed based on Wildfly application server, which is SubSYS-WILDFLY. Based on security communication, logging, DICOM tags stored in DB, and file storage information stored in SubSYS-LDAP, the initialization database SubSYS-POSTGRESQL is used to store, search, and search medical images and meta information. Storage, inquiry and search functions are provided only to authorized users in SubSYS-KEYCLOAK, and unauthorized access is blocked. In addition, it provides a web browser-based PACS/Web viewer UI that can store and search medical images and meta information by interacting with the PACS application program.

6. Predicate Device

Subject Device	Primary Predicate Device	Additional Predicate Device
Aid-U	Agfa HealthCare's ICIS View (K143397)	Novarad Corporation NovaPACS (K171754)

7. Determination of Substantial Equivalence

Aid-U has the same intended use, principle of operation, and similar technological features to the predicate devices ICIS (K143397) and NovaPACS (K171754).

There might be slight differences in features and menu, but these differences between the predicate devices and the proposed device do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. Based on the results of software validation and verification tests, we conclude that the proposed device is substantially equivalent to the predicate devices.

Comparison Table:

Functionality	**Subject Device**	**Predicate Device** **Agfa HealthCare's** **ICIS View** **(K143397)**	**Predicate Device** **Novarad Corporation** **NovaPACS** **(K171754)**
Device Name	Aid-U	ICIS View	NovaPACS
Classification	Class II	Class II	Class II
Regulatory Number	21 CFR 892.2050	21 CFR 892.2050	21 CFR 892.2050
Product Code	LLZ	LLZ	LLZ
Modalities	CT, MR, PT, US, XA, NM, DX, SC	CR, DX, CT, MR, US,	CT, MR, US, CR/DX, NM, PT, and XA
Communication	Same as predicates	DICOM	DICOM
Indication for Use	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.	ICIS® View is a software application used for reference viewing of medical images and associated reports and, as such, fulfills a key role in Agfa HealthCare's Imaging Clinical Information System (ICIS). ICIS® View enables healthcare professionals, including (but not limited to) physicians, surgeons, nurses, and administrators to receive and view patient images and data from multiple departments and organizations within one multidisciplinary viewer. Users may access the product directly via a web-browser, select mobile devices, healthcare portal or within the Electronic Medical Record (EMR). ICIS® View allows users to perform basic image manipulations and measurements (for example window/level, rotation, zoom, and markups). ICIS® View can optionally be configured for Full Fidelity mode, which is intended for diagnostic use, review and analysis of CR, DX, CT, MR,	NovaPACS is intended for the viewing, archiving, analysis, annotation, registration, distribution, editing, fusion, and processing of digital medical images and data acquired from diagnostic imaging devices and all DICOM devices, including mammography. NovaPACS is intended for use by trained healthcare professionals, including radiologists, physicians, technologists, clinicians, and nurses. NovaPACS allows the end user to display, manipulate, archive, and evaluate images. Mobile devices are not intended to replace a full workstation and should be used only when there is no access to a workstation. They are not to be used for mammography or fMRI. Mobile devices are used for diagnosis of medical images from different modalities including CT, MR, US, CR/DX, NM, PT, and XA. For a list of compatible mobile platforms see NovaPACS

		US images and medical reports. ICIS® View Full Fidelity is not intended to replace full diagnostic workstations and should only be used when there is no access to a workstation. ICIS® View full fidelity is not intended for the display of digital mammography images for diagnosis.	Diagnostic Viewer User Manual. While NovaPACS full workstation provides tools to assist the healthcare professional determine diagnostic viability, it is the user's responsibility to ensure quality, display contrast, ambient light conditions, and to confirm image compression ratios are consistent with the generally accepted standards of the clinical application. NovaPACS is intended for providing analysis and visualization of functional MRI data of the human brain, presenting derived properties and parameters in a clinically useful context.
Window Level	Same as primary predicate	Yes	Yes
User Authentication	Same as primary predicate	Yes	Yes
Network Access	Web browser connects to existing PACS	Web browser connects to existing PACS	Workstation, and NovaWeb Web Viewer.
Transfer/Storage/Display of Medical Images	Same as primary predicate	Yes	Yes
Pan/Zoom	Same as primary predicate	Yes	Yes
Measurement	Same as primary predicate	Yes	Yes
Annotation	Same as primary predicate	Yes	Yes

8. Summary of Non-Clinical Test

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

- NEMA PS 3.1 - 3.15, 3.18 (2016), Digital Imaging and Communication in Medicine (DICOM)
- ISO/IEC 15444-1:2016 (JPEG 2000)
- 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.

9. Safety and Effectiveness Information:

Software specifications, design descriptions, hazard analysis, and labeling information are submitted in support of this premarket notification. The device labeling contains instructions for use with cautions to provide for safe and effective use of the device. The results of the hazard analysis, combined with the appropriate preventive measures Taken, indicate the device is of moderate level of concern, as per the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005).

10. Conclusion

The new device Aid-U 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.