Tae Young Soft Co., Ltd.
Gee Yun Hong
Staff
B-1504. B1505, 65, Gwacheon-daero 7-gil
Gwacheon-si, 13840
Korea, South

January 31, 2025

Re: K241694
Trade/Device Name: ZeTTA PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: December 24, 2024
Received: December 26, 2024

Dear Gee Yun Hong:

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
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.

Submission Number *(if known)*

K241694

Device Name

Zetta PACS

Indications for Use *(Describe)*

ZeTTA PACS is intended for use in hospitals and diagnostic centers as a PACS to receive, store, retrieve, and display medical images from DICOM-compliant modalities, including CT, MRI, ultrasound, and radiographic devices. The system enables healthcare professionals to securely access and analyze diagnostic images over hospital networks.
Typical users of ZeTTA PACS include trained professionals such as physicians, radiologists, and medical technicians.
For mammography, only preprocessed DICOM for-presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by FDA.

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

[As required by 21 CFR 807.92]

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

January 31, 2025

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

- Name of Manufacturer: Tae Young Soft Co., Ltd.
- Address: B-1504. B1505, 65, Gwacheon-daero 7-gil Gwacheon-si, Gyeonggi-do, 13840 Republic of Korea / Tel: 82-2-852-5500
- Contact Name: Gee Yun Hong
- Telephone No.: +82 10 2708-0699
- Fax No.: +82-02-3434-3119
- Email Address: gyoonh@tysoft.co.kr

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade name: ZeTTA PACS

Classification Description	21 CFR Section	Product Code
Medical image management and processing system	892.2050	LLZ

As stated in 21 CFR, parts 872.5470 and 892.2050, this generic type of devices has been classified as Class II.

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

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

Predicate device #1

- 510(k) Number: k172803
- Applicant: Infinitt Healthcare Co., Ltd.
- Classification Name: Medical image management and processing system
- Trade Name: Infinitt PACS 7.0

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

ZeTTA PACS is a Windows-based Picture Archiving and Communication System (PACS) used in hospitals and diagnostic centers to receive, store, retrieve, distribute, and display medical images from various DICOM-compliant modalities, such as CT, MRI, ultrasound, and radiographic devices. This system supports the DICOM 3.0 standard and is designed to allow healthcare professionals to securely access and manage medical images over hospital networks.

ZeTTA PACS supports more than two high-resolution monitors to facilitate efficient image interpretation. It provides advanced layout options, multi-worklist functionality, and DICOM GSPS (Grayscale Presentation State), enhancing diagnostic and analytical efficiency. Additionally, it offers image analysis tools such as ruler and angle, along with image manipulation features like windowing and zoom, enabling healthcare professionals to perform more accurate analyses.

ZeTTA PACS integrates multiple medical imaging sources into a centralized solution, ensuring secure storage and management. It is useful across various medical fields such as radiology, cardiology, and neurology. However, it does not provide diagnostic decision-making functions, and all diagnoses, treatments, and prescriptions must be made by qualified medical professionals.

Furthermore, ZeTTA PACS does not support mobile devices and is designed for use in network-based desktop and workstation environments, ensuring stable and secure management of medical images.

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

ZeTTA PACS is intended for use in hospitals and diagnostic centers as a PACS to receive, store, retrieve, and display medical images from DICOM-compliant modalities, including CT, MRI, ultrasound, and radiographic devices. The system enables healthcare professionals to securely access and analyze diagnostic images over hospital networks.

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Typical users of ZeTTA PACS include trained professionals such as physicians, radiologists, and medical technicians.

For mammography, only preprocessed DICOM for-presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meets technical specifications identified by FDA.

7. Determination of Substantial Equivalence [21 CFR 807.92(a)(6) and 21 CFR 807.92(b)]

There are no significant differences between Align Studio and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to this device in design, function, and technical characteristics.

	Proposed Device	Predicate Device #1	SE Decision
K Number	-	K172803	-
Manufacturer	TAE YOUNG SOFT CO., LTD	Infinitt Healthcare Co., Ltd.	-
Model	ZeTTA PACS	Infinitt PACS 7.0	-
Indication for Use	ZeTTA PACS is developed and designed for the confirmation, storage, and maintenance of medical images used for diagnosis within hospitals. It is a DICOM viewer based on Windows OS, enabling the storage, zooming, viewing, and transmission of medical images, as well as report generation. ZeTTA PACS includes DICOM store, DICOM query/retrieve, and DICOM print modules that support the DICOM standard. It simultaneously supports two high-resolution monitors of FHD or higher and provides Worklist functionality for efficient diagnostics. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, and medical technicians.	Infinitt PACS 7.0 is a software device that receives medical images and data from various imaging sources. Image and data can be stored, communicated, processed, and displayed within the system or across computer networks at distributed locations. Only preprocessed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using a monitor that meet technical specification identified by FDA. Typical users of this system are trained professionals.	Same
Module	Imports scanned image of patient	Imports scanned image of patient	Same
	Stand-alone software module	Stand-alone software module	
	Support Built-in report module	Support Built-in report module	

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	Proposed Device	Predicate Device #1	SE Decision
Managing patient and case base data	Creating, editing, deleting and copying patient data	Creating, editing, deleting and copying patient data	Same
Worklist	Supports various worklist mode. ● Study list ● DICOM QR ● DICOM DIR ● Case ● Conference ● Technician worklist ● Viewed history	Supports various worklist mode. ● Study list ● Favorite folder ● DICOM QR ● DICOM DIR ● Case ● Conference ● Technician worklist ● Embedded web browser ● Viewed history	Same
	Supports short cut button for the specific folders of each worklist mode (Quick access)	Supports short cut button for the specific folders of each worklist mode (Quick access)	
	Support open the DICOM files directly (local open)	Support open the DICOM files directly (local open)	
Study list	● Searches the exams that meet the multiple search conditions ● Exam list displays various information describing the exams. ● Add, delete, change position and sort of each information with header column control ● Supports create/edit/delete search folders that contains the predefined search conditions ● Caches the images to the local disk with On-Call function ● Exam list are configurable –font name, size, color ● Launches the 3rd party application or web URL with selected exam information using External link ● Opens only key images in the selected exam ● Scans documents and attaches to the selected exam ● Supports creating and view the comments of the study for private-use or sharing with specified user level. ● Assigns the priority of the study ● Creates and shows technician note ● Searches the historical exams of the selected exam ● Creates and shows the report of the selected exam	● Searches the exams that meet the multiple search conditions ● Configurable fetching count for the exams. ● Exam list displays various information describing the exams. ● Add, delete, change position and sort of each information with header column control ● Supports refreshing the exam list automatically by user configuration ● Exports the list of the selected exams to text file or MS Excel compatible file(CSV) ● Supports create/edit/delete search folders that contains the predefined search conditions ● Caches the images to the local disk with On-Call function ● Exam list are configurable – font name, size, color ● Changes exam status using hospital specific terminology ● Launches the 3rd party application or web URL with selected exam information using External link ● Opens an exam or multiple exams in one click ● Opens only key images in the selected exam ● Scans documents and attaches to the selected exam ● Limit data access (Passcode Rule, Hiding	Same

	Proposed Device	Predicate Device #1	SE Decision
		rule, Folder Lock) ● Supports creating and view the comments of the study for private-use or sharing with specified user level. ● Assigns the priority of the study ● Assigns the referring doctor of the study ● Assigns the Radiologist (Read doctor) of the study ● Creates and shows technician note ● Creates and shows ER note ● Searches the historical exams of the selected exam ● Creates and shows the report of the selected exam	
Technician worklist	Searches order and exam list ● Modifies the information of the exam or the series	Searches order and exam List ● Matches or un-matches the selected order and exams ● Merges or un-merges the exam ● Splits the series from the exam to new one ● Modifies the information of the exam or the series	Same
Embedded web browser	Browses the web pages with predefined web URL	Browses the web pages with predefined web URL	
Dashboard	Queries the number of exams that are met the specified condition. ● Shows the study list that are met the specified conditions	Queries the number of exams that are met the specified condition. ● Shows the study list that are met the specified conditions	
General Viewing	● Displays the DICOM images which are stored in PACS storage ● Accesses historical exams and report: Exam list ● Supports image arrangement and manipulation using toolbar buttons, shortcut keys or screen shortcut ● Support user-configurable mouse button action ● Configures the initial settings for each specific modality ● Supports job saving ● Export or convert the displayed images as DICOM or general image formats	● Displays the DICOM images which are stored in PACS storage ● Accesses historical exams and report: Timeline, Exam list ● Supports image arrangement and manipulation using toolbar buttons, shortcut keys or screen shortcut ● Support user-configurable mouse button action ● Configures the initial settings for each specific modality ● Supports job saving ● Export or convert the displayed images as DICOM or general image formats	Same
Image Display	● Maximize and restore displayed image ● Support linked scrolling by manual-selection ● Support monitor cine control for stack mode ● Sets as key image ● Supports sequence display (Position/Time) for specific data	● Support display mode: Stack / Image / Preset (VR/ MPR / MIP / Web URL /Report) ● Maximize and restore displayed image ● Support crosslink among the series in same study ● Support linked scrolling among the exams,	

	Proposed Device	Predicate Device #1	SE Decision
		even for difference exams ● Support linked scrolling by manual-selection ● Support monitor cine control for stack mode ● Sets as key image ● Rearranges the images by image information (Sort): image time/number/echo time/image position ● Supports sequence display (Position/Time) for specific data	
Output	● Prints the images and report with paper or DICOM printer ● Sends the images and report to DICOM station ● Various layout adjustment ● Report prints with output template which is configurable for specific hospital ● Selects images for printing ● Prints images with or without patient information, annotations and scale bar	● Prints the images and report with paper or DICOM printer ● Sends the images and report to DICOM station ● Export the images and report to MS PowerPoint ● Various layout adjustment ● Report prints with output template which is configurable for specific hospital ● Selects images for printing ● Prints images with or without patient information, annotations and scale bar	

Non-Clinical Test Summary [21 CFR 807.92(b)(1)]

1) Software Validation

ZeTTA PACS contains Basic Documentation Level software. Software was designed and developed according to a software development process and was verified and validated.

The software information is provided in accordance with FDA guidance: Content of premarket submissions for Device Software Functions, on November 04, 2021.

2) Performance Testing

Through the performance test, it was confirmed that ZeTTA PACS meets all performance test criteria and that all functions work without errors. Test results support the conclusion that actual device performance satisfies the design intent and is equivalent to its predicate device.

Clinical Test Summary [21 CFR 807.92(b)(2)]

No clinical studies were considered necessary and performed.

Conclusion [21 CFR 807.92(b)(3)]

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Based on a comparison of intended use, indications, principle of operations, features and technical data, and the test results, the ZeTTA PACS is found to be as safe and as effective as the predicate device.

Intended use and performance is found to be substantially equivalent to the predicate device,

Infinitt PACS 7.0 ^{tm} (k172803) from Infinitt Healthcare Co., Ltd.