December 9, 2025

INFINITT Healthcare Co., Ltd.
Josh Baker
Consultant
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27 Digital-ro 34-gil, Guro-gu
Seoul, 08378
South Korea

Re: K243449
Trade/Device Name: INFINITT DPS
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: November 7, 2024
Received: November 7, 2024

Dear Josh Baker:

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 and Part 809); 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,

Shyam Kalavar -S

Shyam Kalavar
Deputy Branch Chief
Division of Molecular Genetics and Pathology
OHT7: Office of In Vitro Diagnostics
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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.

510(k) Number *(if known)*
K243449

Device Name
INFINITT DPS

Indications for Use *(Describe)*
INFINITT DPS is a software device intended for viewing and management of whole slide digital images derived from scanned surgical pathology slides prepared from formalin-fixed, paraffin-embedded (FFPE) tissue. It serves as an aid for pathologists to review and interpret these digital images for the purpose of pathology primary diagnosis.

INFINITT DPS is intended for use with Hamamatsu NanoZoomer S360MD scanner and Barco MDPC-8127 display.

It is the responsibility of the pathologist to implement appropriate procedures and safeguards that assure the integrity and accuracy of image interpretation when utilizing the INFINITT DPS. The system is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

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

INFINITT DPS

Date of 510(k) Summary: December 8, 2025

1.1 Name & Address of Manufacturer

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1.2 510(k) Contact Person

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1.3 Device Name

Device name: **INFINITT DPS**
Version: 1.1
Applicant: INFINITT Healthcare Co., Ltd.
Classification Product Code: QKQ
Classification Regulation: 21 CFR 864.3700
Classification Name: Whole Slide Imaging System
Device Class: Class II
510(k) Submission Number: K243449
Review Panel: 88 – Pathology

1.4 Identification of the Predicate Device

Predicate Device Name: NanoZoomer S360MD Slide scanner system
Applicant: Hamamatsu Photonics K.K.
Classification Product Code: PSY
Regulation Number: 21 CFR 864.3700
Device Class: Class II
510(k) Submission Number: K233027

2. Intended Use / Indications for Use

A. Intended Use(s):
See Indications for Use below.

B. Indications for Use:
INFINITT DPS is a software device intended for viewing and management of whole slide digital images derived from scanned surgical pathology slides prepared from formalin-fixed, paraffin-embedded (FFPE) tissue. It serves as an aid for pathologists to review and interpret these digital images for the purpose of pathology primary diagnosis.

INFINITT DPS is intended for use with Hamamatsu NanoZoomer S360MD scanner and Barco MDPC-8127 display.

It is the responsibility of the pathologist to implement appropriate procedures and safeguards that assure the integrity and accuracy of image interpretation when utilizing the INFINITT DPS. The system is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.

C. Special Conditions for Use Statement(s):
Rx - For Prescription Use Only

3. Device Description

INFINITT DPS software provides a more efficient and convenient alternative to reviewing slides with physical microscopes. The primary users of INFINITT DPS are pathologists in histopathology , as well as technologists who handle specimens. Users can access whole slide images directly through a web browser, with no need to install additional software on the client PC.

INFINITT DPS, version 1.1, is a web-based software device that enables qualified pathologists to review digital pathology images (WSIs) of formalin-fixed, paraffin-embedded (FFPE) tissue specimens for pathology primary diagnosis. The device operates through a supported web browser without installing any application locally.

- The Operation and Workflow of INFINITT DPS are described below:
    - Data Input
        - The device accepts WSI files in the NDPI file format generated by a Hamamatsu NanoZoomer S360MD Slide Scanner. The WSI files are internally converted into the Digital Imaging and Communications in Medicine (DICOM) file format using the built-in INFINITT DPS Acquisition module.
    - Data Management and Storage
        - The converted images are stored on the INFINITT DPS server. The user is highly recommended to back up the original NDPI files. The device can be

integrated with an external LIS (Laboratory Information System)/EMR (Electronic Medical Record) system to automate case registration and retrieval.

- Image Access and Navigation
  - Users can log in to the device using the INFINITT DPS WebViewer running on a supported web browser (i.e., Chrome, Edge, or Firefox). The stored WSIs can be searched, selected, and opened directly within the INFINITT DPS WebViewer.
- Image Review and Interpretation
  - INFINITT DPS WebViewer provides the following interactive features:
    - Zoom, pan, and rotate for image navigation
    - Measurement tools for length and area analysis

The interoperable components of INFINITT DPS and other system specifications are provided in tables 1 – 3 below.:

Table 1. Interoperable Components for Use with INFINITT DPS

Components	Manufacturer	Model
Scanner	Hamamatsu	NanoZoomer S360MD Slide scanner
Display	Barco	MDPC-8127

Table 2. Computer Environment / System for Use with INFINITT DPS

Component	Requirement
Operating System	Windows 11
Memory	32GB RAM
Processor	Intel Core i7-11800H
Supported Browsers	Google Chrome version 90.0 and above Microsoft Edge version 90.0 and above Mozilla Firefox version 80.0 and above

Table 3. Server System Requirements

Component	Web Server	Database Server
CPU	2.8GHz 12-core or higher	2.2GHz 8-core or higher
Memory	64GB or more	16GB or more
Storage	2TB or more	4TB or more
Software Platforms	Microsoft IIS (Internet Information Services) 10 or higher	
Operating Systems	Microsoft Windows Server 2016 or higher	
Database	N/A	Oracle Database 19c or higher
Network	1Gbps	1Gbps

4.2 Software Operation

Device Features Controlled by Software	The main features of the INFINITT DPS are: • INFINITT DPS is a web-based software device, allowing the app to be used without any need for software installation. • View images in the Hamamatsu WSI (Whole Slide Image) format (NDPI) acquired from the Hamamatsu NanoZoomer S360MD Slide scanner in the same environment. • Easily search and view your cases and slides, as INFINITT DPS serves as an online storage solution for slide images. • User-friendly image manipulation tools (Zoom, Pan, Rotation, etc.) are available. • Precise and accurate measurement and annotation tools are provided. • Layout and synchronization functions are supported for viewing and comparing multiple slide images simultaneously.
Intended Use Environment	Pathology in hospitals.
Software User Groups	The primary software users of INFINITT DPS are pathologists, as the system is intended to aid in the review and interpretation of digital images for primary diagnosis. Secondary users may include laboratory IT staff responsible for system configuration and maintenance, as well as clinical laboratory supervisors who oversee compliance and workflow integration.
Intended Patient Population	Patients can receive cancer diagnosis information interpreted by a pathologist. The product can be used widely regardless of nationality, race, age or gender.
Data Analysis	None
Clinical Actions Performed	It allows to view slides without using a microscope.
Artificial Intelligence (AI)/ Machine Learning (ML) Model Population	None
AI/ML Model Bias/Limitation Considerations	None

5. Performance Testing

Summary of Testing

Software Verification and Validation (V&V) Testing:

- Comprehensive validation and verification (V&V) testing were performed on the INFINITT DPS to confirm functionality, reliability, and compliance with intended performance requirements. This included rigorous testing across all critical software modules, such as administration, image acquisition, worklist management, and viewing capabilities.

- Each test case in the INFINITT DPS test plan was executed according to established protocols. The testing process confirmed that all functions met predefined specifications, with any detected issues resolved before release. The V&V testing validated that INFINITT DPS reliably performs as intended in a clinical setting.

Human Factors Engineering (HFE) and Usability Engineering (UE) Testing:

- Human Factors and Usability Engineering tests for INFINITT DPS ensured that the design supports safe, efficient, and intuitive use by the primary users, including pathologists, medical technologists, and system administrators.
- A simulated-use human factors validation study was conducted with 15 representative users (pathologists and technologists) to evaluate usability and use-related risks. All critical tasks were completed successfully without use errors leading to harm. Minor user interface (UI) improvements (e.g., confirmation pop-ups, case-insensitive search) were made post-validation, and no additional validation was required. The study demonstrated that INFINITT DPS can be used safely and effectively by the intended user population in the intended environment.
- The results demonstrated that INFINITT DPS meets FDA Human Factors Engineering standards and effectively minimizes the risk of user error, supporting its safe and intended use in clinical environments.

Cybersecurity Testing:

- Cybersecurity testing for the INFINITT DPS addressed potential security risks and verified adherence to medical device software cybersecurity requirements.
- Static Analysis (SAST) involved a thorough review of the source code, identifying and mitigating low-level vulnerabilities to ensure secure coding practices were followed throughout the software.
- Dynamic Analysis included comprehensive web application vulnerability assessments and fuzz testing for input validation to confirm data integrity and resistance to unauthorized access. Identified vulnerabilities were addressed with specific mitigations, and ongoing monitoring protocols were established.
- Penetration Testing, following the MITRE ATT&CK framework, simulated potential cyber threats, verifying that the INFINITT DPS has robust security measures in place to protect against unauthorized access and data breaches.

Non-Clinical Bench Performance Testing:

The performance of the INFINITT DPS was validated through a series of non-clinical bench performance tests following the FDA guidance document, Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices (April 20, 2016). The following performance tests were conducted to demonstrate substantial equivalence to the predicate device and to ensure the system performs safely and effectively for its intended use.

- Pixel-wise Color Comparison Test: This test demonstrated identical image reproduction between the subject device (INFINITT DPS) and the predicate viewer using the CIEDE2000 (ΔE_{00}) metric. Whole Slide Images (WSIs) of 30 FFPE H&E-stained slides were analyzed

across three web browsers (Chrome, Edge, Firefox). Each slide included 3 ROIs captured at 3 magnification levels. All 95th percentile ΔE_{00} values averaged 0.00 (maximum 95th percentile ΔE_{00} values were 0), indicating no significant difference between the subject and predicate viewers.

- Measurement Accuracy Test: The subject device was tested for length and area measurement accuracy using various annotation tools (e.g., ruler, region) on multiple WSIs at 20x and 40x magnification, with 2 different orientations. Measurements from INFINITT DPS were compared to those from the predicate device. All results met the predefined acceptance criteria of ±2% or ±5 µm for length and ±5% for area, confirming measurement accuracy.
- Turnaround Time (TAT) Test: This test assessed image load times and responsiveness during interactions such as panning and zooming. Using browser developer tools, timestamps were recorded and analyzed. WSIs loaded within an average of 2.8 seconds, and all interactions responded within an average of 0.48 seconds, meeting the criteria of ≤5 seconds for load time and ≤1 second for interaction latency.

In summary, all testing phases for the INFINITT DPS — including software V&V, Human Factors Engineering, Cybersecurity assessments, and Non-Clinical Bench Performance Testing (Pixel-wise Comparison, Measurement Accuracy, and Turnaround Time) — were completed successfully. INFINITT DPS meets its performance, usability, and security requirements, supporting its safe and effective use in a clinical setting.

6. Predicate Device Substantial Equivalence Comparison

Predicate Device:

- NanoZoomer S360MD Slide scanner system (K233027) by Hamamatsu Photonics K.K.
- Regulation Number 21 CFR 864.3700
- Product Code: PSY
- Classification: Class II

General Function	Subject Device – INFINITT DPS (K243449)	Predicate: NanoZoomer S360MD Slide scanner system (K233027)	If different, Impact on Safety and or Efficacy
Manufacturer Name	INFINITT Healthcare Co., Ltd.	Hamamatsu Photonics K.K.	
Trade Name	INFINITT DPS	NanoZoomer S360MD Slide scanner system	
Common Name	Digital Pathology Image Viewing and Management Software	Whole Slide Imaging System	INFINITT DPS is software-only, whereas NanoZoomer S360MD Slide scanner system includes scanner and hardware components. This difference has no

General Function	Subject Device – INFINITT DPS (K243449)	Predicate: NanoZoomer S360MD Slide scanner system (K233027)	If different, Impact on Safety and or Efficacy
			impact on safety or effectiveness, as image acquisition and display are performed using FDA-cleared devices.
Device Class	Class II	Class II	No difference
Regulation Number	21 CFR 864.3700	21 CFR 864.3700	No difference
Classification Name	Whole Slide Imaging System	Whole Slide Imaging System	No difference
Product Code	QKQ	PSY	There is a difference. INFINITT DPS is a Digital Pathology Image Viewing and Management Software, but NanoZoomer S360MD Slide scanner system is a Whole Slide Imaging System including scanner and hardware components.
Indications for Use	INFINITT DPS is a software device intended for viewing and management of whole slide digital images derived from scanned surgical pathology slides prepared from formalin-fixed, paraffin-embedded (FFPE) tissue. It serves as an aid for pathologists to review and interpret these digital images for the purpose of pathology primary diagnosis. INFINITT DPS is intended for use with Hamamatsu NanoZoomer S360MD scanner and Barco MDPC-8127 display. It is the responsibility of the pathologist to implement appropriate procedures and safeguards that assure the integrity and accuracy of image interpretation when utilizing the INFINITT DPS. The system is not intended for use with frozen sections, cytology, or non-FFPE hematopathology specimens.	The NanoZoomer S360MD Slide scanner system ("NanoZoomer System") is an automated digital slide creation, viewing, and management system. The NanoZoomer System is intended for in vitro diagnostic use as an aid to the pathologist to review and interpret digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded ("FFPE") tissue. The NanoZoomer System is not intended for use with frozen section, cytology, or non-FFPE hematopathology specimens. The NanoZoomer System comprises the NanoZoomer S360MD Slide scanner, the NZViewMD Software and a compatible display that has been 510(k) cleared for use with the NanoZoomer system or a 510(k)-cleared display that has been assessed in accordance with the Predetermined Change Control Plan (PCCP) for qualifying additional compatible displays. The NanoZoomer System is for creation and viewing of digital images of scanned glass slides that would otherwise be appropriate for manual visualization by conventional light microscopy. It is the responsibility of a qualified	INFINITT DPS is a software-only digital pathology image viewing and management system, whereas NanoZoomer S360MD Slide scanner system includes the scanner, software, and display. This difference does not impact safety or effectiveness, as INFINITT DPS relies on the FDA-cleared scanner (Hamamatsu NanoZoomer S360MD Slide scanner system) and display for image acquisition and presentation, and its intended use remains equivalent for primary diagnosis of FFPE surgical pathology slides.

General Function	Subject Device – INFINITT DPS (K243449)	Predicate: NanoZoomer S360MD Slide scanner system (K233027)	If different, Impact on Safety and or Efficacy
		pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using NanoZoomer System.	
Specimen type	Surgical pathology slides prepared from FFPE tissue.	Surgical pathology slides prepared from FFPE tissue.	No difference
Image Storage	Images are stored in an end user provided image storage attached to the local network.	Images are stored in an end user provided image storage attached to the local network.	No difference
Image manipulation functions	Panning, zooming, gamma function, annotations, and measurements (distance & area)	Panning, zooming, annotations, and measurements (distance & area)	No significant difference
Image review and Diagnosis	During review, the pathologist opens WSI images acquired with a Hamamatsu NanoZoomer S360MD scanner from the image storage, performs further QC and reads WSI images of the slides to make a diagnosis.	During review, the pathologist opens WSI images acquired with Hamamatsu NanoZoomer S360MD scanner from the image storage, performs further QC and reads WSI images of the slides to make a diagnosis.	No significant difference
End User's Interface	INFINITT DPS Viewer provides the function to view the selected slide or gross images and manipulate them using various tools.	The NZViewMD software opens the WSI images acquired with slide scanner from the image storage attached to local network and uses the color profile to render the image data to the calibrated display monitor to deliver the image view at the appropriate magnification.	There is a difference. NanoZoomer S360MD Slide scanner system uses their proprietary viewer (NZViewMD software) and INFINITT uses its INFINITT DPS proprietary viewer. The use of INFINITT DPS Viewer does not modify existing risks or raise any new potential safety risks. Therefore, we believe there is no impact on safety or efficacy of the subject device.
Scanner	INFINITT DPS does not include a scanner; however, it is indicated for use with the Hamamatsu NanoZoomer S360MD Slide scanner system.	NanoZoomer S360MD Slide scanner system includes the S360MD Slide scanner system.	INFINITT DPS does not include a scanner but is indicated for use with the FDA-cleared Hamamatsu NanoZoomer S360MD Slide scanner system. NanoZoomer S360MD Slide scanner system includes the scanner as part of the system. This difference does not impact safety or effectiveness, since both devices rely on the same FDA-cleared scanner for image acquisition.
Display monitor	INFINITT DPS does not include a monitor; however, it is indicated for use with the Barco MDPC-8127.	NanoZommer S360MD Slide scanner system does not include a monitor; however, it is indicated for use with the JVC Kenwood JD-	No significant difference

General Function	Subject Device – INFINITT DPS (K243449)	Predicate: NanoZoomer S360MD Slide scanner system (K233027)	If different, Impact on Safety and or Efficacy
		C240BN01A, and Barco MDPC-8127 Display.	

7. Conclusion

The 510(k) Pre-Market Notification for the INFINITT DPS, software device contains adequate information, data, and nonclinical test results to determine substantial equivalence to the predicate device. The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use does not raise any new potential safety risks and is equivalent in performance to existing legally marketed devices.

Non-clinical bench performance tests demonstrate that INFINITT DPS was found to have a safety and effective profile that is substantially equivalent to the predicate device.