510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K243449

B Applicant

INFINITT Healthcare Co., Ltd.

C Proprietary and Established Names

INFINITT DPS

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
QKQ	Class II	21 CFR 864.3700 - Whole Slide Imaging System	PA - Pathology

II Submission/Device Overview:

A Purpose for Submission:

New device

B Type of Test:

Software only device

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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

IV Device/System Characteristics:

A Device Description:

INFINITT DPS, version 1.1, is a web-based software device that enables qualified pathologists to review digital whole slide 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 create a backup of 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 into 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

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

B Instrument Description Information:

1. Instrument Name:
   INFINITT DPS

2. Specimen Identification:
   Glass slides and scanned WSIs are identified based on the previously assigned specimen identifiers such as patient identifiers, barcodes, etc. Digital images of Hematoxylin and Eosin (H&E) stained surgical pathology glass slides prepared from FFPE tissue are obtained using the Hamamatsu NanoZoomer S360MD Slide scanner. INFINITT DPS receives digital image files generated by the Hamamatsu NanoZoomer S360MD Slide scanner. Specimen identification within the system is managed using metadata and digital identifiers associated with each scanned FFPE tissue slide. These identifiers are displayed in the INFINITT DPS interface to allow pathologists to access, review, and organize digital slides. The system does

not modify or assign specimen identifiers and relies on scanner-generated and system-ingested data for digital slide tracking.

3. Specimen Sampling and Handling:
   Specimen sampling and handling are performed upstream and independent of the use of the subject device. Specimen sampling includes surgical pathology biopsy or resection specimens which are processed using standard histology techniques. The FFPE tissue sections are stained using the H&E staining procedure. INFINITT DPS does not perform or manage physical specimen sampling or handling.

4. Calibration:
   INFINITT DPS relies on properly calibrated image input from the scanner and does not modify or perform any calibration functions within the software.

5. Quality Control:
   Prior to using a WSI for diagnosis, it is the responsibility of the laboratory staff, while scanning glass slides and uploading WSIs, and the pathologist, while reviewing the WSIs, to ensure that all scanned slide images have been imported for every case and the images are of acceptable quality for diagnostic purposes per their laboratory standards. Additional details of the quality control procedures are provided in the device's user manual.

V Substantial Equivalence Information:

A Predicate Device Name(s):
NanoZoomer S360MD Slide scanner system

B Predicate 510(k) Number(s):
K233027

C Comparison with Predicate(s):

Device & Predicate Device(s):	K243449	K233027
Device Trade Name	INFINITT DPS	NanoZoomer S360MD Slide scanner system
General Device Characteristic Similarities		
Intended Use/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.	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

	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.	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 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	Same
Diagnostic Image File Format	Hamamatsu NDPI File	Same
Image Storage	User-supplied network attached storage Same	Same
General Device Characteristic Differences		
Image manipulation functions	Panning, zooming, annotations, and measurements (distance & area)	Panning, zooming, annotations, and measurements (distance & area)
Type of Software Application	Internet browser-based application	PC-based installed application
End User's Interface	INFINITT DPS	NZViewMD

VI Standards/Guidance Documents Referenced:

1. FDA Guidance "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices". April 20, 2016.
2. FDA Guidance "Applying Human Factors and Usability Engineering to Medical Devices". February 3, 2016.
3. FDA Guidance "Content of Premarket Submissions for Device Software Functions". June 14, 2023.
4. FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions". September 27, 2023.

5. ISO 14971 Third Edition 2019-12, 5-125, Medical devices – Applications of risk management to medical devices.
6. IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, 13-79. Medical device software – Software life cycle processes.
7. ICE 60812 Edition 3.0 2018-08, 5-120, Analysis techniques for system reliability - Procedure for failure mode and effects analysis (FMEA)

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:
   Not applicable

2. Linearity:
   Not applicable

3. Analytical Specificity/Interference:
   Not applicable

4. Accuracy (Instrument):
   Not applicable

5. Carry-Over:
   Not applicable

B Other Supportive Instrument Performance Characteristics Data:

Technical performance testing was conducted with the subject device, INFINITT DPS as specified below.

1. **Bench Testing - Pixelwise comparison test**
   Pixel-wise comparison testing to demonstrate identical image reproduction was conducted to compare WSIs reproduced by the subject device and the comparators as listed in Table 4 below. The subject device was compared to the predicate device's image review manipulation software (IRMS, as defined in FDA guidance document, "Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices" dated April 20, 2016) using the quantitative pixel-wise comparison method. The basis for the comparison was the CIEDE2000 color difference equation, ΔE_{00}. The devices were tested as operating with the intended components, including the scanner, specific file format, image management systems (subject device with the intended browsers and the comparator [predicate device IRMS]) and displays, as specified in the Table 4 below.

   For each of the configurations in Table 4 below, the device was tested with multiple slides across multiple regions of interest (ROI) at multiple magnification levels. A total of 30 FFPE glass slides of normal and tumor tissues from various human anatomical organs were used in the testing. For each configuration, the glass slides were scanned on a corresponding

intended scanner to obtain 30 WSIs. For each of the 30 WSIs, 3 ROIs from different locations were selected by qualified personnel to represent various features in the tissue samples. Each ROI was captured at 3 magnification levels (10x, 20x, 40x).

Screenshots were captured for the intended display while viewing with the subject device and predicate device IRMS. The screenshots were cropped and registered to be pixelwise comparable. The cropped image included most of the pixels in the image except for those in the viewer-specific user interface areas.

For each configuration, two sets of images were collected: comparator (predicate device IRMS) and the subject device (INFINITT DPS with the intended browser). Each image set included 270 images that covered all combinations of 30 slides, 3 ROIs and 3 magnification levels. The testing data, including the overview images of the 30 glass slides with annotations of the ROIs, registration/cropping information, and captured images, were provided in the FDA specific format.

The comparator (predicate device IRMS) image set was used as the reference to compare the subject device image set to determine whether all the 270 image-pairs were identical for each configuration and each intended display. Two images are considered identical if the 95th percentile of the pixelwise differences, computed using the International Commission on Illumination (CIE) color difference metric CIEDE2000 (ΔE_{00}), is less than 3 ΔE_{00}. Testing results showed that the pixelwise differences across all 270 image-pairs per configuration and per intended display were less than 3 ΔE_{00}. The maximum (max), minimum (min), and mean of the 95th percentile ΔE_{00} value were reported in Table 4. Testing results demonstrated that WSIs reproduced by INFINITT DPS are identical to images reproduced by the predicate devices.

Table 4: INFINITT DPS Pixelwise Comparison Testing Results

Scanner	Subject Device /Browser	Comparator (Predicate device IRMS)	Display	Results
NanoZoomer S360MD Slide scanner	INFINITT DPS /Chrome	NZViewMD	Barco MDPC-8127	max (95^{th} percentile ΔE_{00}) = 0
				min (95^{th} percentile ΔE_{00}) = 0
				mean (95^{th} percentile ΔE_{00}) = 0
	INFINITT DPS /Edge	NZViewMD		max (95^{th} percentile ΔE_{00}) = 0
				min (95^{th} percentile ΔE_{00}) = 0
				mean (95^{th} percentile ΔE_{00}) = 0
	INFINITT DPS /Firefox	NZViewMD		max (95th percentile ΔE_{00}) = 0
				min (95th percentile ΔE_{00}) = 0
				mean (95^{th} percentile ΔE_{00}) = 0

2. **Turnaround Time**

   Turnaround times (TAT) for image loading, panning and zooming were tested with INFINITT DPS when using all the supported browsers, as listed in table 5 below. H&E-stained FFPE slide was scanned using the intended scanner to generate WSI. Below acceptance criteria was used:

- Initial slide load time: ≤ 5 seconds
- Panning/zooming response time: ≤ 1 second

Test results for different scenarios met the test acceptance criteria and showed acceptable turnaround time for the intended use of the subject device, as shown in table 5 below.

Table 5: INFINITT DPS Turnaround Time Testing Results

Subject Device / Browser	Loading (Mean)	Panning (Mean)	Zooming (Mean)
INFINITT DPS / Chrome	2.7 seconds	0.45 seconds	0.48 seconds
INFINITT DPS / Edge	2.9 seconds	0.51 seconds	0.49 seconds
INFINITT DPS / Firefox	2.8 seconds	0.48 seconds	0.46 seconds

3. Measurement – length and area

Measurement accuracy testing was performed to demonstrate that INFINITT DPS accurately represents length and area measurements. A total of 3 H&E-stained, FFPE slides containing normal and tumor tissue from various organs were used. Measurements were taken at 20x and 40x magnifications with 2 different orientations across 7 annotation types: Arrow, Freehand Region, Freehand Line, Circle, Rectangle, Ruler, and Pin. Tests were performed using three browsers (Chrome, Edge, Firefox), and results were compared against the predicate viewer. Each measurement was repeated and analyzed to assess both accuracy and repeatability.

The acceptance criteria were

- Length: within ±2% or ±5 μm, whichever is greater
- Area: within ±5%

Test results show that all measurements performed using INFINITT DPS fell within the predefined tolerance ranges. The subject device performed accurate measurements across multiple magnification settings with respect to its intended use.

4. Human Factor (Usability) Testing

The usability test was conducted per FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices (2016)". A summative human factors test, designed around critical user tasks and use scenarios using multiple representative users (pathologists), was conducted. All tasks associated with reviewing and reporting results for cases including confirmation that all slides belonging to specific cases are reviewed before reporting results were included in the study. The INFINITT DPS device has been found to be safe and effective for the intended users, uses and use environments.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.