



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY**

I Background Information:

A 510(k) Number

K233027

B Applicant

Hamamatsu Photonics K.K.

C Proprietary and Established Names

NanoZoomer S360MD Slide scanner system

D Regulatory Information

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

II Submission/Device Overview:

A Purpose for Submission:

- Add the BARCO MDPC-8127 display (monitor), cleared independently in K203364, to the NanoZoomer S360 MD Slide scanner system originally cleared in K213883.
- Establish a Pre-Determined Change Control Plan (PCCP) for qualifying and adding additional FDA-cleared displays as interoperable component to the NanoZoomer S360 MD Slide scanner system.

B Measurand:

Not applicable

C Type of Test:

Digital pathology whole slide imaging

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

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 pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using NanoZoomer System.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The NanoZoomer S360MD Slide scanner system is comprised of the NanoZoomer S360MD Slide scanner, NZAcquireMD acquisition software, NZViewMD image viewing software and compatible displays. The NanoZoomer S360MD Slide scanner system is an automated system for creating, viewing, and managing digital slides. The NanoZoomer S360MD Slide scanner system creates digital whole slide images (WSIs) of glass slides containing formalin-fixed paraffin-embedded (“FFPE”) tissue for pathology primary diagnosis purposes. The digital WSIs of glass slides may be viewed, stored, retrieved, annotated, and/or shared, permitting the pathologist to make a primary diagnosis based on the review of the WSIs. The NanoZoomer system does not include any automated Image Analysis Applications that would constitute computer aided detection or diagnosis.

The NanoZoomer slide scanner can be loaded with a maximum of 360 glass slides placed in 12 cassettes each with 30 standard-sized slides (length 75.0–76.5 mm, width 24.7–26.5 mm, thickness 0.9–1.2 mm). Each cassette is manually loaded with slides by the operator, with the slide labels facing outward so they can still be read while the cassette is loaded into the scanner. Once the slide's position is secured, the macro camera located directly above the slide first takes a picture of the slide's barcode image as illuminated by an overhead LED, and then takes a macro image of the actual tissue trans-illuminated by a flat-panel LED underneath. The slide holder then moves to the micro imaging position for scanning. The system automatically detects areas where tissues are present and scans a single overall rectangular area containing all detected tissues. The scanning area is automatically determined using a macro image of the slide. The NanoZoomer System uses its motorized stage, 20x objective lens, CMOS camera and LED to detect appropriate focusing points and scan the identified areas of interest. A single micro camera acquires one square image at a time and the acquired images (tiles) are stitched together to make a single composite high-resolution image. Images are automatically saved to the hard disk during scanning and may be viewed later by using the included viewing software. The NZAcquireMD software organizes all WSI tiles into a single NDPI file. Each digital image covers an entire slide and typically contains billions of image pixels. The NZAcquireMD software allows the user to operate the scanner and to store and archive digital images.

The NZViewMD software is a software component intended to run on a separate viewing workstation PC with a compatible display. The NZViewMD software opens the WSI images acquired with the NZAcquireMD software and slide scanner from the image storage attached to local network and renders the image data to the compatible display to deliver the image view at various magnification levels. The NZViewMD software has the following functionalities: continuous panning and zooming, comparing multiple slide images simultaneously in multiple windows, creating annotations during review using annotation tools, tracking of visited areas and annotations and digital bookmarks.

The new display Barco MDPC-8127 was cleared in K203364. Based on the testing data, it has equivalent display characteristics as the predicate display JVC JD-C240BN01. The Barco MDPC-8127 has been validated to be compatible with the NanoZoomer S360MD Slide scanner system by both Hamamatsu and Barco.

The NanoZoomer S360MD Slide scanner system can be connected to a server over a customer-provided local area network (LAN). The supporting networking hardware and software are not part of the system and may be located in a room separately from the workstation, viewing software, and display.

B Instrument Description Information:

1. Instrument Name:
NanoZoomer S360MD Slide scanner system (NanoZoomer System)
2. Specimen Identification:

Glass slides and scanned images are identified based on the previously assigned specimen identifiers such as patient identifiers, barcodes, etc. Digital images of surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue.

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 specimens such as biopsy or resection specimens which are processed using standard histology techniques. The FFPE tissue sections are H&E stained. Then digital images are obtained from these glass slides using the NanoZoomer S360MD Slide scanner.

4. Calibration:

When the system is launched (powered up), automatic system diagnosis is performed by the software using the provided calibration slides. This process evaluates the proper functioning of the light source, imaging sensor, and macro sensor and light source. When necessary, based on the automatic system diagnosis, adjustment of the shading correction and color balance correction features is performed automatically by the system. Monthly cleaning such as dusting of the scan mechanism and optical components is also performed by the user.

System administrators and field service personnel may also complete a system check following the NZAcquireMD Instructions for Use and the NZTuneMD service software and the calibration slides. This checks correction status and acquires correction data for whole slide and scanned images.

Additional calibration and quality control procedures are performed during field service visits following procedures provided in the NanoZoomer S360MD Maintenance Manual. These include annual testing of several critical components in the system and annual calibration of the components and the display.

5. Quality Control:

Quality control (QC) activities are performed by the user. Prior to scanning slides using the NanoZoomer S360MD Slide scanner, the user conducts QC of the slides per the laboratory's standards and professional guidelines (e.g., staining, cover-slipping, and barcode placement, etc.). After completing a scan, the user checks the image data and image quality using Quality Check (QC) mode in NZAcquireMD which includes the following steps:

- Display the Scan Result screen by selecting a slide for which scanning has been completed.
- Confirm scan area, focus quality, and barcode information. Confirm that the barcode information displayed above the slide image is consistent with the barcode label.
- Check the slide image to ensure all tissue on the slide are present within the scan area.

Manually verifying tissue block with the scanned images is also performed as needed. Slides are rescanned if necessary.

Before reading the scanned WSIs, the pathologist should ensure that all scanned slide images have been imported for every case and the images are of acceptable quality for diagnostic

purposes. The pathologist reviews scanned images from all the slides associated with a case before rendering a diagnosis.

V Substantial Equivalence Information:

A Predicate Device Name (s):

NanoZoomer S360MD Slide scanner system

B Predicate 510(k) Number(s):

K213883

C Comparison with Predicate(s):

The subject device is similar to the predicate, having similar indications for use, the same intended use, and the same technological characteristics as its predicate device, with the exception of the implementation of a Predetermined Change Control Plan (PCCP) that specifies the protocols and acceptance criteria for validating and adding additional FDA-cleared displays as interoperable component to the NanoZoomer S360 MD Slide scanner system in a controlled manner, such that the device is as safe and as effective as the predicate.

The sponsor's PCCP for validating the use of additional FDA-cleared display is part of the quality system and comprises the following phases:

1. When a new FDA-cleared display is identified as the candidate, the candidate display, and its supplier will be evaluated based on various considerations. A design change request will be generated if the candidate display, and its supplier pass the evaluation.
2. The candidate display will be tested with a set of FDA-approved test methods and acceptance criteria, including a system-level test for the complete WSI system specified in the PCCP. The tests will be conducted by a qualified tester according to the quality management system. If there is a failure detected during the test, the failure(s) will be recorded, and the design change will not be implemented.
3. If the candidate display meets the acceptance criteria, the design change will be implemented according to the quality management system and the new display may be added as an interoperable component to the NanoZoomer S360 MD Slide scanner system without additional premarket review. The system labeling and company website will be revised to identify the new display according to the quality management system.

The similarities and differences between the subject and predicate devices are summarized in Table 1.

Table 1: Comparison with Predicate

Device & Predicate Device(s):	<u>K233027</u>	<u>K213883</u>
Device Trade Name	NanoZoomer S360MD Slide scanner system	Same
General Device Characteristic: Similarities		
Intended Use/Indications For Use	<p>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.</p> <p>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</p>	<p>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.</p> <p>The NanoZoomer System comprises the NanoZoomer S360MD Slide scanner, the NZViewMD Software and the JVC Kenwood JD- C240BN01A display. The NanoZoomer System is for creation and viewing of digital images of scanned glass slides that would</p>

Device & Predicate Device(s):	<u>K233027</u>	<u>K213883</u>
	<p>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.</p>	<p>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.</p>
Slide Feeder	360 Slides	360 Slides
Scanner	NanoZoomer S360MD Slide scanner	NanoZoomer S360MD Slide scanner
Viewer	NZViewMD	NZViewMD
General Device Characteristic: Differences		
Display	<ul style="list-style-type: none"> • JVC Kenwood JD-C24BN01A • BARCO MDPC-8127 Display 	<ul style="list-style-type: none"> • JVC Kenwood JD-C24BN01A

VI Standards/Guidance Documents Referenced:

1. FDA Guidance document: Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices. Guidance for Industry and Food and Drug Administration Staff. April 20, 2016.
2. ISO/CIE 11664-1, Colorimetry - Part 1: CIE standard colorimetric observers

3. ISO/CIE 11664-2, Colorimetry - Part 2: CIE standard illuminants
4. ISO/CIE 11664-3, Colorimetry - Part 3: CIE tristimulus values
5. ISO/CIE 11664-4, Colorimetry - Part 4: CIE 1976 L*a*b* colour space
6. ISO/CIE 11664-5, Colorimetry - Part 5: CIE 1976 L*u*v* colour space and u'v' uniform chromaticity scale diagram
7. ISO/CIE 11664-6, Colorimetry - Part 6: CIEDE2000 colour-difference formula
8. ISO/CIE 61966-2-1, Multimedia systems and equipment - Colour measurement and management - Part 2-1: Colour management - Default RGB colour space - sRGB

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. Assay Reportable Range:
Not applicable
5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):
Not applicable
6. Detection Limit:
Not applicable
7. Assay Cut-Off:
Not applicable
8. Accuracy (Instrument):
Not applicable
9. Carry-Over:
Not applicable

B Other Supportive Instrument Performance Characteristics Data:

Display Equivalency Study:

Technical performance testing for the Barco MDPC-8127 display was performed and compared with the JVC JD-C240BN01 display. The test results are summarized in Table 2 below.

Table 2: Display Equivalency Test

Test	Test Method	Results	
		Subject Device Barco MDPC-8127	Predicate Device JVC JD-C240BN01
1. Spatial resolution	The measurement of the modulation transfer function based on 7.7 Effective Resolution, IDMS v1.03 (Slanted-Edge)	Both horizontal and vertical MTFs are greater than 85% at Nyquist frequency	Both horizontal and vertical MTFs are greater than 58% at Nyquist frequency
2. Pixel defects	Measurements (counts) of pixel defects based on 7.6 Defective Pixels, IDMS v1.03	Total number of bright and dark pixels ≤ 5 with a distance of 15 mm	Total number of pixel defects ≤ 5
3. Artifacts	Evaluate for image artifacts such as noise, periodic spatial irregularities (Moiré), or periodic temporal irregularities. 4.6 Artifacts & Irregularities, IDMS v1.03	$< 0.65\%$	Artifacts not observed
4. Maximum luminance and contrast ratio	Measurements of the maximum luminance and contrast ratio based on 2.4 Vantage-Point Suite of Measurements, IDMS v1.03	Maximum luminance ≥ 678.6 and Minimum luminance $< 0.633 \text{ cd/m}^2$ Maximum calibrated luminance = 450 cd/m^2 Contrast ratio $\geq 1000:1$	Maximum luminance $\geq 162 \text{ cd/m}^2$ Minimum luminance $< 0.162 \text{ cd/m}^2$ Contrast ratio $\geq 1000:1$
5. Luminance uniformity	Measurements of the uniformity of the luminance across the display screen based on 8.1.2 Sampled Vintage-	Non-uniformity on 80% video level $< 10\%$	Uniformity (white point): Non-uniformity $< 30\%$

Test	Test Method	Results	
		Subject Device Barco MDPC-8127	Predicate Device JVC JD-C240BN01
	Point Uniformity, IDMS v1.03		
6. Grayscale	Measurement of the mapping between image values and the luminance based on 6.1 Gray scale, IDMS v1.03	Maximum luminance deviation $\leq 1.4\%$	Max luminance deviation $\leq 10\%$
7. Stability of luminance	Luminance characteristics measured with temperature and time based on 10. Temporal Measurements IDMS v1.03	Deviation from maximum luminance (450 cd/m ²): 0.44% Maximum luminance deviation $< 5\%$	Maximum luminance deviation $\leq 10\%$
8. Bidirectional reflection distribution function	Measurements of the reflection coefficients based on 11 Reflection Measurements, IDMS v1.03	Specular reflection coefficient: 1.90% Diffuse reflection coefficient: 2.87%	Diffused reflection coefficient (Rd) $\leq 2.00\%$
9. Gray tracking	Chromaticity at different luminance levels based on 6.15 Gray-scale Color Changes, IDMS v1.03	$\Delta u'v' < 0.01$	$\Delta u'v' < 0.0028$
10. Color difference	Measurements of the color difference using a spectrometer based on 6.2 Primary Color Scales, IDMS v1.03	Average color error $< 1 \Delta E_{00}$ Maximum color error $< 3 \Delta E_{00}$	Average color error $< 1 \Delta E_{00}$
11. Color gamut volume	Measurements of the color gamut volume by volume-color reproduction	2D color gamut area with respect to sRGB: 137.1%	Verc with respect to sRGB: 97.3%

Test	Test Method	Results	
		Subject Device Barco MDPC-8127	Predicate Device JVC JD-C240BN01
	capability based on 5.18.1 Relative Gamut Area, IDMS v1.03	2D color gamut area within sRGB: 99.6%	2D color gamut area with respect to sRGB: 98.2%
12. Temporal response	Measurements of the response by blurred edge time based on 10.2.3 Gray-to-Gray Response Time, IDMS v1.03	Average: 5.01 ms	Average 18.66 ms (Blurred Edge Time)

VIII Proposed Labeling:

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

IX Conclusion:

The subject device, NanoZoomer S360MD Slide scanner system, has similar indications for use, the same intended use, and the same principles of operation as its predicate device, K213883. The technological characteristics are identical with the exception of the implementation of a PCCP, and this difference does not raise new questions of safety and effectiveness. Thus, the subject device is substantially equivalent.

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