7/22/2026

Hamamatsu Photonics K.K.
% Adrienne Lenz
Principal Medical Device Regulatory Expert
Hyman, Phelps & McNamara, P.C.
1101 K St. NW
Suite 700
Washington, DC 20005

Re: K260964
Trade/Device Name: NanoZoomer S540MD Slide Scanner System
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging system
Regulatory Class: Class II
Product Code: PSY
Dated: March 23, 2026
Received: March 23, 2026

Dear Adrienne Lenz:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP), (Document No.: 2607-1063, Version 01), titled Predetermined Change Control Plan (PCCP) for the NanoZoomer S540MD Slide scanner system (C17400-01MD).
Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K260964

Device Name
NanoZoomer S540MD Slide scanner system

Indications for Use *(Describe)*
The NanoZoomer S540MD Slide scanner system ("NanoZoomer System") is an automated digital slide creation, viewing, and management system. 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. 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.

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.

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
NanoZoomer S540MD Slide Scanner System

Date Prepared: July 13, 2026

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DEVICE

Proprietary Name: NanoZoomer S540MD Slide scanner system
Common Name: Whole Slide Imaging System
Classification Name: Whole Slide Imaging System
Regulatory Section: 21 C.F.R. § 864.3700
Regulatory Classification: Class II
Product Code: PSY
Review Panel: 88 – Pathology

PREDICATE DEVICE

Proprietary Name: NanoZoomer S360MD Slide scanner system
Submission Number: K233027

PURPOSE OF THE SUBMISSION

The purpose of this Abbreviated 510(k) Premarket Notification is as follows:

- New Device: NanoZoomer S540MD Slide scanner system
- Establish a Pre-Determined Change Control Plan (PCCP) for qualifying and adding additional FDA-cleared displays as interoperable components to the NanoZoomer S540MD Slide scanner system.

DEVICE DESCRIPTION

The NanoZoomer S540MD Slide scanner system ("S540MD System" or "S540MD") is an automated system for creating, viewing, and managing digital slides. They create diagnostic-quality digital images of glass slides containing formalin-fixed paraffin-embedded ("FFPE") tissue. Each digital image covers an entire slide and typically contains billions of image pixels. Slide images may be viewed, stored, retrieved, duplicated, annotated, and/or shared, permitting the pathologist to make a primary diagnosis without needing to view the original glass slides through a light microscope.

The NanoZoomer S540MD Slide scanner system is comprised of the NanoZoomer S540MD Slide scanner, NZViewMD image viewing software and interoperable display that has been validated for use with this device. Interoperable displays that may be used with the S540MD Systems include the JVC JD-C240BN01A (K213883), BARCO MDPC-8127 (K203364), or a 510(k) cleared display that has been assessed in accordance with the Predetermined Change Control Plan (PCCP).

INTENDED USE

The NanoZoomer S540MD Slide scanner system ("NanoZoomer System") is an automated digital slide creation, viewing, and management system. 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. 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.

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.

TECHNOLOGY

The proposed NanoZoomer S540MD System has the same indications for use, and uses the same fundamental technology, as the legally marketed predicate device to which substantial equivalency is claimed, the NanoZoomer S360MD Slide scanner system (K233027). The S540MD System is very similar in design and function to the S360MD System. The primary difference between the two devices is the number of slides that can be scanned at one time. The S540MD can scan up to 540 slides while S360MD can scan up to 360 slides at one time. The

S540MD is being added to the product line to provide greater flexibility and choices to customers. There are also minor differences in the scanner hardware. Both the S540MD and S360MD Systems use the same scanner firmware, NZAcquireMD software for acquisition of whole slide images from the scanner, and NZViewMD software for viewing of whole slide images.

Table 1 summarizes the similarities and differences between the S50MD System and the currently cleared S360MD System.

Table 1. Comparison of Subject and Predicate Devices

	S540MD System **New Device**	**S360MD System** **Predicate Device** **(K233027)**
Indications for Use	The NanoZoomer S540MD Slide scanner system ("NanoZoomer System") is an automated digital slide creation, viewing, and management system. 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. 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. 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.	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.
Intended Use	Intended for use in primary surgical pathology diagnosis in lieu of optical microscopy	Intended for use in primary surgical pathology diagnosis in lieu of optical microscopy

	S540MD System New Device	S360MD System Predicate Device (K233027)
Slide Feeder	540 slides(18 cassettes; each holds up to 30 standard-sized slides) 360 slides(18 cassettes; each holds up to 20 standard-sized slides)	360 slides (12 cassettes; each holds up to 30 standard-sized slides)
Image File Formats	NDPi	NDPi
Image Review Manipulation Software	NZViewMD	NZViewMD
Display System	JVC Kenwood JD-C24BN01A BARCO MDPC-8127 Display, or FDA-cleared display validated per the PCCP to ensure performance requirements are met prior to modifications being implemented.	JVC Kenwood JD-C24BN01A BARCO MDPC-8127 Display, or FDA-cleared display validated per the PCCP to ensure performance requirements are met prior to modifications being implemented.
Viewer Software	NZViewMD	NZViewMD
Remote Service of Scanner	Remote maintenance may be performed using the customer's virtual private network (VPN) and Window's Remote Desktop Protocol (RDP) or using Teamviewer, Microsoft Teams, or WebEx software installed on the NanoZoomer S20MD Control PC.	Remote maintenance may only be performed using the customer's virtual private network (VPN) and Window's Remote Desktop Protocol (RDP). No additional software should be installed on the computer targeted for remote maintenance.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

SUMMARY OF NON-CLINICAL TESTS

Electrical Safety and Electromagnetic Compatibility

The following electrical safety and electromagnetic compatibility ("EMC") testing was provided for the S540MD System.

- Electrical safety testing per IEC61010-1 and IEC61010-2-101.
- Electromagnetic compatibility testing in accordance with IEC 61326-2-6 for laboratory use of in vitro diagnostic equipment.

Software/Firmware and Cybersecurity/Interoperability

The S540MD System uses the same scanner firmware, NZAcquireMD software, and NZViewMD software as are used and have been cleared with the S360MD System (K213883 and K233027). Software validation was performed to confirm the software performs as intended when used with the S540MD System.

Cybersecurity documentation as recommended in FDA's guidance *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions* was provided for the S540MD System.

Technical Performance Assessment

Given the similarities in the design, FDA's guidance *Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices* ("TPA Guidance") and 21 C.F.R. § 864.3700(b)(1)(ii) and (iii) were evaluated to determine what testing needed to be performed with the S540MD System and which sections of the TPA Guidance and regulation, if any, could be supported by data obtained with the S360MD System.

The following technical performance assessment tests were performed with the S540MD System:

- Color Reproducibility: Test data to quantify the accuracy and precision of the color transformation from the slide to the display monitor was provided.

The following technical performance assessments for the S540MD System utilize data submitted for the S360MD System:

- Light Source
- Imaging Optics
- Mechanical Scanner Movement
- Digital Imaging Sensor
- Image Processing Software
- Image Review Manipulation Software
- Image Composition
- Image File Format
- Display (K213883 and K233027)
- Spatial Resolution
- Focusing Test
- Whole Slide Tissue Coverage
- Turnaround Time

NanoZoomer S540MD Slide Scanner System Pixel-Wise Comparison Study:

A pixel-wise comparison (PWC) study was conducted to evaluate the difference in image quality between NanoZoomer S540MD and S360MD Slide scanner systems. Most of the components in the imaging pipelines of the predicate and subject devices are identical. Therefore, a PWC study was conducted in lieu of a clinical study to assess the image quality equivalency between the devices. The test data was to demonstrate that the difference between subject and predicate device instances is equal to or less than that among FDA-cleared predicate device instances. For each comparison, two scanned images of the same glass slide—generated by two different device instances—were compared at the pixel level using the standard CIEDE2000 color difference metric (ΔE). Each comparison yielded a distribution of ΔE values, and the Wasserstein-1 metric was used to quantify the distance between two ΔE distributions, where a smaller distance indicates greater agreement between the distributions. The acceptance criterion was met if image quality equivalence between the subject scanner units and predicate scanner units demonstrated that the minimum W1 distance to a predicate unit was lower than the maximum W1 distance observed among predicate-unit (S360MD) comparisons.

The study was conducted with three S540MD units and three S360MD units using 13 clinical glass slides. Study results showed that all S540MD units met the predefined acceptance criterion. Based on the successful results of the technical studies described above and the pixel-wise comparison study, Hamamatsu concluded that the images generated with the S540MD scanner have the same quality as images generated with the S360MD scanner image such as color and resolution. As such, precision, repeatability, and clinical studies conducted with the S360MD System can also be used to support performance of the S540MD system.

SUMMARY OF CLINICAL TESTS

No clinical studies were required to demonstrate substantial equivalence of the modified NanoZoomer S540MD Slide scanner system.

PRE-DETERMINED CHANGE CONTROL PLAN (PCCP)

Hamamatsu provided a PCCP (version 01) that is similar to the PCCP cleared in K233027 and will be followed to validate compatibility of additional FDA-cleared displays with the NanoZoomer S540MD Slide scanner system, including specific performance requirements that must be met prior to updating the device labeling to reference the newly added displays. The PCCP also includes verification that any display-specific software will not impact performance of the NanoZoomer S540MD software. With inclusion of the PCCP, future changes to add additional FDA-cleared displays to the labeling can be made in accordance with the PCCP without a premarket submission. The Hamamatsu website will provide information on additional displays that are compatible with the NanoZoomer S540MD Slide scanner systems and allow users to request updated versions of the system labeling.

PROPOSED LABELING

The labeling supports the finding of substantial equivalence for NanoZoomer S540MD

Slide scanner system.

CONCLUSION

Hamamatsu Photonics K.K. considers the NanoZoomer S540MD Slide scanner system to be substantially equivalent to the predicate device cleared in K233027.