December 22, 2023

Hamamatsu Photonics K.K.
℅ Adrienne Lenz
Principal Medical Device Regulatory Expert
Hyman, Phelps & McNamara, P.C.
700 Thirteenth St., N.W.
Suite 1200
Washington, District of Columbia 20005

Re: K233027
Trade/Device Name: NanoZoomer S360MD Slide scanner system
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole Slide Imaging System
Regulatory Class: Class II
Product Code: PSY
Dated: September 22, 2023
Received: September 25, 2023

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), titled “NanoZoomer S360MD Slide scanner system Predetermined Change Control Plan (PCCP) for the use of additional FDA-cleared monitors” (Document Number 2311-0329,

Version 01). 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 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.

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
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OHT7: Office of In Vitro Diagnostics
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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)*
K233027

Device Name
NanoZoomer S360MD Slide scanner system

Indications for Use *(Describe)*
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.

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
NanoZoomer S360MD Slide Scanner System

Date Prepared: December 22, 2023

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DEVICE

Proprietary Name:	NanoZoomer S360MD Slide scanner system
Common Name:	Whole Slide Imaging System
Classification Name:	Whole Slide Imaging System
Regulation Section:	21 CFR 864.3700
Regulatory	Classification: Class II
Product Code:	PSY
Review Panel:	88 – Pathology

PREDICATE DEVICE

Proprietary Name:	NanoZoomer S360MD Slide scanner system
Submission Number:	K213883

PURPOSE OF THE SUBMISSION

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

- 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 components to the NanoZoomer S360 MD Slide scanner system.

DEVICE DESCRIPTION

The NanoZoomer S360MD Slide scanner system is an automated system for creating, viewing, and managing digital slides. The NanoZoomer S360MD Slide scanner system creates 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 S360MD Slide scanner system is comprised of the NanoZoomer S360MD Slide scanner, NZViewMD image viewing software and compatible display.

INTENDED 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.

TECHNOLOGY

The proposed NanoZoomer 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 (K213883). This

submission introduced compatibility with the BARCO MDPC-8127 Display with the NanoZoomer S360 MD Slide scanner system. In addition, this submission provided a Predetermined Change Control Plan (PCCP) that Hamamatsu will follow to validate compatibility with and that performance requirements are met for use of the system with additional FDA-cleared displays prior to updating the labeling to reference the display. With inclusion of the PCCP, future changes to add additional FDA-cleared displays to the labeling will 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 S360MD Slide scanner system and allow users to request updated versions of the system labeling.

Table 1: Comparison of Subject and Predicate Devices

Specification	**Predicate Device** **NanoZoomer S360MD Slide scanner system (K213883)**	**Subject Device** **NanoZoomer S360MD Slide scanner system (K233027)**
Product Code	PSY	PSY
Regulation	21 C.F.R. § 864.3700	21 C.F.R. § 864.3700
Regulation Name	Whole Slide Imaging System	Whole Slide Imaging System
Classification	II	II
Intended Use	Intended for use in primary surgical pathology diagnosis in lieu of light microscopy	Intended for use in primary surgical pathology diagnosis in lieu of light microscopy
Indications 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	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

Specification	Predicate Device NanoZoomer S360MD Slide scanner system (K213883)	Subject Device NanoZoomer S360MD Slide scanner system (K233027)
	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 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.	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.
Slide Feeder	360 slides	360 slides
Scanner	NanoZoomer S360MD Slide scanner	NanoZoomer S360MD Slide scanner
Viewer	NZViewMD	NZViewMD
Compatible Display	JVC Kenwood JD-C24BN01A	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.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

SUMMARY OF NON-CLINICAL TESTS

Compatibility of the NanoZoomer S360MD Slide scanner system with the BARCO MDPC-8127 Display (K203364) was determined based on testing the below specified parameters and per Special Controls described under 21 C.F.R. § 864.3700. This test includes:

1. Spatial resolution
2. Pixel defects (count and map)
3. Artifacts
4. Maximum and minimum luminance
5. Luminance uniformity and Mura test
6. Grayscale
7. Stability of luminance and chromaticity
8. Bidirectional reflection distribution function
9. Gray tracking
10. Color difference (the display only)
11. Color gamut volume
12. Temporal response

In addition to the above, as a system-level test, color reproducibility testing was performed to validate performance of the NanoZoomer System with the BARCO MDPC-8127 Display. The test used three NanoZoomer Systems with BARCO MDPC-8127 displays and was conducted using a color calibration slide and a chroma meter. The differences between the ground truth and the measured colors were evaluated using the ΔE2000 CIEDE2000 metric. Test data to quantify the accuracy and precision of the color transformation from the slide to the display monitor was provided and demonstrated that the product met the acceptance criteria for color accuracy.

Justifications to retest or not to retest each special control described under 21 C.F.R. § 864.3700 were also provided.

The BARCO MDPC-8127 display also has calibration software, QA-WEB, that runs on the NanoZoomer System Scan and Viewing PCs. Software verification was performed to confirm this additional software did not introduce any issues with performance of the NanoZoomer S360MD software.

SUMMARY OF CLINICAL TESTS

No clinical studies were required to demonstrate substantial equivalence of the modified NanoZoomer S360MD Slide scanner system.

Predetermined Change Control Plan (PCCP)

This submission provided a PCCP that Hamamatsu will follow to validate compatibility of additional FDA-cleared displays with the NanoZoomer S360MD 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 S360MD 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 S360MD Slide scanner system and allow users to request updated versions of the system labeling.

CONCLUSION

Hamamatsu Photonics K.K. considers the modified NanoZoomer S360MD Slide scanner system to be substantially equivalent to the predicate version of the device cleared in K213883.