Indica Labs, Inc.
Michele Fredrickson
Sr Manager, Quality and Regulatory
8700 Education Place NW
Building B
Albuquerque, New Mexico 87114

May 7, 2024

Re: K232833
Trade/Device Name: HALO AP Dx
Regulation Number: 21 CFR 864.3700
Regulation Name: Whole slide imaging System
Regulatory Class: Class II
Product Code: QKQ
Dated: September 13, 2023
Received: September 13, 2023

Dear Michele Fredrickson:

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.

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)*
K232833

Device Name
HALO AP Dx

Indications for Use *(Describe)*

For In Vitro Diagnostic Use

HALO AP Dx is a software only device intended as an aid to the pathologist to review, interpret and manage digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue for the purposes of pathology primary diagnosis. HALO AP Dx 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 quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. HALO AP Dx is intended for use with the Hamamatsu NanoZoomer S360MD Slide scanner and the JVC Kenwood JD-C240BN01A display.

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.

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510(k) Summary

HALO AP Dx

1. Submitter

Indica Labs, Inc.
8700 Education Place, Building B
Albuquerque, NM, 87114 USA
Contact Person: Michele Fredrickson, Sr. Manager Quality & Regulatory
Tel: 505-492-0972
Date Prepared: May 6, 2024

2. Device

Device Trade Name:	HALO AP Dx
Version:	2.1
Regulation Name:	Whole Slide Imaging System
Regulation:	21 CFR §864.3700
Regulatory Class:	Class II
Product Classification Code:	QKQ
Review Panel:	88 – Pathology
510 (k) Submission Number:	K232833

3. Predicate Device

Predicate Manufacturer:	Hamamatsu Photonics K.K.
Predicate Trade Name:	NanoZoomer S360MD Slide scanner system
Predicate 510(k):	K213883

No reference devices were used in this submission.

4. Device Description

HALO AP Dx, version 2.1 is a browser-based software-only device intended to aid pathology professionals in viewing, manipulating, management and interpretation of digital pathology whole slide images (WSI) of glass slides obtained from the Hamamatsu Photonics K.K. NanoZoomer S360MD scanner and viewed on the JVC Kenwood JD-C240BN01A display.

HALO AP Dx is typically operated as follows:

1. Image acquisition is performed using the predicate device, NanoZoomer S360MD Slide scanner according to its Instructions for Use. The operator performs quality control of the digital slides per the instructions of the NanoZoomer and lab specifications to determine if re-scans are necessary.

2. Once image acquisition is complete, the unaltered image is saved by the scanner's software to an image storage location. HALO AP Dx ingests the image, and a copy of image metadata is stored in the subject device's database to improve viewing response times.
3. Scanned images are reviewed by scanning personnel such as histotechnicians to confirm image quality and initiate any re-scans before making it available to the pathologist.
4. The reading pathologist selects a patient case from a selected worklist within HALO AP Dx whereby the subject device fetches the associated images from external image storage.
5. The reading pathologist uses the subject device to view the images and can perform the following actions, as needed:
    a. Zoom and pan the image.
    b. Measure distances and areas in the image.
    c. Annotate images.
    d. View multiple images side by side in a synchronized fashion.
    6. The above steps are repeated as necessary.

After viewing all images belonging to a particular case (patient), the pathologist will make a diagnosis which is documented in another system, such as a Laboratory Information System (LIS).

The interoperable components of HALO AP Dx are provided in table 1 below:

Table 1. Interoperable Components for Use with HALO AP Dx

Components	Manufacturer	Model
Scanner	Hamamatsu	NanoZoomer S360MD Slide scanner
Display	JVC	JD-C240BN01A

5. Intended Use

For In Vitro Diagnostic Use

HALO AP Dx is a software only device intended as an aid to the pathologist to review, interpret and manage digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue for the purposes of pathology primary diagnosis. HALO AP Dx 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 quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. HALO AP Dx is intended for use with the Hamamatsu NanoZoomer S360MD Slide scanner and the JVC Kenwood JD-C240BN01A display.

6. Summary of Technological Characteristics

Item	Predicate (K213883)	Subject Device
Device Trade Name	Hamamatsu NanoZoomer S360MD Slide scanner system	HALO AP Dx

Item	Predicate (K213883)	Subject Device
Product Code	PSY	QKQ
Regulation	864.3700	864.3700
Regulation Name	Whole Slide Imaging System	Whole Slide Imaging System
Classification	Class II	Class II
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 for the purposes of pathology primary diagnosis. 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 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.	HALO AP Dx is a software only device intended as an aid to the pathologist to review, interpret and manage digital images of scanned surgical pathology slides prepared from formalin-fixed paraffin embedded (FFPE) tissue for purposes of pathology primary diagnosis. HALO AP Dx 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 quality of the images obtained and, where necessary, use conventional light microscopy review when making a diagnostic decision. HALO AP Dx is intended for use with the Hamamatsu NanoZoomer S360MD Slide scanner and the JVC Kenwood JD-C240BN01A display.
Specimen Type	Surgical pathology slides prepared from FFPE tissue	Same
Diagnostic Image File Format	Hamamatsu NDPi File	Same
Image Manipulation	Functions for continuous panning and zooming, annotations, distance/area measurements, track visited areas,	Functions for continuous panning and zooming, annotations, image adjustments, distance/area measurements, organize

Item	Predicate (K213883)	Subject Device
and Review Functions	export images, discrete Z-axis displacement, and display of diagnostic status of images.	workload and view patient data, export images, and display of diagnostic status of images.
Type of Software Application	PC-based installed application	Internet browser-based application: Google Chrome version 116 and above Microsoft Edge version 116 and above
Principle of Operation	During review, the pathologist opens the WSI images acquired with the scanner from the network storage, performs further QC, and reviews and interprets the WSI images to make a diagnosis.	Same
Image Storage	User-supplied network attached storage	Same
End User's Interface	NZViewMD	HALO AP Dx
Scanner	Hamamatsu S360MD	Same
Display Monitor	JVC Kenwood JD-C240BN01A	Same

7. Performance Data

Performance data	Description
Identical Image Reproduction	Based on pixel-wise comparison to NZViewMD viewer, across multiple tiles at multiple magnification levels, it was determined that color images reproduced by HALO AP Dx demonstrated identical image reproduction compared to the predicate device.
Turnaround time	Turnaround times for image loading, panning, and zooming have been determined and found to be adequate for the intended use of the subject device. The system requirements have been fulfilled: • When selecting a case, it should not take longer than 4 seconds until the image is fully loaded. • When panning the image, it should not take longer than 3 seconds until the image is fully loaded.
Measurements	Measurement accuracy has been verified using a test image containing objects with known sizes.
Human factors testing	HALO AP Dx has been found to be safe and effective for the intended users, uses, and use environments.

8. Substantial Equivalence Comparison

The major difference between the subject and predicate device is that the predicate includes the Hamamatsu S360MD scanner and the JVC Kenwood JD-C240BN01A monitor, whereas the subject device is indicated for use with the same scanner and monitor. Therefore, the indications for use for the predicate contain a section detailing the creation of the WSI, while HALO AP Dx is only focused on viewing those images.

As proposed, when HALO AP Dx is used with the Hamamatsu S360MD scanner and the JVC Kenwood JD-C240BN01A monitor, it has similar indications for use, inputs, outputs, intended user types, and technological characteristics as the NZViewMD viewing software included with the predicate device. Therefore, HALO AP Dx is substantially equivalent to the predicate device (K213883).

9. Summary of Studies

Non-clinical test results

Conducted per FDA's Guidance on Technical Performance Assessment of Digital Pathology Whole Slide Imaging Devices (2016):

- Pixelwise comparison testing was conducted in the Windows 10 environment to support identical image reproduction. Pixel-level comparisons were made across multiple tiles at multiple magnification levels, to compare color images reproduced by HALO AP Dx and Nanozoomer NZViewMD. After alignment of the image pair, the pixelwise differences were computed. The mean, minimum and maximum of the 95th percentile were reported compositely and separately, per Region of Interest (ROI), image, magnification level, scanner, and browser. The 95th percentile values (CIEDE2000) across all ROIs taken from images with varied tissue types and diagnoses are less than 3 ΔE00. It was determined that color images reproduced by HALO AP Dx demonstrated identical image reproduction compared to the predicate device.
- Turnaround times for panning and zooming have been determined and found to be adequate for the intended use of the subject device. Concurrent multi-user load testing confirms HALO AP Dx performance remains responsive under constant utilization over a long time period.
- The subject device has been found to perform accurate measurements with respect to its intended use.

Conducted per FDA's Guidance on Applying Human Factors and Usability Engineering to Medical Devices (2016):

- Task-based usability tests verified the HALO AP Dx user interface to be intuitive, safe, and effective for the range of intended users.

10. Conclusion

When HALO AP Dx is used with the Hamamatsu Photonics K.K. NanoZoomer S360MD scanner and JVC Kenwood JD-C240BN01A display, it has similar Indications for Use, Functional, and Technological Characteristics as the predicate's viewing software. The results of non-clinical testing demonstrate the device is substantially equivalent to the predicate device (K213883).