July 2, 2026

OptraSCAN, Inc.
Mona Advani
Regulatory Consultant
Addwin Consulting
Herndon, VA 20171

Re: K260755
Trade/Device Name: OptraSCAN System
Regulation Number: 21 CFR 864.1860
Regulation Name: Immunohistochemistry reagents and kits
Regulatory Class: Class II
Product Code: NOT
Dated: March 6, 2026
Received: March 9, 2026

Dear Mona Advani:

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.

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 2
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)*
K260755

Device Name
OptraSCAN System

Indications for Use *(Describe)*
The OptraSCAN System is an automated digital slide creation, management, viewing and analysis system which consists of the OS-Ultra Scanner, Color Display Monitor (Model No. Dell U2424HE) and a Workstation, preinstalled with software to operate the scanner and the ImagePath application (Image Management software and HER2 Image Analysis Software).

The OptraSCAN System is intended for in vitro diagnostic use as an aid to the pathologist in the review and semi-quantitative scoring of HER2 protein expression in scanned digital images obtained using OS-Ultra Scanner of slides prepared from formalin-fixed paraffin embedded (FFPE) breast tissue and stained with the Dako HercepTest™.

The HER2 Image Analysis Software outputs the scores for individual Regions of Interest (ROIs) as well as the slide level score based on all the ROIs. The pathologist is responsible for making the final decision of the score, based on the output provided by the system. The OptraSCAN System software makes no independent interpretations of the data.
Note: The HER2 Image Analysis Software is an adjunctive computer-assisted methodology to assist qualified pathologists in HER2 scoring in breast cancer. The accuracy of the test result depends upon the quality of the immunohistochemical staining.

It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for use for the Dako HercepTest™ to assure the validity of the HER2 Image Analysis Software assisted HER2 score. The actual correlation of the Dako HercepTest™ to Herceptin® clinical outcome has not been established.

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
OptraSCAN System

Date Prepared	July 1, 2026
Applicant	OptraSCAN, Inc 2001 Gateway Pl, Suite 150W San Jose, CA 95110 United States
Sponsor Contact	Abhi Gholap OptraSCAN, Inc Email: abhi@Optraventures.com Tel: 408-564-9010
Primary Contact	Mona Advani Addwin Consulting Corporation Phone (650) 575-5819 mona@addwinconsulting.com
Trade Name	OptraSCAN System
510 (k) Submission Number	K260755
Device Classification:	Class II
Regulatory Sections	21 CFR §864.1860
Classification Name	Immunohistochemistry Reagents and Kits
Product Code	NOT-Microscope, Automated, Image Analysis, Operator Intervention
Predicate Device	• Aperio ePathology eIHC IVD System, AT Turbo and CS2 models (K141109)

INTENDED USE/INDICATIONS FOR USE

The OptraSCAN System is an automated digital slide creation, management, viewing and analysis system which consists of the OS-Ultra Scanner, Color Display Monitor (Model No. Dell U2424HE) and a Workstation, preinstalled with software to operate the scanner and the ImagePath application (Image Management software and HER2 Image Analysis Software).

The OptraSCAN System is intended for in vitro diagnostic use as an aid to the pathologist in the review and semi-quantitative scoring of HER2 protein expression in scanned digital images obtained using OS-Ultra Scanner of slides prepared from formalin-fixed paraffin embedded (FFPE) breast tissue and stained with the Dako HercepTest™.

The HER2 Image Analysis Software outputs the scores for individual Regions of Interest (ROIs) as well as the slide level score based on all the ROIs. The pathologist is responsible for making the final decision of the score, based on the output provided by the system. The OptraSCAN System software makes no independent interpretations of the data.

Note: The HER2 Image Analysis Software is an adjunctive computer-assisted methodology to assist qualified pathologists in HER2 scoring in breast cancer. The accuracy of the test result depends upon the quality of the immunohistochemical staining.
It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for use for the Dako HercepTest™ to assure the validity of the HER2 Image Analysis Software assisted HER2 score. The actual correlation of the Dako HercepTest™ to Herceptin® clinical outcome has not been established.

DESCRIPTION:

The OptraSCAN System is intended for in vitro diagnostic use as an aid to the pathologist in the review and semi-quantitative scoring of HER2 protein expression in digital whole slide images (WSIs) of slides prepared from formalin-fixed paraffin embedded (FFPE) breast tissue and stained with the Dako HercepTest™. The system uses computer-assisted image analysis software to support the pathologist in the semi-quantitative assessment of Dako HercepTest™ -stained histological specimens.
The OptraSCAN System is an automated digital pathology system that converts glass microscope slides into high-resolution WSIs and provides tools for managing, viewing, and analyzing those images. This system is intended to be used in a laboratory environment.
The OptraSCAN System is comprised of the following main components:

- OS-Ultra Scanner
- Color Monitor Display: Dell Model No. U2424HE.
- Dell Precision 3680 Tower Workstation Loaded with
    - Scanner App Software – Version 1.0.0
    - ImagePath Image Management Software – Version 1.0.0
    - HER2 Image Analysis Software – Version 1.0.0

The OptraSCAN System is operated as below:

1. WSIs of pathology glass slides are produced using the OS-Ultra Scanner.
2. The WSIs are viewed on the Color Dell Monitor Display, Model No. U2424HE.
3. Using the Image Management Software, which is loaded on the Dell Precision 3680 Tower Workstation, the pathologist views, navigates, annotates, and reviews the WSIs. The pathologist runs the HER2 Image Analysis Software on the selected WSIs. Control slides are used to confirm the quality and validity of the IHC staining independent of the OptraSCAN System.
4. OptraSCAN System supports pathologist interpretation based on Regions of Interests (ROIs) selected by the pathologist and outputs the HER2 scores for individual ROIs. Additionally, a slide level score is generated based on all selected ROIs. Note: The Pathologist is responsible for making the final decision of the score, based on the output provided by the system. The system makes no independent interpretations of the data.
5. A report is generated.

COMPARISON OF SUBJECT DEVICE WITH PREDICATE DEVICE

Device Name	Subject Device OptraSCAN, Inc OptraSCAN System	Predicate Device Leica Biosystems Imaging, Inc. Aperio ePathology eIHC IVD System, AT Turbo and CS2 Models
510(k)#	K260755	K141109
Intended Use /Indications for use	The OptraSCAN System is an automated digital slide creation, management, viewing and analysis system which consists of the OS-Ultra Scanner, Color Display Monitor (Model No. Dell U2424HE) and a Workstation, preinstalled with software to operate the scanner and the ImagePath application (Image Management software and HER2 Image Analysis Software). The OptraSCAN System is intended for in vitro diagnostic use as an aid to the pathologist in the review and semi-quantitative scoring of HER2 protein expression in scanned digital images obtained using OS-Ultra Scanner of slides prepared from formalin-fixed paraffin embedded (FFPE) breast tissue and stained with the Dako HercepTest™. The HER2 Image Analysis Software outputs the scores for individual Regions of Interest (ROIs) as well as the slide level score based on all the ROIs. The pathologist is responsible for making the final decision of the score, based on the output provided by the system. The OptraSCAN System software makes no independent interpretations of the data.	The Aperio ePathology eIHC IVD System is an automated digital slide creation, management, viewing and analysis system. It is intended for in vitro diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest based on particular color, intensity, size, pattern and shape. The IHC HER2 Image Analysis application is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in formalin-fixed, paraffin embedded neoplastic tissue. The IHC HER2 Image Analysis application is intended for use as an accessory to the Dako HercepTest™ to aid in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in formalin-fixed, paraffin-embedded neoplastic tissue. When used with the Dako HercepTest™, it is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN®(Trastuzumab) treatment is being considered. Note: The IHC HER2 Image Analysis application is an adjunctive computer-assisted methodology to assist the

Device Name	Subject Device OptraSCAN, Inc OptraSCAN System	Predicate Device Leica Biosystems Imaging, Inc. Aperio ePathology eIHC IVD System, AT Turbo and CS2 Models
	Note: The HER2 Image Analysis Software is an adjunctive computer-assisted methodology to assist qualified pathologists in HER2 scoring in breast cancer. The accuracy of the test result depends upon the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for use for the Dako HercepTest™ to assure the validity of the HER2 Image Analysis Software assisted HER2 score. The actual correlation of the Dako HercepTest™ to Herceptin® clinical outcome has not been established.	reproducibility of a qualified pathologist in the acquisition and measurement of images from microscope slides of breast cancer specimens stained for the presence of HER-2 receptor protein. The IHC HER2 Image Analysis application is intended to be used on images viewed on a computer monitor. The accuracy of the test result depends upon the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for the Dako HercepTest™ to assure the validity of the IHC HER2 Image Analysis application assisted HER-2/neu score. The actual correlation of the Dako HercepTest™ to Herceptin® clinical outcome has not been established.
Intended Use	An adjunctive computer-assisted methodology to assist the reproducibility of a qualified pathologist in the acquisition and measurement of images from microscope slides of breast cancer specimens stained for the presence of HER-2 receptor protein	Same
Method of Operation/ Cell Detection	Use of deterministic image processing and pattern matching based image analysis rule engine to determine the HER2 score for each ROI based on completeness of membrane staining. Threshold-based segmentation techniques are used to detect tumor cells.	Same

Device Name	Subject Device OptraSCAN, Inc OptraSCAN System	Predicate Device Leica Biosystems Imaging, Inc. Aperio ePathology eIHC IVD System, AT Turbo and CS2 Models
Assay Type Used	DAKO HercepTest Reagent Kit	Same
Immunohistochemistry Test Type	HER2	HER2, ER, PR
Specimen Type	Formalin-Fixed, Paraffin embedded breast tissue specimens	Same
System Components	1. OS-Ultra Scanner 2. Color Display Monitor 3. Workstation with ImagePath Software (Image Management Software with HER2 Image Analysis Software)	1. ScanScope AT Turbo Slide Scanner 2. Color Monitor 3. Workstation with eSlideManager Software and IHC HER2 Image Analysis Software
Image Management Software	HER2 Image Analysis Software	IHC HER2 Image Analysis Software
Software Description	The software makes no independent interpretations of the data and requires competent human intervention for all steps in the analysis process.	Same
Slide Scanner Capacity	480	400

SUMMARY OF PERFORMANCE DATA

OptraSCAN Inc. conducted two analytical performance evaluations on the OptraSCAN System, the Precision/Reproducibility Study and the Accuracy Study as summarized below.

Precision/Reproducibility Analytical Study

The Precision/Reproducibility Analytical study was designed to generate quantitative evidence that the OptraSCAN System produces consistent HER2 scoring outputs when subjected to expected sources of operational variability. Based on the demonstration of acceptable repeatability and reproducibility, it was concluded that the system performs reliably under normal conditions of use, and that observed variability remains within clinically acceptable limits for semi-quantitative HER2 interpretation. The OptraSCAN System demonstrated stable and reproducible HER2 scoring across scanners, readers, timepoints, and laboratory environments. These results support the conclusion that the system produces consistent HER2 classification outputs under intended conditions of operational and clinical use.

Clinical Performance Study

This study evaluated the pathologist performance when using the OptraSCAN System for assisted scoring of Dako HercepTest HER2 immunohistochemistry (IHC) slides from breast cancer specimens and compared with performance of pathologist manual microscope based HER2 scoring classification. OptraSCAN System assisted scoring was evaluated in comparison to independently established Ground Truth (GT) scores for each study slide. System performance was assessed relative to independently established Ground Truth (GT) scores and manual pathologist scoring classification. The following tables summarize the results of the study.

Table 1. Sensitivity: Manual and "IA- assisted" vs Ground Truth (GT)

Scoring Category	Manual vs GT (%) 95%CI	"IA- assisted" vs GT (%) 95%CI	Point of Estimate Difference (IA–M)	95%CI Difference
0,1+,2+ vs 3+	62.774% (62.774%, 83.357%)	75.875% (75.875%, 92.647%)	13.10%	(3.66%, 19.72%)
0,1+ vs 2+,3+	79.462% (79.462%, 90.782%)	82.292% (82.292%, 92.789%)	2.83%	(-1.71%, 6.64%)
0 vs 1+,2+,3+	96.330% (96.330%, 99.737%)	96.972% (96.972%, 99.897%)	0.64%	(-1.65%, 1.65%)

Table 2. Specificity: Manual and "IA- assisted" vs GT

Scoring Category	Manual vs GT (%) 95%CI	"IA- assisted" vs GT (%) 95%CI	Point of Estimate Difference (IA–M)	95%CI Difference
0,1+,2+ vs 3+	98.359% (98.359%, 100.000%)	96.119% (96.119%, 99.722%)	-2.24%	(-2.86%, 0.17%)
0,1+ vs 2+,3+	82.707% (82.707%, 93.787%)	90.777% (90.777%, 98.388%)	8.07%	(0.43%, 12.62%)
0 vs 1+,2+,3+	64.307% (64.307%, 86.248%)	66.030% (66.030%, 87.493%)	1.72%	(-11.97%, 15.14%)

The results demonstrate that the OptraSCAN System provides accurate and clinically concordant HER2 scoring performance comparable to manual microscopy interpretation. Observed variability across sites and score categories were consistent with known biological heterogeneity, staining differences, and reader variability inherent to HER2 IHC assessment, and did not indicate device-related limitations.

Overall, the study results support the conclusion that the system performs within the expected range of clinical variability and does not introduce additional diagnostic risk relative to standard manual interpretation.

SUMMARY OF EMC AND ELECTRICAL SAFETY TESTING:

Electrical Safety Testing has been completed to the following standard IEC 61010-2-101, Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment and EMC testing to IEC61326-1 Edition 3.0 2020-10, Electrical equipment for measurement control and laboratory use - EMC requirements - Part 1: General requirements, and IEC 60601-1-2: 2014 + Amd1 2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance. The EMC and Electrical Safety testing demonstrated that the OptraSCAN System performs as intended and has performance characteristics that are substantially equivalent to the listed predicate device and is safe and effective for use.

SUMMARY OF SOFTWARE VERIFICATION AND VALIDATION:

Software verification and validation activities were completed following the FDA Guidances "*Content of Premarket Submissions for Software Contained in Medical Devices*", June 14, 2023, and "*Off-The-Shelf Software Use in Medical Devices*", August 11, 2023, and demonstrated that the OptraSCAN system meets the required system specifications to ensure the OptraSCAN System is safe and effective. Based on the system's intended use, the design of the system, and the risks associated with the system's software function in context with system's intended use, OptraSCAN determined that the enhanced software documentation was required and completed. During the validation activities, OptraSCAN determined that all software functionality testing met the predetermined requirements, and no unresolved anomalies were found.

SUMMARY OF CYBERSECURITY VERIFICATION AND VALIDATION

Cybersecurity verification and validation activities were completed following the FDA Guidance "*Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions*", June 27, 2025, and demonstrated that the OptraSCAN system met or exceeding the required system specifications to ensure safe and effective results. During the validation activities, OptraSCAN determined that all functionalities met requirements.

CONCLUSION:

In accordance with Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, OptraSCAN has demonstrated that the OptraSCAN System is safe and substantially equivalent to the predicate device. The software testing, EMC and safety testing, cybersecurity testing and analytical performance evaluations demonstrate that the OptraSCAN can be used as an in vitro diagnostic aid to the pathologist in the review and semi-quantitative scoring of HER2 protein expression.